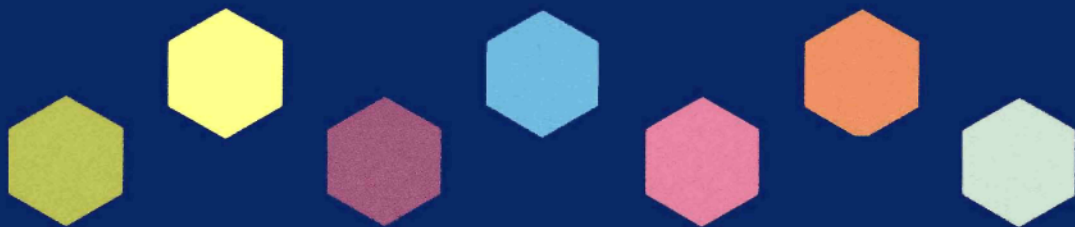

WHO DRUG



INFORMATION

VOLUME 12 · NUMBER 1B · 1998

RECOMMENDED INN LIST 39
INTERNATIONAL NONPROPRIETARY NAMES
FOR PHARMACEUTICAL SUBSTANCES



WORLD HEALTH ORGANIZATION · GENEVA

WHO Drug Information

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Essential Drugs

WHO Model List (revised in December 1997)

Section 1: Anaesthetics

1.1 GENERAL ANAESTHETICS AND OXYGEN

ether, anaesthetic (1c) (2)	inhalation
halothane (2)	inhalation
ketamine (2)	injection, 50 mg (as hydrochloride)/ml in 10-ml vial
nitrous oxide (2)	inhalation
oxygen	inhalation (medicinal gas)
*thiopental (2)	powder for injection, 0.5 g, 1.0 g (sodium salt) in ampoule

1.2 LOCAL ANAESTHETICS

*bupivacaine (2, 9)	injection, 0.25%, 0.5% (hydrochloride) in vial
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*lidocaine	injection for spinal anaesthesia, 0.5% (hydrochloride) in 4-ml ampoule to be mixed with 7.5% glucose solution
	injection, 1%, 2% (hydrochloride) in vial
	injection, 1%, 2% (hydrochloride) + epinephrine 1:200 000 in vial
	injection for spinal anaesthesia, 5% (hydrochloride) in 2-ml ampoule to be mixed with 7.5% glucose solution
	topical forms, 2 – 4% (hydrochloride)
	dental cartridge, 2% (hydrochloride) + epinephrine 1:80 000

Complementary drug

ephedrine (C) (To prevent hypotension in spinal anaesthesia during delivery)	injection, 30 mg (hydrochloride)/ml in 1-ml ampoule
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* Example of a therapeutic group. *Various drugs can serve as alternatives.*

Explanatory Notes

When the strength of a drug is specified in terms of a selected salt or ester, this is mentioned in brackets; when it refers to the active moiety, the name of the salt or ester in brackets is preceded by the word "as".

Many drugs included in the list are preceded by an asterisk (*) to indicate that they represent an example of a therapeutic group and that various drugs could serve as alternatives. It is imperative that this is understood when drugs are selected at national level, since choice is then influenced by the comparative cost and availability of equivalent products. Examples of acceptable substitutions include:

- * Hydrochlorothiazide: any other thiazide-type diuretic currently in broad clinical use.
- * Hydralazine: any other peripheral vasodilator having an antihypertensive effect.
- * Senna: any stimulant laxative (either synthetic or of plant origin).
- * Sulfadiazine: any other short-acting systemically-active sulfonamide unlikely to cause crystalluria.

Numbers, in parentheses, following the drug names indicate: (1) Drugs subject to international control under (a) the Single Convention on Narcotic Drugs (1961); (b) the Convention on Psychotropic Substances (1971); and (c) the Convention on

Illicit Traffic in Narcotic Drugs and Psychotropic Substances (1988);

- (2) Specific expertise, diagnostic precision, individualization of dosage or special equipment required for proper use;
- (3) Greater potency or efficacy;
- (4) In renal insufficiency, contraindicated or dosage adjustments necessary;
- (5) To improve compliance;
- (6) Special pharmacokinetic properties;
- (7) Adverse effects diminish benefit/risk ratio;
- (8) Limited indications or narrow spectrum of activity;
- (9) For epidural anaesthesia;
- (10) Sustained release preparations are available. The fact of proper sustained release of the dosage form should be documented;
- (11) Therapeutic drug monitoring, i.e. plasma concentration, can improve safety and efficacy.

Letters in parentheses following the drug names indicate the reasons for the inclusion of *complementary drugs*:

- (A) When drugs in the main list cannot be made available;
- (B) When drugs in the main list are known to be ineffective or inappropriate for a given individual;
- (C) For use in rare disorders or in exceptional circumstances.
- (D) Reserve antimicrobials to be used only when there is significant resistance to other drugs on the list.

Drugs are listed in alphabetical order.

1.3 PREOPERATIVE MEDICATION & SEDATION FOR SHORT-TERM PROCEDURES

atropine	injection, 1 mg (sulfate) in 1-ml ampoule
chloral hydrate	syrup, 200 mg/5 ml
*diazepam (1b)	injection, 5 mg/ml in 2-ml ampoule tablet, 5 mg
*morphine (1a)	injection, 10 mg (sulfate or hydrochloride) in 1-ml ampoule
*promethazine	elixir or syrup, 5 mg (hydrochloride)/5 ml

Section 2: Analgesics, Antipyretics, Nonsteroidal Anti-Inflammatory Drugs (NSAIDs), Drugs Used to Treat Gout and Disease-Modifying Agents in Rheumatic Disorders (DMARDs)**2.1 NON-OPIOID ANALGESICS & NSAIDs**

acetylsalicylic acid	tablet, 100 – 500 mg suppository, 50 – 150 mg
*ibuprofen	tablet, 200 mg, 400 mg
paracetamol	tablet, 100 – 500 mg suppository, 100 mg syrup, 125 mg/5 ml

2.2 OPIOID ANALGESICS

*codeine (1a)	tablet, 30 mg (phosphate)
*morphine (1a)	injection, 10 mg (sulfate or hydrochloride) in 1-ml ampoule oral solution, 10 mg (hydrochloride or sulfate)/5 ml tablet, 10 mg (sulfate)

Complementary drug

*pethidine (A) (1a, 4)	injection, 50 mg (hydrochloride) in 1-ml ampoule tablet, 50 mg, 100 mg (hydrochloride)
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2.3 DRUGS USED TO TREAT GOUT

allopurinol (4)	tablet, 100 mg
colchicine (7)	tablet, 500 µg

2.4 DISEASE MODIFYING AGENTS IN RHEUMATIC DISORDERS

chloroquine (2)	tablet, 100 mg, 150 mg (as phosphate or sulfate)
methotrexate (2)	tablet, 2.5 mg (as sodium salt)
penicillamine (2)	capsule or tablet, 250 mg
sulfasalazine (2)	tablet, 500 mg
azathioprine (2)	tablet, 50 mg
cyclophosphamide (2)	tablet, 25 mg

Section 3: Antiallergics and Drugs Used in Anaphylaxis

*chlorphenamine	tablet, 4 mg (hydrogen maleate) injection, 10 mg (hydrogen maleate) in 1-ml ampoule
*dexamethasone	tablet, 500 µg, 4 mg injection, 4 mg dexamethasone phosphate (as disodium) in 1-ml ampoule
epinephrine	injection, 1 mg (as hydro- chloride or hydrogen tartrate) in 1-ml ampoule
hydrocortisone	powder for injection, 100 mg (as sodium succinate) in vial
*prednisolone	tablet, 5 mg

Section 4: Antidotes and Other Substances Used in Poisonings**4.1 NON-SPECIFIC**

*charcoal, activated	powder
ipecacuanha	syrup, containing 0.14% ipecacuanha alkaloids calculated as emetine

4.2 SPECIFIC

atropine	injection, 1 mg (sulfate) in 1-ml ampoule
calcium gluconate (2, 8)	injection, 100 mg/ml in 10-ml ampoule
deferoxamine	powder for injection, 500 mg (mesilate) in vial
dimercaprol (2)	injection in oil, 50 mg/ml in 2-ml ampoule
*DL-methionine	tablet, 250 mg

* Example of a therapeutic group. Various drugs can serve as alternatives.

methylthionium chloride (methylene blue)	injection, 10 mg/ml in 10-ml ampoule
naloxone	injection, 400 µg (hydrochloride) in 1-ml ampoule
penicillamine (2)	capsule or tablet, 250 mg
potassium ferric hexacyano-ferrate(II) (Prussian blue)	powder for oral administration
sodium calcium edetate (2)	injection, 200 mg/ml in 5-ml ampoule
sodium nitrite	injection, 30 mg/ml in 10-ml ampoule
sodium thiosulfate	injection, 250 mg/ml in 50-ml ampoule

Section 5: Anticonvulsants/ Antiepileptics

carbamazepine (10, 11)	scored tablet, 100 mg, 200 mg
*diazepam (1b)	injection, 5 mg/ml in 2-ml ampoule (intravenous or rectal)
ethosuximide	capsule, 250 mg syrup, 250 mg/5 ml
phenobarbital (1b, 11)	tablet, 15 – 100 mg elixir, 15 mg/5 ml
phenytoin (7, 11)	capsule or tablet, 25 mg, 50 mg, 100 mg (sodium salt) injection, 50 mg (sodium salt)/ml in 5-ml vial
valproic acid (7, 11)	enteric coated tablet, 200 mg, 500 mg (sodium salt)
<i>Complementary drugs</i>	
*clonazepam (B) (1b)	scored tablets, 500 µg
magnesium sulfate (C)	injection, 500 mg/ml in 2-ml ampoule, 5 g in 10-ml ampoule

Section 6: Anti-infective Drugs

6.1 ANTHELMINTHICS

6.1.1 INTESTINAL ANTHELMINTHICS

albendazole	chewable tablet, 400 mg
levamisole	tablet, 50 mg, 150 mg (as hydrochloride)
*mebendazole	chewable tablet, 100 mg, 500 mg

niclosamide	chewable tablet, 500 mg
praziquantel	tablet, 150 mg, 600 mg
pyrantel	chewable tablet, 250 mg (as embonate) oral suspension, 50 mg (as embonate)/ml

6.1.2 ANTIFILARIALS

diethylcarbamazine	tablet, 50 mg, 100 mg (dihydrogen citrate)
ivermectin	scored tablet, 3 mg, 6 mg

Complementary drug

suramin sodium (B) (2, 7)	powder for injection, 1 g in vial
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6.1.3 ANTISCHISTOSOMALS AND OTHER ANTITREMATODE DRUGS

praziquantel	tablet, 600 mg
triclabendazole	tablet, 250 mg

Complementary drug

oxamniquine (C) (8)	capsule, 250 mg syrup, 250 mg/5 ml
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6.2 ANTIBACTERIALS

6.2.1 BETA LACTAM DRUGS

*amoxicillin	capsule or tablet, 250 mg, 500 mg (anhydrous) powder for oral suspension, 125 mg (anhydrous)/5 ml
ampicillin	powder for injection, 500 mg, 1 g (as sodium salt) in vial
benzathine benzylpenicillin	powder for injection, 1.44 g benzylpenicillin (= 2.4 million IU) in 5-ml vial
benzylpenicillin	powder for injection, 600 mg (= 1 million IU), 3 g (= 5 million IU) (sodium or potassium salt) in vial
*cloxacillin	capsule, 500 mg, 1 g (as sodium salt) powder for oral solution, 125 mg (as sodium salt)/5 ml powder for injection, 500 mg (as sodium salt) in vial
phenoxymethylpenicillin	tablet, 250 mg (as potassium salt) powder for oral suspension, 250 mg (as potassium salt)/5 ml

* Example of a therapeutic group. Various drugs can serve as alternatives.

procaine benzylpenicillin	powder for injection, 1 g (= 1 million IU), 3 g (= 3 million IU)	*sulfamethoxazole + trimethoprim (4)	tablet, 100 mg + 20 mg, 400 mg + 80 mg oral suspension, 200 mg + 40 mg/5 ml
<i>Reserve antibacterials</i>			
*amoxicillin + *clavulanic acid (D)	tablet, 500 mg + 125 mg,		injection, 80 mg + 16 mg/ml in 5-ml and 10-ml ampoule
ceftazidime (D)	powder for injection, 250 mg (as pentahydrate) in vial	trimethoprim (8)	tablet, 100 mg, 200 mg injection, 20 mg/ml in 5-ml ampoule
*ceftriaxone (D)	powder for injection, 250 mg (as sodium salt) in vial	<i>Complementary drugs</i>	
imipenem + cilastatin (D)	powder for injection, 250 mg (as monohydrate) + 250 mg, (as sodium salt) 500 mg (as monohydrate) + 500 mg in vial (as sodium salt)	chloramphenicol (C)	oily suspension for injection, 0.5 g (as sodium succinate)/ml in 2-ml ampoule
6.2.2 OTHER ANTIBACTERIALS			
*chloramphenicol (7)	capsule, 250 mg oral suspension, 150 mg (as palmitate)/5 ml powder for injection, 1 g (sodium succinate) in vial	clindamycin (B) (8)	capsule, 150 mg injection, 150 mg (as phosphate)/ml
<i>Reserve antibacterial</i>			
*ciprofloxacin	tablet, 250 mg (as hydrochloride)	vancomycin (D)	powder for injection 250 mg (as hydrochloride) in vial
*doxycycline (5, 6)	capsule or tablet, 100 mg (hyclate)	6.2.3 ANTILEPROSY DRUGS	
*erythromycin	capsule or tablet, 250 mg (as stearate or ethyl succinate) powder for oral suspension, 125 mg (as stearate or ethyl succinate) powder for injection, 500 mg (as lactobionate) in vial	clofazimine	capsule, 50 mg, 100 mg
*gentamicin (2, 4, 7, 11)	injection, 10 mg, 40 mg (as sulfate)/ml in 2-ml vial	dapsone	tablet, 25 mg, 50 mg, 100 mg
*metronidazole	tablet, 200 – 500 mg injection, 500 mg in 100-ml vial suppository, 500 mg, 1 g oral suspension, 200 mg (as benzoate)/5 ml	rifampicin	capsule or tablet, 150 mg, 300 mg
nalidixic acid (8)	tablet, 250 mg, 500 mg	6.2.4 ANTITUBERCULOSIS DRUGS	
nitrofurantoin (4, 8)	tablet, 100 mg	ethambutol (4)	tablet, 100 – 400 mg (hydrochloride)
spectinomycin (8)	powder for injection, 2 g (as hydrochloride) in vial	isoniazid	tablet, 100 – 300 mg
*sulfadiazine (4)	tablet, 500 mg injection, 250 mg (sodium salt) in 4-ml ampoule	isoniazid + ethambutol (5)	tablet, 150 mg + 400 mg (hydrochloride)
		pyrazinamide	tablet, 400 mg
		rifampicin	capsule or tablet, 150 mg, 300 mg
		rifampicin + isoniazid (5)	tablet, 150 mg + 75 mg, 300 mg + 150 mg, 150 mg + 150 mg (for intermittent use 3 times weekly)
		rifampicin + isoniazid + pyrazinamide	tablet, 150 mg + 75 mg + 400 mg, 150 mg + 150 mg + 500 mg (for intermittent use 3 times weekly)
		streptomycin (4)	powder for injection, 1 g (as sulfate) in vial
		<i>Complementary drug</i>	
		thioacetazone + isoniazid (A) (5, 7)	tablet, 50 mg + 100 mg, 150 mg + 300 mg

* Example of a therapeutic group. *Various drugs can serve as alternatives.*

6.3 ANTIFUNGAL DRUGS

amphotericin B (4)	powder for injection, 50 mg in vial
griseofulvin (8)	capsule or tablet, 125 mg, 250 mg
*ketoconazole (2)	tablet, 200 mg oral suspension, 100 mg/5 ml
nystatin	tablet, 100 000, 500 000 IU lozenge, 100 000 IU pessary, 100 000 IU

Complementary drugs

flucytosine (B) (4, 8)	capsule, 250 mg infusion, 2.5 g in 250 ml
potassium iodide (A)	saturated solution

6.4 ANTIVIRALS

6.4.1 ANTIHERPES

aciclovir (8)	tablet, 200 mg powder for injection, 250 mg (as sodium salt)
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6.4.2 ANTIRETROVIRALS

zidovudine (8)	capsule, 100 mg, 250 mg injection, 10 mg/ml in 20-ml vial oral solution, 50 mg/5 ml
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Drugs for treatment of HIV/AIDS include nucleoside reverse transcriptase inhibitors (NRTIs), non-nucleoside reverse transcriptase inhibitors (NNRTIs) and protease inhibitors (PIs). The prototype drug, zidovudine, has been shown to reduce or prevent mother-to-child transmission. **This is the only indication for which it is included here.** Single drug use with zidovudine, except in pregnancy, is now regarded as obsolete because of the development of resistance. Triple therapy is beyond the budgets of most national drug programmes and therefore HIV/AIDS treatment policies must be decided at country or institutional level.

6.5 ANTIPROTOZOAL DRUGS

6.5.1 ANTIAMOEBIC AND ANTIGIARDIASIS DRUGS

* diloxanide	tablet, 500 mg (furoate)
* metronidazole	tablet, 200 – 500 mg injection, 500 mg in 100-ml vial oral suspension, 200 mg (as benzoate)/5 ml

6.5.2 ANTILEISHMANIASIS DRUGS

* meglumine antimonate	injection, 30%, equivalent to approx. 8.5% antimony, in 5-ml ampoule
pentamidine (5)	powder for injection, 200 mg, 300 mg (isetionate) in vial

Complementary drug

amphotericin B (4) (B)	powder for injection, 50 mg in vial
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6.5.3 ANTIMALARIAL DRUGS

(a) FOR CURATIVE TREATMENT

* chloroquine	tablet, 100 mg, 150 mg (as phosphate or sulfate) syrup, 50 mg (as phosphate or sulfate)/5 ml injection, 40 mg (as hydrochloride, phosphate or sulfate)/ml in 5-ml ampoule
primaquine	tablet, 7.5 mg, 15 mg (as diphosphate)
* quinine	tablet, 300 mg (bisulfate or sulfate) injection, 300 mg (as dihydrochloride)/ml in 2-ml ampoule

Complementary drugs

* doxycycline (B) (for use only with quinine)	capsule or tablet, 100 mg (hyclate)
mefloquine (B)	tablet, 250 mg (as hydrochloride)
* sulfadoxine + pyrimethamine (B)	tablet, 500 mg + 25 mg
<i>Reserve antimalarial</i> artemether (D)	injection, 80 mg/ml in 1-ml ampoule

(b) FOR PROPHYLAXIS

chloroquine	tablet, 150 mg (as phosphate or sulfate) syrup, 50 mg (as phosphate or sulfate)/5 ml
mefloquine	tablet, 250 mg (as hydrochloride)
proguanil (for use only in combination with chloroquine)	tablet, 100 mg (hydrochloride)

6.5.4 ANTIPNEUMOCYSTOSIS AND ANTITOXOPLASMOSIS DRUGS

pyrimethamine	tablet, 25 mg
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* Example of a therapeutic group. Various drugs can serve as alternatives.

sulfamethoxazole + trimethoprim injection, 80 mg + 16 mg/ml in 5-ml ampoule
 pentamidine (2) tablet, 200 mg, 300 mg (isetionate)

6.5.5 ANTITRYPANOSOMAL DRUGS

(a) AFRICAN TRYPANOSOMIASIS

melarsoprol (2) injection, 3.6% solution
 pentamidine (2) powder for injection, 200 mg, 300 mg, (isetionate) in vial
 suramin sodium powder for injection, 1 g in vial

Complementary drug

eflornithine (C) injection, 200 mg (hydrochloride)/ml in 100-ml bottles

(b) AMERICAN TRYPANOSOMIASIS

benznidazole (7) tablet, 100 mg
 nifurtimox (2, 8) tablet, 30 mg, 120 mg, 250 mg

6.6 INSECT REPELLENTS

diethyltoluamide topical solution, 50%, 75%

Section 7: Antimigraine Drugs

7.1 FOR TREATMENT OF ACUTE ATTACK

acetylsalicylic acid tablet, 300 – 500 mg
 ergotamine (7) tablet, 1 mg (tartrate)
 paracetamol tablet, 300 – 500 mg

7.2 FOR PROPHYLAXIS

*propranolol tablet, 20 mg, 40 mg (hydrochloride)

Section 8: Antineoplastics, Immunosuppressives and Drugs Used in Palliative Care

8.1 IMMUNOSUPPRESSIVE DRUGS

*azathioprine (2) tablet, 50 mg
 powder for injection, 100 mg (as sodium salt) in vial
 ciclosporin (2) capsule, 25 mg
 (for organ transplantation) concentrate for injection 50 mg/ml in 1-ml ampoule

8.2 CYTOTOXIC DRUGS

asparaginase (2) powder for injection 10 000 IU in vial
 bleomycin (2) powder for injection, 15 mg (as sulfate) in vial
 calcium folinate (2) tablet, 15 mg
 injection, 3 mg/ml in 10-ml ampoule
 chlormethine (2) powder for injection 10 mg (hydrochloride) in vial
 cisplatin (2) powder for injection, 10 mg, 50 mg in vial
 cyclophosphamide (2) tablet, 25 mg
 powder for injection, 500 mg in vial
 cytarabine (2) powder for injection, 100 mg in vial
 dacarbazine (2) powder for injection, 100 mg in vial
 dactinomycin (2) powder for injection 500 µg in vial
 *doxorubicin (2) powder for injection, 10 mg, 50 mg (hydrochloride) in vial
 etoposide (2) capsule, 100 mg
 injection, 20 mg/ml in 5-ml ampoule
 fluorouracil (2) injection, 50 mg/ml in 5-ml ampoule
 levamisole (2) tablet, 50 mg (as hydrochloride)
 mercaptopurine (2) tablet, 50 mg
 methotrexate (2) tablet, 2.5 mg (as sodium salt)
 powder for injection, 50 mg (as sodium salt) in vial
 procarbazine capsule, 50 mg (as hydrochloride)
 vinblastine (2) powder for injection, 10 mg (sulfate) in vial
 vincristine (2) powder for injection, 1 mg, 5 mg (sulfate) in vial

8.3 HORMONES AND ANTIHORMONES

*prednisolone tablet, 5 mg
 powder for injection, 20 mg, 25 mg, (as sodium phosphate or sodium succinate) in vial
 tamoxifen tablet, 10 mg, 20 mg (as citrate)

* Example of a therapeutic group. Various drugs can serve as alternatives.

8.4 DRUGS USED IN PALLIATIVE CARE

It is recommended that all the drugs mentioned in the WHO publication *Cancer Pain Relief with a Guide to Opioid Availability, 2nd. edition*, be considered essential. The drugs are included in the relevant section of the model list according to their therapeutic use, e.g. analgesics.

heparin sodium	injection, 1000 IU/ml, 5000 IU/ml, 20 000 IU/ml in 1-ml ampoule
phytomenadione	injection, 10 mg/ml in 5-ml ampoule tablet, 10 mg
protamine sulfate	injection, 10 mg/ml in 5-ml ampoule
*warfarin (2, 6)	tablet, 1, 2 and 5 mg (sodium salt)

Section 9: Antiparkinsonism Drugs

*biperiden	tablet, 2 mg (hydrochloride) injection, 5 mg (lactate) in 1-ml ampoule
levodopa + *carbidopa (5, 6)	tablet, 100 mg + 10 mg, 250 mg + 25 mg

Section 10: Drugs affecting the Blood

10.1 ANTIANAEMIA DRUGS

ferrous salt	tablet, equivalent to 60 mg iron oral solution, equivalent to 25 mg iron (as sulfate)/ml
ferrous salt + folic acid (nutritional supplement for use during pregnancy)	tablet, equivalent to 60 mg iron + 400 µg folic acid
folic acid (2)	tablet, 1 mg, 5 mg injection, 1 mg (as sodium salt) in 1-ml ampoule
hydroxocobalamin (2)	injection, 1 mg in 1-ml ampoule

Complementary drug

*iron dextran (B) (5)	injection, equivalent to 50 mg iron (as complex of iron(III) hydroxide with dextrans)/ ml in 2-ml ampoule
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10.2 DRUGS AFFECTING COAGULATION

desmopressin (8)	injection, 4µg (acetate)/ml in 1-ml ampoule nasal spray 10 µg (acetate)/ metered dose
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* Example of a therapeutic group. Various drugs can serve as alternatives.

¹ All plasma fractions should comply with the Requirements for the collection, processing and quality control of blood, blood components, and plasma derivatives (revised 1992). WHO Technical Report Series, No. 840, 1994, Annex 2.

Section 11: Blood Products and Plasma Substitutes

11.1 PLASMA SUBSTITUTES

*dextran 70	injectable solution, 6%
*polygeline	injectable solution, 3.5%

11.2 PLASMA FRACTIONS FOR SPECIFIC USE ¹

*albumin, human (2, 8)	injectable solution, 5%, 25%
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Complementary drugs

*factor VIII concentrate (C) (2, 8)	(dried)
*factor IX complex (coagulation factors II, VII, IX, X) concentrate (C) (2, 8)	(dried)

Section 12: Cardiovascular Drugs

12.1 ANTIANGINAL DRUGS

*atenolol	tablet, 50 mg, 100 mg
glyceryl trinitrate	tablet (sublingual), 500 µg
*isosorbide dinitrate	tablet (sublingual), 5 mg
*verapamil (10)	tablet, 40 mg, 80 mg (hydrochloride)

12.2 ANTIARRHYTHMIC DRUGS

*atenolol	tablet, 50 mg, 100 mg
digoxin (4, 11)	tablet, 62.5 µg, 250 µg oral solution, 50 µg/ml injection, 250 µg/ml in 2-ml ampoule
lidocaine	injection, 20 mg (hydrochloride)/ml in 5-ml ampoule
verapamil (8, 10)	tablet, 40 mg, 80 mg (hydrochloride) injection, 2.5 mg (hydrochloride)/ml in 2-ml ampoule

Complementary drugs

isoprenaline (C)	injection 20 µg (hydrochloride)/ml
epinephrine (C)	injection, 1 mg (as hydrochloride)/ml
*procainamide (B)	tablet, 250 mg, 500 mg (hydrochloride)
	injection, 100 mg (hydrochloride)/ml in 10-ml ampoule
*quinidine (A) (7)	tablet, 200 mg (sulfate)

12.3 ANTIHYPERTENSIVE DRUGS

*atenolol	tablet, 50 mg, 100 mg
*captopril	scored tablet, 25 mg
*hydralazine	tablet, 25 mg, 50 mg (hydrochloride)
	powder for injection, 20 mg (hydrochloride) in ampoule
*hydrochlorothiazide	scored tablet, 25 mg
methyl dopa (7)	tablet, 250 mg
*nifedipine (10)	modified release formulations
	tablet, 10 mg
*reserpine	tablet, 100 µg, 250 µg
	injection, 1 mg in 1-ml ampoule

Complementary drugs

doxazosin (B)	tablet, 1 mg, 2 mg, 4 mg (mesilate)
*sodium nitroprusside (C) (2, 8)	powder for infusion, 50 mg in ampoule

12.4 DRUGS USED IN HEART FAILURE

*captopril	scored tablet, 25 mg
digoxin (4, 11)	tablet, 62.5 µg, 250 µg
	oral solution, 50 µg/ml
	injection, 250 µg/ml in 2-ml ampoule
dopamine	injection, 40 mg (hydrochloride)/ml in 5-ml vial
*hydrochlorothiazide	tablet 25 mg, 50 mg

12.5 ANTITHROMBOTIC DRUGS

acetylsalicylic acid	tablet, 100 mg
<i>Complementary drug</i>	
streptokinase (C)	powder for injection, 100 000 IU, 750 000 IU in vial

12.6 LIPID-LOWERING AGENTS

The Committee recognizes the value of lipid-lowering drugs in treating patients with hyperlipidaemia. However, there are many other risk factors for atherosclerosis and its complications including tobacco smoking and inadequately controlled hypertension. Most hyper-lipidaemias can be controlled by diet.

HMG CoA reductase inhibitors, often referred to as "statins" are potent and effective lipid-lowering drugs with a good tolerability profile. Several of them have now been shown to reduce fatal and non-fatal myocardial infarction, stroke, need for coronary by-pass surgery and all-cause mortality. All remain very costly but for primary prevention in some very high risk patients and secondary prevention they may be cost effective. Since no drug stands out for greater efficacy or lower cost, none is included in the List; each country should make its own decisions for use in highest risk patients.

**Section 13:
Dermatological Drugs (topical)****13.1 ANTIFUNGAL DRUGS**

benzoic acid + salicylic acid	ointment or cream, 6% + 3%
*miconazole	ointment or cream, 2% (nitrate)
sodium thiosulfate	solution, 15%

Complementary drug

selenium sulfide (C)	detergent-based suspension, 2%
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13.2 ANTI-INFECTIVE DRUGS

*methylrosanilinium chloride (gentian violet)	aqueous solution, 0.5% tincture, 0.5%
neomycin + *bacitracin (7)	ointment, 5 mg (sulfate) + 500 IU bacitracin zinc/g
potassium permanganate	aqueous solution, 1:10 000
silver sulfadiazine	cream, 1%, in 500-g container

**13.3 ANTI-INFLAMMATORY AND
ANTIPRURITIC DRUGS**

*betamethasone (3)	ointment or cream, 0.1% (as valerate)
*calamine lotion	lotion
*hydrocortisone	ointment or cream, 1% (acetate)

* Example of a therapeutic group. Various drugs can serve as alternatives.

13.4 ASTRINGENT DRUGS

aluminium diacetate solution, 13% for dilution

**13.5 DRUGS AFFECTING SKIN
DIFFERENTIATION AND PROLIFERATION**

benzoyl peroxide lotion or cream, 5%

coal tar solution, 5%

dithranol ointment, 0.1 – 2%

flourouracil ointment, 5%

*podophyllum resin (7) solution, 10 – 25%

salicylic acid solution, topical 5%

urea ointment or cream, 10%

13.6 SCABICIDES AND PEDICULICIDES

*benzyl benzoate lotion, 25%

permethrin cream, 5%,
 lotion, 1%**13.7 ULTRAVIOLET BLOCKING AGENTS***Complementary drugs*topical sun protection agent with
activity against UVA and UVB (C) cream, lotion or gel**Section 14: Diagnostic Agents****14.1 OPHTHALMIC DRUGS**

fluorescein eye drops, 1% (sodium salt)

*tropicamide eye drops, 0.5%

14.2 RADIOCONTRAST MEDIA*amidotrizoate injection, 140 – 420 mg iodine
(as sodium or meglumine
amidotrizoate)/ml in 20-ml ampoule

barium sulfate aqueous suspension

*iopanoic acid tablet, 500 mg

*propylidone oily suspension,
(*This suspension is for
administration only into
the bronchial tree.*) 500-600 mg/ml
 in 20-ml ampoule*Complementary drug**meglumine iotroxate (C) solution, 5 – 8 g iodine
 in 100–250 ml**Section 15:
Disinfectants and Antiseptics****15.1 ANTISEPTICS***chlorhexidine solution, 5%
(digluconate) for dilution

*povidone-iodine solution, 10%

15.2 DISINFECTANTS*chlorine base compound powder (0.1% available
chlorine) for solution

*chloroxylonol solution, 4.8%

glutaral solution, 2%

Section 16: Diuretics

*amiloride (4, 7, 8) tablet, 5 mg (hydrochloride)

*furosemide tablet, 40 mg
 injection, 10 mg/ml in
 2-ml ampoule

*hydrochlorothiazide tablet, 25 mg, 50 mg

spironolactone (8) tablet, 25 mg

Complementary drugs

*mannitol (C) injectable solution, 10%, 20%

Section 17: Gastrointestinal Drugs**17.1 ANTACIDS AND OTHER ANTIULCER
DRUGS**aluminium hydroxide tablet, 500 mg
 oral suspension, 320 mg/5 ml*cimetidine tablet, 200 mg
 injection, 200 mg in 2-ml ampoulemagnesium hydroxide oral suspension,
 equivalent to 550 mg
 magnesium oxide/10 ml**17.2 ANTIEMETIC DRUGS**metoclopramide tablet, 10 mg (hydrochloride)
 injection, 5 mg (hydrochloride)/ml
 in 2-ml ampoule* Example of a therapeutic group. *Various drugs can serve as alternatives.*

*promethazine	tablet, 10 mg, 25 mg (hydrochloride) elixir or syrup, 5 mg (hydrochloride)/5 ml injection, 25 mg (hydrochloride)/ml in 2-ml ampoule
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17.3 ANTIHAEMORRHOIDAL DRUGS

*local anaesthetic, astringent and anti-inflammatory drug	ointment or suppository
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17.4 ANTI-INFLAMMATORY DRUGS

hydrocortisone	suppository, 25 mg (acetate), retention enema
*sulfasalazine (2)	tablet, 500 mg suppository, 500 mg retention enema

17.5 ANTISPASMODIC DRUGS

*atropine	tablet, 0.6 mg (sulfate) injection, 1 mg (sulfate) in 1-ml ampoule
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17.6 LAXATIVES

*senna	tablet, 7.5 mg (sennosides) (or traditional dosage forms)
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17.7 DIARRHOEA, DRUGS USED IN**17.7.1 ORAL REHYDRATION**

oral rehydration salts (for glucose- electrolyte solution)	powder, 27.9 g/l
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Components to reconstitute 1 litre of glucose-electrolyte solution:	g/l
sodium chloride	3.5
trisodium citrate dihydrate ²	2.9
potassium chloride	1.5
glucose, anhydrous	20.0

**17.7.2 ANTIDIARRHOEAL (SYMPTOMATIC)
DRUGS**

*codeine (1a)	tablet, 30 mg (phosphate)
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**Section 18: Hormones, other Endo-
crine Drugs and Contraceptives****18.1 ADRENAL HORMONES AND
SYNTHETIC SUBSTITUTES**

*dexamethasone	tablet, 500 µg, 4 mg injection, 4 mg dexamethasone phosphate (as disodium) in 1-ml ampoule
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hydrocortisone	powder for injection, 100 mg (as sodium succinate) in vial
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*prednisolone	tablet, 1 mg, 5 mg
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Complementary drug

fludrocortisone (C)	tablet, 100 µg (acetate)
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18.2 ANDROGENS*Complementary drug*

testosterone (C) (2)	injection, 200 mg (enantate) in 1-ml ampoule
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18.3 CONTRACEPTIVES**18.3.1 HORMONAL CONTRACEPTIVES**

*ethinylestradiol + *levonorgestrel	tablet, 30 µg + 150 µg,
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*ethinylestradiol + *norethisterone	tablet, 35 µg + 1.0 mg
--	------------------------

Complementary drugs

*ethinylestradiol + *levonorgestrel (C)	50 µg + 250 µg (pack of four)
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*levonorgestrel (B)	tablet 30 µg
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medroxy- progesterone acetate (B) (7, 8)	depot injection 150 mg/ml in 1-ml,
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norethisterone enantate (B) (7, 8)	oily solution, 200 mg/ml in 1-ml ampoule
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18.3.2 INTRAUTERINE DEVICES

copper-containing device

18.3.3 BARRIER METHODS

condoms with or without spermicide (nonoxinol)

diaphragms with spermicide (nonoxinol)

* Example of a therapeutic group. *Various drugs can serve as alternatives.*² Trisodium citrate dihydrate may be replaced by sodium bicarbonate (sodium hydrogen carbonate) 2.5 g/litre. However, as the stability of this latter formulation is very poor under tropical conditions, it is only recommended when manufactured for immediate use.

18.4 ESTROGENS

*ethinylestradiol tablet, 10 µg, 50 µg

18.5 INSULINS AND OTHER ANTIDIABETIC AGENTSinsulin injection (soluble) injection,
40 IU/ml in 10-ml vial,
100 IU/ml in 10-ml vialintermediate-acting insulin injection,
40 IU/ml in 10-ml vial,
100 IU/ml in 10-ml vial
(as compound insulin zinc suspension
or isophane insulin)

*glibenclamide tablet, 2.5 mg, 5 mg

metformin tablet, 500 mg

18.6 OVULATION INDUCERS

*clomifene (2, 8) tablet, 50 mg (citrate)

18.7 PROGESTOGENS

norethisterone tablet, 5 mg

Complementary drug

medroxyprogesterone acetate (B) tablet, 5 mg

18.8 THYROID HORMONES AND ANTITHYROID DRUGSlevothyroxine tablet, 50 µg, 100 µg
(sodium salt)

potassium iodide tablet, 60 mg

*propylthiouracil tablet, 50 mg

Section 19: Immunologicals**19.1 DIAGNOSTIC AGENTS**tuberculin,³ injection
purified protein derivative (PPD)**19.2 SERA AND IMMUNOGLOBULINS⁴**anti-D immunoglobulin, injection, 250 µg in
(human) single-dose vial

antiscorpion sera injection

*antitetanus immunoglobulin, injection, 500 IU
(human) in vial

antivenom serum injection

diphtheria antitoxin injection, 10 000 IU,
20 000 IU in vialimmunoglobulin, injection (intramuscular)
human normal (2)immunoglobulin, injection (intravenous)
human normal (2, 8)

*rabies immunoglobulin injection, 150 IU/ml

19.3 VACCINES⁵**19.3.1 FOR UNIVERSAL IMMUNIZATION**

BCG vaccine (dried) injection

diphtheria-pertussis-tetanus
vaccine injection

diphtheria-tetanus vaccine injection

hepatitis B vaccine injection

measles-mumps-rubella vaccine injection

measles vaccine injection

poliomyelitis vaccine (inactivated) injection

poliomyelitis vaccine oral solution
(live attenuated)

tetanus vaccine injection

tetanus-diphtheria (Td) injection

19.3.2 FOR SPECIFIC GROUPS OF INDIVIDUALS

influenza vaccine injection

meningococcal vaccine injection

rabies vaccine injection (in cell culture)

rubella vaccine injection

typhoid vaccine injection

yellow fever vaccine injection

* Example of a therapeutic group. *Various drugs can serve as alternatives.*³ All tuberculins should comply with the WHO requirements for tuberculins (Revised 1985). WHO Technical Report Series, No. 745, 1987. Annex 1.⁴ All plasma fractions should comply with the WHO requirements for the collection, processing and quality control of blood, blood components and plasma derivatives (Revised 1992). WHO Technical Report Series, No. 840, 1994, Annex 2.⁵ All vaccines should comply with the WHO requirements for biological substances.

Section 20: Muscle Relaxants (peripherally acting) and Cholinesterase Inhibitors

*alcuronium chloride (2)	injection, 5 mg/ml in 2-ml ampoule
*neostigmine	tablet, 15 mg (bromide) injection, 500 µg, 2.5 mg (metilsulfate) in 1-ml ampoule
pyridostigmine bromide (2, 8)	tablet, 60 mg injection, 1 mg in 1-ml ampoule
suxamethonium chloride (2)	injection, 50 mg/ml in 2-ml ampoule powder for injection
<i>Complementary drug</i>	
vecuronium bromide (C)	powder for injection, 10 mg in vial

Section 21: Ophthalmological Preparations

21.1 ANTI-INFECTIVE AGENTS

*gentamicin	solution (eye drops), 0.3% (as sulfate)
*idoxuridine	solution (eye drops), 0.1% eye ointment, 0.2%
silver nitrate	solution (eye drops), 1%
*tetracycline	eye ointment, 1% (hydrochloride)

21.2 ANTI-INFLAMMATORY AGENTS

*prednisolone	eye drops, 0.5% (sodium phosphate)
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21.3 LOCAL ANAESTHETICS

*tetracaine	solution (eye drops), 0.5% (hydrochloride)
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21.4 MIOTICS AND ANTIGLAUCOMA DRUGS

acetazolamide	tablet, 250 mg
*pilocarpine	solution (eye drops), 2%, 4% (hydrochloride or nitrate)
*timolol	solution (eye drops), 0.25%, 0.5% (as maleate)

21.5 MYDRIATICS

atropine	solution (eye drops), 0.1%, 0.5%, 1% (sulfate)
<i>Complementary drug</i>	
epinephrine (A)	solution (eye drops), 2% (as hydrochloride)

Section 22: Oxytocics and Antioxytocics

22.1 OXYTOCICS

*ergometrine	tablet, 200 µg (hydrogen maleate) injection, 200 µg (hydrogen maleate) in 1-ml ampoule
oxytocin	injection, 10 IU in 1-ml ampoule

22.2 ANTIOXYTOCICS

*salbutamol (2)	tablet, 4 mg (as sulfate) injection, 50 µg (as sulfate)/ml in 5-ml ampoule
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Section 23: Peritoneal Dialysis Solution

intraperitoneal dialysis solution (of appropriate composition)	parenteral solution
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Section 24: Psychotherapeutic Drugs

24.1 DRUGS USED IN PSYCHOTIC DISORDERS

*chlorpromazine	tablet, 100 mg (hydrochloride) syrup, 25 mg (hydrochloride)/5 ml injection, 25 mg (hydrochloride)/ml in 2-ml ampoule
*fluphenazine (5)	injection, 25 mg (decanoate or enantate) in 1-ml ampoule
*haloperidol	tablet, 2 mg, 5 mg injection, 5 mg in 1-ml ampoule

* Example of a therapeutic group. *Various drugs can serve as alternatives.*

24.2 DRUGS USED IN MOOD DISORDERS**24.2.1 DRUGS USED IN DEPRESSIVE DISORDERS**

*amitriptyline tablet, 25 mg (hydrochloride)

24.2.2 DRUGS USED IN BIPOLAR DISORDERS

carbamazepine (10, 11) scored tablet, 100 mg, 200 mg

lithium carbonate (2, 4) capsule or tablet, 300 mg

valproic acid (7, 11) enteric coated tablet,
200 mg, 500 mg (sodium salt)**24.3 DRUGS USED FOR GENERALIZED ANXIETY AND SLEEP DISORDERS**

*diazepam (1b) scored tablet, 2 mg, 5 mg

24.4 DRUGS USED FOR OBSESSIVE COMPULSIVE DISORDERS AND PANIC ATTACKSclomipramine capsules, 10 mg, 25 mg
(hydrochloride)**Section 25: Drugs Acting on the Respiratory Tract****25.1 ANTI-ASTHMATIC DRUGS***aminophylline (2) injection, 25 mg/ml
in 10-ml ampoule*beclometasone inhalation (aerosol), 50 µg, 250 µg,
(dipropionate) per dose*epinephrine injection, 1 mg (as hydrochloride
or hydrogen tartrate) in 1-ml ampoule

ipratropium bromide inhalation, 20 µg/metered dose

*salbutamol tablet, 2 mg, 4 mg (as sulfate)
inhalation (aerosol), 100 µg
(as sulfate) per dose
syrup, 2 mg (as sulfate)/5 ml
injection, 50 µg (as sulfate)/ml
in 5-ml ampoule
respirator solution for use in nebulizers,
5 mg (as sulfate)/ml

theophylline (10, 11) tablet, 100 mg, 200 mg

*Complementary drug**cromoglicic acid (B) inhalation (aerosol),
20 mg (sodium salt) per dose**25.2 ANTITUSSIVES**

*dextromethorphan oral solution, 3.5 mg/5 ml

Section 26:**Solutions correcting Water, Electrolyte and Acid-base Disturbances****26.1 ORAL**oral rehydration salts (for glucose-
electrolyte solution) see section
17.7.1

potassium chloride powder for solution

26.2 PARENTERAL* compound solution of
sodium lactate injectable solutionglucose injectable solution,
5% isotonic, 50% hypertonicglucose with sodium chloride injectable solution, 4%
glucose, 0.18% sodium chloride
(equivalent to Na⁺ 30 mmol/l
Cl⁻ 30 mmol/l)potassium chloride (2) 11.2% solution in
20-ml ampoule, (equivalent to
K⁺ 1.5 mmol/ml, Cl⁻ 1.5 mmol/ml)sodium chloride injectable solution, 0.9%
isotonic (equivalent to Na⁺ 154
mmol/l, Cl⁻ 154 mmol/l)sodium hydrogen carbonate injectable solution, 1.4%
isotonic (equivalent to Na⁺ 167
mmol/l, HCO₃⁻ 167 mmol/l)
8.4% solution in 10-ml ampoule
(equivalent to Na⁺ 1000 mmol/l,
HCO₃⁻ 1000 mmol/l)**26.3 MISCELLANEOUS**

water for injection 2-ml, 5-ml, 10-ml ampoules

Section 27: Vitamins and Minerals

ascorbic acid tablet, 50 mg

*ergocalciferol capsule or tablet, 1.25 mg
(50 000 IU)oral solution,
250 µg/ml (10 000 IU/ml)iodine (8) iodized oil, 1 ml (480 mg iodine),
0.5 ml (240 mg iodine) in
ampoule (oral or injectable)* Example of a therapeutic group. *Various drugs can serve as alternatives.*

	solution, 0.57 ml, (308 mg iodine) in dispenser bottle		dispenser (as palmitate)
	capsule, 200 mg		water-miscible injection, 100 000 IU (as palmitate) (55 mg) in 2-ml ampoule
*nicotinamide	tablet, 50 mg		
pyridoxine	tablet, 25 mg (hydrochloride)	riboflavin	tablet, 5 mg
*retinol	sugar-coated tablet, 10 000 IU (as palmitate) (5.5 mg)	*sodium fluoride	in any appropriate formulation
	capsule, 200 000 IU (as palmitate) (110 mg)	thiamine	tablet, 50 mg (hydrochloride)
	oral oily solution, 100 000 IU/ml in multidose	<i>Complementary drug</i>	
		calcium gluconate (C), (2, 8)	injection, 100 mg/ml in 10-ml ampoule

The following changes in the WHO Model List were approved by the WHO Expert Committee on the Use of Essential Drugs which met in December 1997. The report of the meeting will be published in the WHO Technical Report Series.

Deletions: hydrogen peroxide; metrifonate.

Additions: aciclovir for use in herpes infections; amoxicillin + clavulanic acid for treatment of infections resistant to the production of beta lactamase; dextromethorphan for treatment of cough; ephedrine for treatment of hypotension in spinal anaesthesia during delivery; imipenem + cilastatin for treatment of *Pseudomonas* and *Acinetobacter* spp.; ipratropium bromide for the treatment of asthma; metformin for the treatment of non-insulin dependent diabetes; triclabendazole for treatment of liver and lung flukes; zidovudine to reduce or prevent mother-to-child transmission of HIV infection.

Replacements: chloroxlenol to replace phenol disinfectant; chlorine (NaDCC) for calcium hypochlorite; glibenclamide for tolbutamide; sulfadiazine for sulfadimidine; topical sunscreen for benzophenones and zinc oxide.

* Example of a therapeutic group. *Various drugs can serve as alternatives.*

Recent Publications and Documents

Extended release oral dosage forms: guidance for applicants

The United States Food and Drug Administration has announced the availability of a guidance document entitled *Extended Release Oral Dosage Forms: development, evaluation and application of in vitro/in vivo correlations (IVIVC)*, which is intended to provide recommendations for the development of documentation in support of a new drug application, abbreviated new drug application or antibiotic drug application.

This document provides a comprehensive perspective on methods of developing an IVIVC and evaluating its predictability, using an IVIVC to set dissolution specifications, and applying an IVIVC as a surrogate for in vivo bioequivalence when it is necessary to document this during the initial approval process or because of certain pre-approval or post-approval changes in formulation, equipment, process, or a manufacturing site. However, the guidance is not binding and an alternative approach may be used if this satisfies the requirements of the applicable statute, regulations, or both.

Extended Release Oral Dosage Forms: development, evaluation and application of in vitro/in vivo correlations. Available from: Drug Information Branch, HFD 210, Center for Drug Evaluation and Research, Food and Drug Administration, Rockville, MD 20857, USA. Or: <http://www.fda.gov/cder/guidance/index.htm>.

United Nations Consolidated List

The Consolidated List of Products whose Consumption and/or Sale have been Banned, Withdrawn, Severely Restricted or Not Approved by Governments is a unique list of restrictive regulatory actions on pharmaceuticals taken by ninety-four governments which has been compiled in response to a 1982 United Nations General Assembly resolution aimed to protect the public against products harmful to health.

Published in two parts, the first part provides information to inform governments of regulatory decisions taken in other countries and assists them in

considering their own regulatory action. For regulatory agencies reviewing applications for product registration, it provides information on the status of products globally.

To ensure that the List focuses on products harmful to health, criteria for the inclusion of products have been developed. None the less, it is drawn to the reader's attention that decisions taken by a limited number of governments on a specific product may not be representative of the position of other governments, particularly in view of differing risk/benefit considerations. It is also important to note that all pharmaceutical products are potentially harmful if not correctly used. Inversely, the fact that a given product is not listed as regulated by a country does not necessarily mean that it is permitted in that country.

Part two of the list presents commercial information, including data on trade names. It thus provides an easy method of cross-referencing commercial names with recognized common scientific names.

Consolidated List of Products whose Consumption and/or Sale have been Banned, Withdrawn, Severely Restricted or Not Approved by Governments. United Nations, New York, 1997. Price US\$ 120.- ISBN 92 1 130183 1

Manual on quality assurance

Assurance of the quality, safety and efficacy of pharmaceutical products is a continuing concern of WHO's Division of Drug Management & Policies. Despite efforts made in many parts of the world to ensure the supply of high-quality and effective drugs, inadequate pharmaceutical regulation and the presence of substandard, spurious or counterfeit products still compromise health care delivery in many countries.

In response to the need for adequate quality assurance of pharmaceuticals, the WHO Expert Committee on Specifications for Pharmaceutical Preparations has, over the years, made numerous recommendations to promote quality assurance and the application of internationally agreed standards. Many of the recommendations, even though en-

dorsed several years ago, are still valid and are essential to all concerned with the quality assurance of medicines. They provide complementary parts of a comprehensive system to uphold quality assurance and will be reproduced by WHO in two accompanying volumes, supplemented by other relevant supporting material. The two manuals are designed to address not only the pharmaceutical aspects of the quality of medicines but also the intrinsic safety and efficacy of pharmacologically-active substances.

Volume 1 is now available and sets out to cover basic aspects of national drug regulation, assessment of drug products and herbals, stability, basic tests, laboratory services, international trade in pharmaceuticals, counterfeit products and training. Volume 2 is planned to be issued this year and will address issues of good manufacturing practice and inspection.

Quality Assurance of Pharmaceuticals. Volume 1. World Health Organization, Geneva. Price Sw.fr. 50.- (Sw.fr. 35.- developing countries) . ISBN 92 4 154504 6

Medicinal claims and food products

Food products are often advertised, marketed and sold to the public with health claims that are similar or mimic therapeutic indications which have been scientifically established for pharmaceutical products. The National Agency for Medicines in Finland has now published a guide indicating which medicinal claims are allowed for food products and which are prohibited.

Under the Foodstuffs Act of Finland, control and marketing of foodstuffs should be carried out by the National Food Administration. This covers advertising and labelling, as well as any other information supplied in a sales context. When required, the National Agency for Medicines assists in deciding whether a marketing claim made for a food product can be considered medicinal or therapeutic. The Act forbids any health related claims, or the supply of medicinal information as a part of the marketing strategy. This also means any suggestive statements indicating that use of the said food product could prevent, treat or cure an illness or its symptoms.

The guide lists some 70 claims that are considered a reference to an illness or a medical condition. The following are listed as examples: prevents insom-

nia, depression; prevents blood clotting and thus vascular obstruction; reduces the risk of cardiovascular disease; boosts circulation; prevents osteoporosis, muscle or joint pain, rheumatism, arthritis; prevents otitis; travel sickness, eczema, herpes or psoriasis; asthma, allergy; strengthens the nervous system; stimulates the memory; activates the endocrine glands; balances hormonal activity; deactivates free radicals known to cause heart disease and cancer; stimulates melatonin production; reduces the need for insulin; reinforces blood cells; heightens potency; increases the body's tolerance.

The guide also sets out statements which are acceptable. These should be based on substantiated medical evidence and should not mislead the consumer. Education on nutritional matters is considered to be in the interests of the consumer and such information may be supplemented with examples when certain foods are clearly beneficial to the vital functions of the body. It is therefore permitted to provide information on nutrition and to educate consumers on what constitutes a healthy diet. This would include information on fat or iron content, quality of the product, stimulation of body functions, contribution to lowering cholesterol levels, etc.

The usefulness of the guide will be evaluated in two years' time when a comparison is made with past and present promotional claims.

Guidebook on Monitoring the Medicinal Marketing of Foods in Finland. Department of Pharmacology, National Agency for Medicines, P.O. Box 55, 00301 Helsinki, Finland.

Paediatric prescribing information

Many physicians and health care providers are faced with the challenge of providing relevant information to patients on the correct use of medications which they have prescribed. Although there has been an increase in both research and studies on drug use in paediatric patients, until now very little specific prescribing information has been produced with children in mind and physicians are often forced to sift through information which has been provided for adult patients.

The American College of Clinical Pharmacy has recently published medication information sheets, in English and Spanish, designed to provide a con-

cise, understandable source of written information for paediatric patients. Two hundred medications are described, focusing on those products most frequently prescribed at hospital discharge or during physician home visits.

The medication sheets also include information on formulations and liquids which can be prepared by pharmacists from solid oral dosage forms. The use of these formulations allows the manipulation of available dosage forms into products more appropriate for small children.

All information relies on United States Food and Drug Administration recommendations and data provided for products available within the United States of America. However, before prescribing, physicians are reminded to consult package leaflets which will give the latest information on dosages, contraindications and use of the medication in question.

Pediatric Medication Education Text is available from: The American College of Clinical Pharmacy, 3101 Broadway, Suite 380, Kansas City, MO 64111, USA. ISBN 1 880401 89 4. e-mail: accp@accp.com.

International Nonproprietary Names for Pharmaceutical Substances (INN)

RECOMMENDED International Nonproprietary Names (Rec. INN): List 39

Notice is hereby given that, in accordance with paragraph 7 of the Procedure for the Selection of Recommended International Nonproprietary Names for Pharmaceutical Substances [*Off. Rec. Wld Health Org.*, 1955, **60**, 3 (Resolution EB15.R7); 1969, **173**, 10 (Resolution EB43.R9)], the following names are selected as Recommended International Nonproprietary Names. The inclusion of a name in the lists of Recommended International Nonproprietary Names does not imply any recommendation of the use of the substance in medicine or pharmacy. Lists of Proposed (1–73) and Recommended (1–35) International Nonproprietary Names can be found in *Cumulative List No 9, 1996*.

Dénominations communes internationales des Substances pharmaceutiques (DCI)

Dénominations communes internationales RECOMMANDÉES (DCI Rec): Liste 39

Il est notifié que, conformément aux dispositions du paragraphe 7 de la Procédure à suivre en vue du choix de Dénominations communes internationales recommandées pour les Substances pharmaceutiques [*Actes off. Org mond. Santé*, 1955, **60**, 3 (résolution EB15.R7); 1969, **173**, 10 (résolution EB43.R9)] les dénominations ci-dessous sont mises à l'étude par l'Organisation mondiale de la Santé en tant que dénominations communes internationales proposées. L'inclusion d'une dénomination dans les listes de DCI proposées n'implique aucune recommandation en vue de l'utilisation de la substance correspondante en médecine ou en pharmacie.

On trouvera d'autres listes de Dénominations communes internationales proposées (1–73) et recommandées (1–35) dans la *Liste récapitulative No 9, 1996*.

Denominaciones Comunes Internacionales para las Sustancias Farmacéuticas (DCI)

Denominaciones Comunes Internacionales RECOMENDADAS (DCI Rec.): Lista 39

De conformidad con lo que dispone el párrafo 7 del Procedimiento de Selección de Denominaciones Comunes Internacionales Recomendadas para las Sustancias Farmacéuticas [*Act. Of. Mund. Salud*, 1955, **60**, 3 (Resolución EB15.R7); 1969, **173**, 10 (Resolución EB43.R9)], se comunica por el presente anuncio que las denominaciones que a continuación se expresan han sido seleccionadas como Denominaciones Comunes Internacionales Recomendadas. La inclusión de una denominación en las listas de las Denominaciones Comunes Recomendadas no supone recomendación alguna en favor del empleo de la sustancia respectiva en medicina o en farmacia. Las listas de Denominaciones Comunes Internacionales Propuestas (1–73) y Recomendadas (1–35) se encuentran reunidas en *Cumulative List No. 9, 1996*.

Discussions have recently taken place between the World Intellectual Property Organization and WHO's Division of Drug Management and Policies regarding the *protection of International Nonproprietary Names (INN)* against (mis)use as domain names on INTERNET. These discussions were initiated *inter alia* in view of INN having been registered as domain names on Internet, for purposes not necessarily related to the global identification of a specific pharmaceutical substance to protect the safety of patients. In this regard, there have been several reported cases where an INN-based domain name has been registered on the Internet and then sold to a company which had an interest in avoiding proprietary use of the INN in question.

In order to help ensure that INN are used exclusively for the identification of a specific pharmaceutical substance under one single, globally available name and that no party can claim any proprietary rights to INN, a paragraph relating to INN has been proposed for inclusion in the *Trademark Dispute Resolution, Draft Substantive Guidelines concerning Administrative Domain Name Challenge Panels*. Details are available on:

<http://www.gtld-mou.org/docs/tracps.htm> and
<http://www.wipo.int/eng/internet/domains/index.htm>

After further consultation, it is suggested that the text of the proposed paragraph, as contained in clause 1 (b) of Annex B of the *Guidelines*, should read as follows^a:

"A name published by the World Health Organization (WHO) in the Cumulative List of International Nonproprietary Names for Pharmaceutical Substances (INN), and updated regularly in WHO Drug Information, pursuant to World Health Assembly (WHA) Resolution 3.11 and subsequent resolutions "

It is hoped that the inclusion of this paragraph will allow interested parties to challenge the registration of a domain name "if identical or confusingly identical" to an INN, in particular if such a registration has been made in bad faith.

WHO would like to emphasize that its main concern is the safety of patients. In accordance with WHA resolution 3.11 on Non-proprietary Names for Drugs (adopted in May 1950 by the Third World Health Assembly), the Organization is responsible for selecting and promoting the protection of recommended International Nonproprietary Names as a means of identifying pharmaceutical substances under one single, globally available name, in which no party can claim any proprietary rights.

For any further information or comments, please contact the Secretariat of the INN Programme (Division of Drug Management and Policies, World Health Organization, 20 av. Appia, CH-1211 Geneva 27, Fax: +41 22 791 4730, e-mail: koppkubels@who.ch).

^a Based on the third revised draft of the *Guidelines* dated 16 January 1998.

Latin, English, French, Spanish.

Recommended INN

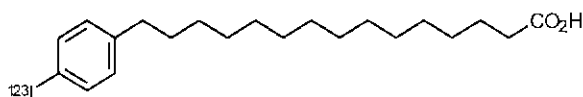
Chemical name or description; Molecular formula; Graphic formula

DCI Recommandée

Nom chimique ou description; Formule brute; Formule développée

DCI Recomendada

Nombre químico o descripción; Fórmula empírica; Fórmula desarrollada

acidum iocanlidicum (¹²³I)iocanlidic acid (¹²³I)15-(*p*-[¹²³I]iodophenyl)pentadecanoic acidacide iocanlidique (¹²³I)acide 15-(4-[¹²³I]iodophényl)pentadécanoïqueácido iocanlidico (¹²³I)ácido 15-(*p*-[¹²³I]iodofenil)pentadecanoicoC₂₁H₃₃¹²³IO₂**acrezastum**

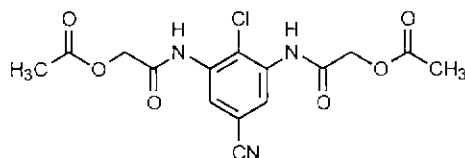
acrezast

N,N'-(2-chloro-5-cyano-*m*-phenylene)bis[glycolamide]diacetate (ester)

acréozast

diacétate de 2,2'-[2-chloro-5-cyano-1,3-phénylènebis(imino)]bis(2-oxoéthyle)

acrezast

éster diacético de *N,N'*-(2-cloro-5-ciano-*m*-fenilen)bis[glicolamida]C₁₅H₁₄ClN₃O₆**argatrobanum**

argatroban

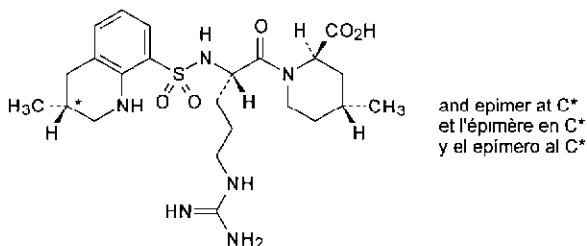
(2*R*,4*R*)-4-methyl-1-[(*S*)-*N*²-[[(*R**S*)-1,2,3,4-tetrahydro-3-methyl-8-quinolyl]-sulfonyl]arganyl]pipecolic acid

argatroban

acide (2*R*,4*R*)-4-méthyl-1-[(*S*)-*N*²-[[(*R**S*)-1,2,3,4-tetrahydro-3-méthyl-8-quinolyl]-sulfonyl]arganyl]pipecolique

argatroban

ácido (2*R*,4*R*)-4-metil-1-[(*S*)-*N*²-[[(*R**S*)-1,2,3,4-tetrahydro-3-metil-8-quinolil]-sulfonyl]arginil]pipecólico



aseripidum

aseripide

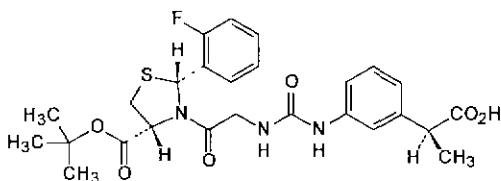
(2*R*,4*R*)-3-[*N*-[[3-[(*S*)-1-carboxyethyl]phenyl]carbonyl]glycyl]-2-(*o*-fluorophenyl)-4-thiazolidinecarboxylic acid, 4-*tert*-butylester

aséripide

acide (2*S*)-2-[3-[3-[2-[(2*R*,4*R*)-4-[(1,1-diméthyléthoxy)carbonyl]-2-(2-fluorophényl)thiazolidin-3-yl]-2-oxoéthyl]uréido]phényl]propanoïque

aseripida

(2*R*,4*R*)-3-[*N*-[[3-[(*S*)-1-carboxiethyl]fenil]carbamoil]glicil]-2-(*o*-fluorofenil)-4-tiazolidinacarboxilato de *tert*-butilo



avotermimum

avotermín

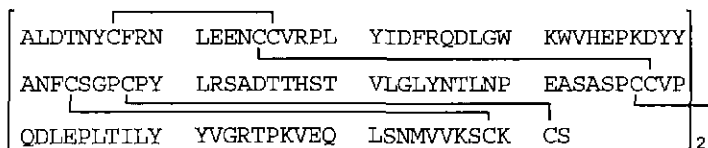
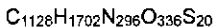
transforming growth factor β3 (human), dimer

avotermine

facteur de croissance transformant β3 (humain)

avotermína

factor β3 de crecimiento transformador(humano), dímero



cedelizumabum

cedelizumab

immunoglobulin G 4 (human-mouse monoclonal OKTcdr4a complementary determining region-grafted γ -chain anti-human CD 4 antigen), disulfide with human-mouse monoclonal OKTcdr4a complementary determining region-grafted κ -chain, dimer

cédélizumab

immunoglobuline G 4 (chaîne γ de l'anticorps monoclonal de souris humanisé OKTcdr4a dirigé contre l'antigène CD 4 humain), dimère du disulfure avec la chaîne κ de l'anticorps monoclonal de souris humanisé OKTcdr4a

cedelizumab

inmunoglobulina G 4 (cadena γ del anticuerpo monoclonal humanizado de ratón OKTcdr4a, dirigido contra el antígeno CD4 humano), dímero del disulfuro con la cadena κ del anticuerpo monoclonal humanizado de ratón OKTcdr4a

ceftizoximum alapivoxilum

ceftizoxime alapivoxil

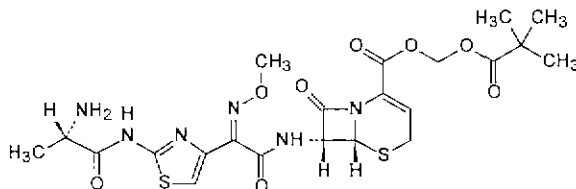
(+)-(pivaloyloxy)methyl (6R,7R)-7-[2-[2-(L-alanyl amino)thiazol-4-yl]glyoxylamido]-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylate 7²-(Z)-(O)-methyloxime)

ceftizoxime alapivoxil

(+)-(6R,7R)-7-[[2-[2-[(2S)-2-aminopropanoyl]amino]thiazol-4-yl]-2-[(Z)-méthoxyimino]acétyl]amino]-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-ène-2-carboxylate de [(2,2-diméthylpropanoyl)oxy]méthyle

ceftizoxima alapivoxilo

(6R,7R)-7-[2-[2-(L-alanil amino)thiazolin-4-il]glioxilamido]-8-oxo-5-tia-1-azabicyclo[4.2.0]oct-2-en-2-carboxilato de (+)-pivaloxi)metil, 7²-(Z)-(O)-methiloxime)

C₂₂H₂₆N₆O₈S₂**celgosivirum**

celgosivir

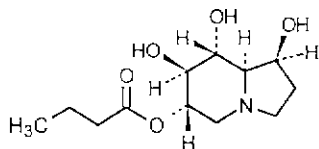
(1S,6S,7S,8R,8aR)-octahydro-1,7,8-trihydroxy-6-indoliziny] butyrate

celgosivir

butanoate de (1S,6S,7S,8R,8aR)-1,7,8-trihydroxyoctahydroindolizin-6-yle

celgosivir

butrato de (1S,6S,7S,8R,8aR)-1,7,8-trihidroxi octahidro 6-indoliziniilo

C₁₂H₂₁NO₅

clenoliximabum

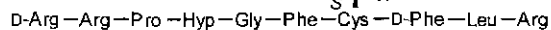
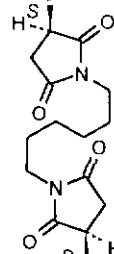
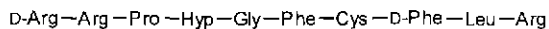
- clenoliximab immunoglobulin G 4 (human-Macaca monoclonal CE9γ4PE γ4-chain anti-human antigen CD 4), disulfide with human-Macaca monoclonal CE9γ4PE κ-chain, dimer
- clenoliximab immunoglobuline G 4 (chaîne γ4 de l'anticorps monoclonal chimérique homme-Macaque CE9γ4PE dirigé contre l'antigène CD 4 humain), dimère du disulfure avec la chaîne κ de l'anticorps monoclonal chimérique homme-Macaque CE9γ4PE
- clenoliximab inmunoglobulina G 4 (cadena γ4 del anticuerpo monoclonal quimérico hombre-Macaca CE9γ4PE dirigido contra el antígeno antigen CD 4 humano), dimero del disulfuro con la cadena κ del anticuerpo monoclonal quimérico hombre-Macaca CE9γ4PE

colesevelamum

- colesevelam allylamine polymer with 1-chloro-2,3-epoxypropane, [6-(allylamino)hexyl]=trimethylammonium chloride and *N*-allyldecylamine
- colésévélam copolymère de prop-2-én-1-amine, de dodécan-1-amine et de *N,N,N*-triméthyl-6-(prop-2-énylamino)hexan-1-aminium réticulé à l'aide de 2-(chlorométhyl)oxirane (épichlorhydrine)
- colesevelam copolímero de prop-2-en-1-amino, de dodecan-1-amino y de *N,N,N*-trimetil-6-(prop-2-enilamino)hexan-1-amino reticulado con 2-(clorometil)oxirano (epiclorhidrina)

deltibantum

- deltibant *D*-arginyl-L-arginyl-L-prolyl-*trans*-4-hydroxy-L-prolylglycyl-L-phenylalanyl-L-cysteinyl-D-phenylalanyl-L-leucyl-L-arginine, 7,7'-bis(sulfide) with (2*R*,2'*S*)-*N,N*'-hexamethylenebis[2-mercaptosuccinimide]
- deltibant *S*⁷,*S*^{7'}-[hexane-1,6-diylbis[(3*R*,3'*S*)-2,5-dioxopyrrolidin-1,3-diyl]]bis[*D*-arginyl-L-arginyl-L-prolyl-[(4*R*)-4-hydroxy-L-prolyl]-glycyl-L-phénylalanyl-L-cystéinyl-L-phénylalanyl-L-leucyl-L-arginine]
- deltibant *D*-arginil-L-arginil-L-proil-*trans*-4-hidroxi-L-proliilglicil-L-fenilalanil-L-cisteinil-D-fenilalanil-L-leucil-L-arginina, 7,7'-bis(sulfuro) con (2*R*,2'*S*)-*N,N*'-hexametilenbis[2-mercaptosuccinimida]
- C128H194N40O28S2



eniluracilum

eniluracil

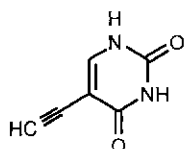
5-ethynyluracil

eniluracil

5-éthynylpyrimidine-2,4(1*H*,3*H*)-dione

eniluracilo

5-etiniluracilo

C₆H₄N₂O₂**enlimomabum pegolum**

enlimomab pegol

immunoglobulin G 2a (mouse monoclonal BI-RR-1 anti-human antigen CD 54), disulfide with mouse monoclonal BI-RR-1 light chain, dimer, reaction product with α -(2-carboxyethyl)- ω -methoxypoly(oxy-1,2-ethanediyil)

enlimomab pégol

N, *N'*, *N''*, *N'''*, *N''''*-pentakis[α -méthylpoly(oxyéthylène)- ω -(oxypropanoyl)]immunoglobuline G2a (anticorps monoclonal de souris BI-RR-1 dirigé contre l'antigène CD 54 humain), dimère du disulfure avec la chaîne légère de l'anticorps monoclonal de souris BI-RR-1

enlimomab pegol

inmunoglobulina G 2a (anticuerpo monoclonal de ratón BI-RR-1 dirigido contra el antígeno CD 54 humano), dímero del disulfuro con la cadena ligera del anticuerpo de ratón BI-RR-1, producto de reacción con α -(2-carboxietil)- ω -metoxipoli(oxi-1,2-etanodil)**eplerenonum**

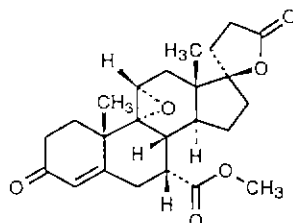
eplerenone

9,11 α -epoxy-17-hydroxy-3-oxo-17 α -pregn-4-ene-7 α ,21-dicarboxylic acid, γ -lactone, methyl ester

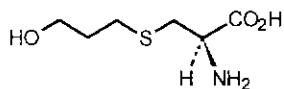
éplérénone

(2'*R*)-9,11 α -epoxy-3,5'-dioxo-4',5'-dihydrospiro[androst-4-ène-17, 2'(3*H*)-furane]-7 α -carboxylate de méthyle

eplerenona

éster metílico de la γ -lactona del ácido 9,11 α -epoxi-17-hidroxi-3-oxo-17 α -pregn-4-en-7 α ,21-dicarboxílicoC₂₄H₃₀O₈

felvizumabum	
felvizumab	immunoglobulin G 1 (human-mouse monoclonal, γ -chain anti-respiratory syncytial virus), disulfide with human-mouse monoclonal κ -chain, dimer
felvizumab	immunoglobuline G 1 (chaîne γ de l'anticorps monoclonal de souris humanisé dirigé contre le virus syncytial respiratoire), dimère du disulfure avec la chaîne κ de l'anticorps monoclonal de souris humanisé
felvizumab	inmunoglobulina G 1 (cadena γ del anticuerpo monoclonal humanizado de ratón, dirigido contra el virus sincitial respiratorio), dimero del disulfuro con la cadena κ del anticuerpo humanizado de ratón
follitropinum beta	
follitropin beta	follicle-stimulating hormone, glycoform β α -subunit: chorionic gonadotropin (human α -subunit protein moiety reduced) β -subunit: follicle-stimulating hormone (human β -subunit protein moiety reduced)
follitropine bêta	hormone folliculo-stimulante, forme glycosylée β sous-unité α : gonadotropine chorionique (partie protéique réduite de la sous-unité α humaine) sous-unité β : hormone folliculo-stimulante (partie protéique réduite de la sous-unité β humaine)
follitropina beta	hormona estimulante del foliculo, glicofoma β subunidad α : gonadotropina coriónica (fracción proteica reducida de la subunidad α humana) subunidad β : hormona estimulante del foliculo (fracción proteica reducida de la subunidad β) α : C ₄₃₇ H ₆₈₂ N ₁₂₂ O ₁₃₄ S ₁₃ β : C ₅₃₈ H ₆₃₃ N ₁₄₅ O ₁₇₁ S ₁₃
	APDVQDCPEC TLQENPFFSQ PGAPILQCMG CCFSRAYPT LRSKKTMLVQ KNVTSSTCC VAKSYNRVTV MGGFKVENH ACHCSTCYHH KS NSCELTNITI AIEKEECRFC ISINTTWCAG YCYTRDLVY DPAKPQIKT CTFKELVYET VRVPGCAHHA DSLYTFPVA QCHCGKCDSD STDCTVRGLG PSYCSFGEMK E
fudosteinum	
fudosteine	(-)-3-[(3-hydroxypropyl)thio]-L-alanine
fudostéine	(-)-acide (2R)-2-amino-3-[(3-hydroxypropyl)sulfanyl]propanoïque
fudosteína	(-)-3-[(3-hidroxiopropil)tio]-L-alanina

$C_6H_{13}NO_3S$ **gavestinelum**

gavestinel

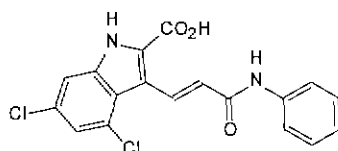
4,6-dichloro-3-[(E)-2-(phenylcarbamoyl)vinyl]indole-2-carboxylic acid

gavestinel

acide 4,6-dichloro-3-[(E)-2-(phénylcarbamoyl)éthényl]-1H-indole-2-carboxylique

gavestinel

ácido 4,6-dicloro-3-[(E)-2-(fenilcarbamoyl)vinil]indol-2-carboxílico

 $C_{18}H_{12}Cl_2N_2O_3$ **glufosamidum**

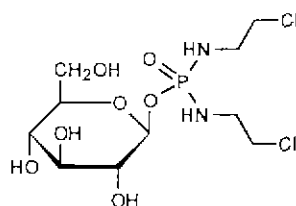
glufosamide

 β -D-glucopyranose 1-[N,N'-bis(2-chloroethyl)phosphorodiamidate]

glufosamide

N,N'-bis(2-chloroéthyl)phosphorodiamidate de β -D-glucopyranosyle

glufosamida

1-[N,N'-bis(2-cloroetil)fosforodiamidato] de β -D-glucopiranososa $C_{10}H_{21}Cl_2N_2O_7P$ **infliximabum**

infliximab

immunoglobulin G (human-mouse monoclonal cA2 heavy chain anti-human tumor necrosis factor), disulfide with human-mouse monoclonal cA2 light chain, dimer

infliximab

immunoglobuline G (chaîne lourde de l'anticorps monoclonal chimérique homme-souris cA2 dirigé contre le facteur de nécrose tumorale humaine), dimère du disulfure avec la chaîne légère de l'anticorps monoclonal chimérique homme-souris cA2

infliximab

immunoglobulina G (cadena pesada del anticuerpo monoclonal quimérico hombre-ratón cA2 dirigido contra el factor de necrosis tumoral humano), dímero del disulfuro con la cadena ligera del anticuerpo monoclonal quimérico hombre-ratón cA2

interferonum alfacon-1

interferon alfacon-1

N-L-methionyl-22-L-arginine-76-L-alanine-78-L-aspartic acid-79-L-glutamic acid-86-L-tyrosine-90-L-tyrosine-156-L-threonine-157-L-asparagine-158-L-leucineinterferon α 1 (human lymphoblast reduced)

interféron alfacon-1

N-L-méthionyl-[22-L-arginine-76-L-alanine-78-L-acide aspartique-79-L-acide glutamique-86-L-tyrosine-90-L-tyrosine-156-L-thréonine-157-L-asparagine-158-L-leucine]interféron α 1 (lymphoblastique humain réduit)

interferón alfacón-1

N-L-metionil-22-L-arginina-76-L-alanina-78-ácido L-aspártico-79-ácido L-glutámico-86-L-tirosina-90-L-tirosina-156-L-treonina-157-L-asparagina-158-L-leucinainterferón α 1 (infoblástica humano reducido)

 $C_{670}H_{1366}N_{236}O_{259}S_9$

MCDLPQTHSLG NRRALILLAQ MRRISPFSC L KDRHDFGFPQ
 EEFDGNQFQK AQAISVLHEM IQQTFNLFST KDSSAAWDES
 LLEKFYTELY QQLNDLEACV IQEVGVEETP LMNVDSILAV
 KKYFQRITLY LTEKKYSPCA WEVVRAEIMR SFSLSLTLNQE
 RLRKE

lanepitantum

lanepitant

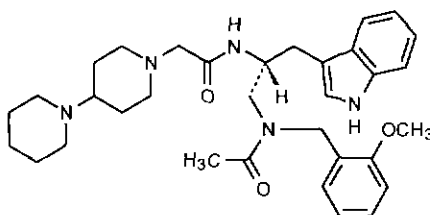
N-[(*R*)-2-indol-3-yl-1-[[*N*-(*o*-methoxybenzyl)acetamido] methyl]ethyl] [1,4'-bipiperidine]-1'-acetamide

lanépitant

N-[(1*R*)-1-[[acétyl(2-méthoxybenzyl)amino]méthyl]-2-(1*H*-indol-3-yl)éthyl]-2-(1,4'-bipéridin-1'-yl)acétamide

lanepitant

N-[(*R*)-2-indol-3-il-1-[[*N*-(*o*-metoxibencil)acetamido]metil]etil] [1,4'-bipiperidina]-1'-acetamida

 $C_{33}H_{45}N_5O_3$
**licostinelum**

licostinel

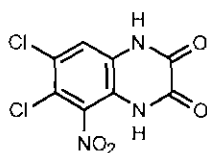
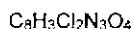
6,7-dichloro-1,4-dihydro-5-nitro-2,3-quinoxalinedione

licostinel

6,7-dichloro-5-nitro-1,4-dihydroquinoxaline-2,3-dione

licostinel

6,7-dicloro-1,4-dihidro-5-nitro-2,3-quinoxalinadiona



lumefantrinum
lumefantrine

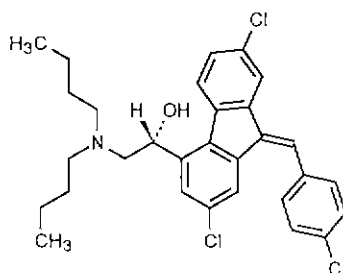
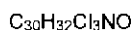
(±)-2,7-dichloro-9-[(Z)-p-chlorobenzylidene]-α[(dibutylamino)methyl]fluorene-4-methanol

luméfantrine

(1*RS*)-2-(dibutylamino)-1-[(Z)-2,7-dichloro-9-(4-chlorobenzylidène)-9*H*-fluorén-4-yl]éthanol

lumefantrina

(±)-2,7-dichloro-9-[(Z)-p-chlorobenzylideno]-α[(dibutylamino)methyl]fluoreno-4-methanol



and enantiomer
et énantiomère
y enantiomero

milacainidum
milacainide

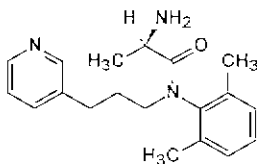
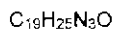
(-)-(R)-2-amino-N-[3-(3-pyridyl)propyl]-2',6'-propionoxylidide

milacainide

(-)-(R)-2-amino-N-(2,6-diméthylphényl)-N-[3-(pyridin-3-yl)propyl]propanamide

milacainida

(-)-(R)-2-amino-N-[3-(3-piridil)propil]-2',6'-propionoxilidida



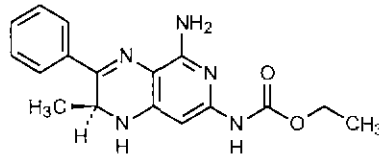
mivobulinum

mivobulin ethyl (*S*)-5-amino-1,2-dihydro-2-methyl-3-phenylpyrido[3,4-*b*]pyrazine-7-carbamate

mivobuline [(2*S*)-5-amino-2-méthyl-3-phényl-1,2-dihydropyrido[3,4-*b*]pyrazin-7-yl]carbamate d'éthyle

mivobulina (*S*)-5-amino-1,2-dihidro-2-metil-3-fenilpirido [3,4-*b*]pirazina-7-carbamato de etilo

$C_{17}H_{19}N_5O_2$

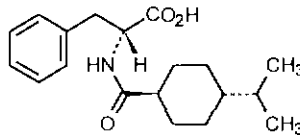
**nateglinidum**

nateglinide (-)-*N*-[(*trans*-4-isopropylcyclohexyl)carbonyl]-*D*-phenylalanine

natéglinide (-)-acide (2*R*)-2-[[[*trans*-4-(1-méthyléthyl)cyclohexyl]carbonyl]amino]-3-phénylpropanoïque

nateglinida (-)-*N*-[(*trans*-4-isopropilciclohexil)carbonyl]-*D*-fenilalanina

$C_{19}H_{27}NO_3$

**nonacogum alfa**

nonacog alfa blood-coagulation factor IX (human), glycoform α

nonacog alfa facteur IX de coagulation sanguine humaine, glycoforme α

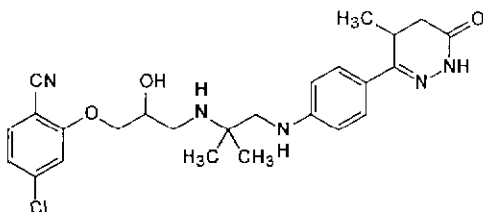
nonacog alfa factor IX (humano) de la coagulación sanguínea, forma glucosilada α

oberadilolum

oberadilol (\pm)-4-chloro-2-[3-[[1,1-dimethyl-2-[*p*-(1,4,5,6-tetrahydro-4-methyl-6-oxo-3-pyridazinyl)anilino]ethyl]amino]-2-hydroxypropoxy]benzotrile

obéradiól (\pm)-4-chloro-2-[3-[[1,1-diméthyl-2-[[4-(4-méthyl-6-oxo-1,4,5,6-tétrahydropyridazin-3-yl)phényl]amino]éthyl]amino]-2-hydroxypropoxy]benzotrile

oberadilól (\pm)-4-cloro-2-[3-[[1,1-dimetil-2-[*p*-(1,4,5,6-tetrahidro-4-metil-6-oxo-3-piridazinil)anilino]etil]amino]-2-hidroxiropoxi]benzotrilo

$C_{25}H_{30}ClN_5O_3$ **opanaxilum**

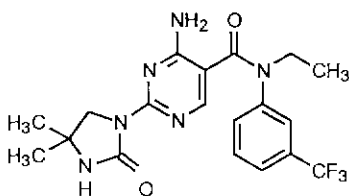
opanaxil

4-amino-2-(4,4-diméthyl-2-oxo-1-imidazolidinyl)-*N*-éthyl- α,α,α -trifluoro-5-pyrimidinecarboxy-*m*-toluidide

opanaxil

4-amino-2-(4,4-diméthyl-2-oxoimidazolidin-1-yl)-*N*-éthyl-*N*-[3-(trifluorométhyl)phényl]pyrimidin-5-carboxamide

opanaxilo

4-amino-2-(4,4-diméthyl-2-oxo-1-imidazolidinyl)-*N*-éthyl- α,α,α -trifluoro-5-pyrimidinecarboxy-*m*-toluidide $C_{19}H_{21}F_3N_6O_2$ **oraziponum**

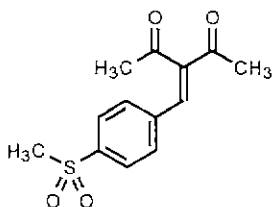
orazipone

3-[*p*-(methylsulfonyl)benzylidène]-2,4-pentanedione

orazipone

3-[4-(méthylsulfonyl)benzylidène]pentane-2,4-dione

orazipona

3-[*p*-(méthylsulfonyl)benzylidène]-2,4-pentanedione $C_{13}H_{14}O_4S$ 

pegmusirudinum

pegmusirudin

L-valyl-L-valyl-L-tyrosyl-L-threonyl- L- α -aspartyl-L-cysteinyl-L-threonyl-
L- α -glutamyl-L-serylglycyl-L-glutaminy-L-asparaginy-L-leucyl-L-cysteinyl-
L-leucyl-L-cysteinyl-L- α -glutamylglycyl-L-seryl-L-asparaginy-L-valyl-
L-cysteinylglycyl-L-glutamylglycyl- L-asparaginy-L- N^6 -carboxy-L-lysyl-L-cysteinyl-
L-iso-leucyl-L-leucylglycyl-L-seryl- N^6 -carboxy-L-lysylglycyl-L- α -glutamyl-
L-arginyl-L-asparaginy-L-glutaminy-L-cysteinyl-L-valyl-L-threonylglycyl-
L- α -glutamylglycyl-L-threonyl-L-prolyl-L-arginyl-L-prolyl-L-glutaminy-
L-seryl-L-histidyl-L-asparaginy-L- α -aspartylglycyl-L- α -aspartyl-L-phenylalanyl-
L- α -glutamyl-L- α -glutamyl-L-iso-leucyl-L-prolyl-L- α -glutamyl-L- α -glutamyl-
L-tyrosyl-L-leucyl-L-glutamine cyclic (6 \rightarrow 14), (16 \rightarrow 28), (22 \rightarrow 39)-
tris(disulfide), 27,33-diester with polyethylene glycol monoethyl ether

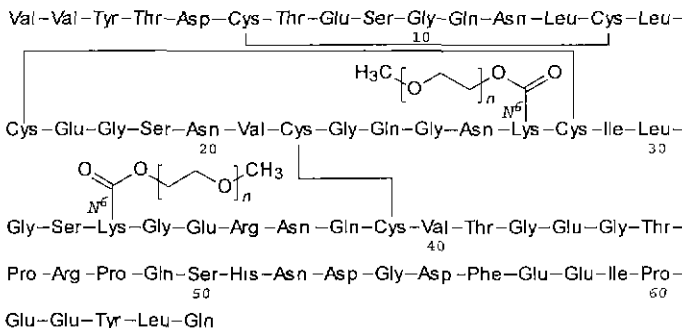
pegmusirudine

$N^{6,27},N^{6,33}$ -bis[α -méthylpoly(oxyéthylène)- ω -(oxycarbonyl)]-[33-L-lysine-
36-L-arginine-47-L-arginine]- $O^{6,3}$ -désulfohirudine (*hirudo medicinalis*)

pegmusirudina

L-valil-L-valil-L-tirosil-L-treonil- L- α -aspartil-L-cisteinil-L-treonil-L- α -glutamil-
L-serilglicil-L-glutamini-L-asparaginil-L-leucil-L-cisteinil-L-leucil-L-cisteinil-
L- α -glutamilglicil-L-seril-L-asparaginil-L-valil-L-cisteinilglicil-L-glutamilglicil-
L-asparaginil- N^6 -carboxi-L-lisil-L-cisteinil-L-iso-leucil-L-leucilglicil-L-seril- N^6 -
carboxi- L-lisilglicil-L- α -glutamil-L-arginil-L-asparaginil-L-glutamini-L-cisteinil-
L-valil-L-treonilglicil-L- α -glutamilglicil-L-treonil-L-prozil-L-arginil-L-prozil-
L-glutamini-L-seril-L-histidil-L-asparaginil-L- α -aspartilglicil-L- α -aspartil-
L-fenilalanil-L- α -glutamil-L- α -glutamil-L-iso-leucil-L-prozil-L- α -glutamil-
L- α -glutamil-L-tirosil-L-leucil-L-glutamine tris(disulfuro) ciclico (6 \rightarrow 14),
(16 \rightarrow 28), (22 \rightarrow 39), 27,33-diester con polietilen glicol monoetil eter

(C₂H₄O)_n (C₂H₄O)_n C₃₀₂H₄₅₁N₈₅O₁₁₂S₆



pifonakinum

pifonakin

36-L-aspartic acid-141-L-serineinterleukin 1 α (human clone p10A)

pifonakine

[36-acide L-aspartique-141-L-sérine]interleukine 1 α (clone humain p10A)

pifonakina

36-L-ácido aspártico-141-L-serrnainterleuquina 1 α (clon humano p10A)

SAPFSFLSNV KYNFMRIIKY EFILNDALNQ SIIRADDQYL
 TAAALHNLDE AVKFDMGAYK SSKDDAKITV ILRISKTQLY
 VTAQDEDQPV LLKEMPEIPK TITGSETNLL FFWETHGTKN
 YFTSVAHPNL FIATKQDYWV SLAGGPPSIT DFQILENQA

pleconarilum

pleconaril

3-[4-[3-(3-methyl-5-isoxazolyl)propoxy]-3,5-xylyl]-5-(trifluoromethyl)-
 1,2,4-oxadiazole

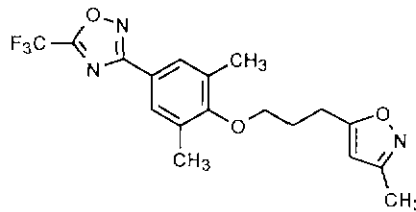
pléconaril

3-[3,5-diméthyl-4-[3-(3-méthylisoxazol-5-yl)propoxy]phényl]-5-
 (trifluorométhyl)-1,2,4-oxadiazole

pleconarilo

3-[4-[3-(3-metil-5-isoxazolil)propoxi]-3,5-xili]-5-(trifluorometil)-1,2,4-oxadiazol

$C_{18}H_{18}F_3N_3O_3$

**pralmorelinum**

pralmorelin

D-alanyl-3-(2-naphthyl)-D-alanyl-L-alanyl-L-tryptophyl-D-phenylalanyl-
 L-lysynamide

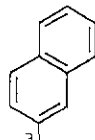
pralmoreline

D-alanyl-[3-(naphthalén-2-yl)-D-alanyl]-L-alanyl-L-tryptophyl-D-phénylalanyl-
 L-lysynamide

pralmorelina

D-alanil-3-(2-naftil)-D-alanil-L-alanil-L-triptofil-D-fenilalanil-L-lisnamida

$C_{45}H_{55}N_5O_6$



D-Ala-D-Ala-Ala-Trp-D-Phe-Lys-NH₂

promazinum

promazine

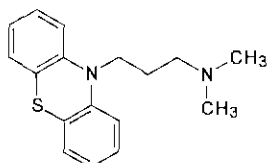
10-(3-dimethylaminopropyl)phenothiazine

promazine

(diméthylamino-3-propyl)-10-aza-1-phénothiazine

promazina

10-(3-dimetilaminopropil)fenotiazina

C₁₇H₂₀N₂S**rituximabum**

rituximab

immunoglobulin G 1 (human-mouse monoclonal IDEC-C2B8 γ 1-chain anti-human antigen CD 20), disulfide with human-mouse monoclonal IDEC-C2B8 κ -chain, dimer

rituximab

immunoglobuline G1 (chaîne γ 1 de l'anticorps monoclonal chimérique homme-souris IDEC-C2B8 dirigé contre l'antigène CD20 humain), dimère du disulfure avec la chaîne κ de l'anticorps monoclonal chimérique homme-souris IDEC-C2B8

rituximab

immunoglobulina G 1 (cadena γ 1 del anticuerpo monoclonal quimérico hombre-ratón IDEC-C2B8 dirigido contra el antígeno CD 20 humano), dímero del disulfuro con la cadena κ del anticuerpo monoclonal quimérico hombre-ratón IDEC-C2B8

rivastigminum

rivastigmine

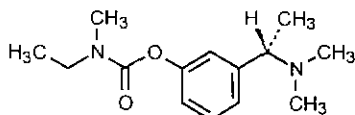
(-)-*m*-[(1*S*)-1-(dimethylamino)ethyl]phenyl ethylmethylcarbamate

rivastigmine

(-)-éthylméthylcarbamate de 3-[(1*S*)-1-(diméthylamino)éthyl]phényle

rivastigmina

etilmetilcarbamato de (-)-*m*-[(1*S*)-1-(dimetilamino)etil]fenilo

C₁₄H₂₂N₂O₂**roflumilastum**

roflumilast

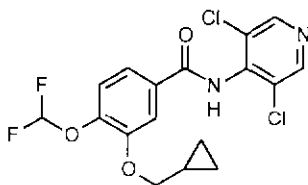
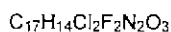
3-(cyclopropylmethoxy)-*N*-(3,5-dichloro-4-pyridyl)-4-(difluoromethoxy)=benzamide

roflumilast

3-(cyclopropylméthoxy)-*N*-(3,5-dichloropyridin-4-yl)-4-(difluorométhoxy)=benzamide

roflumilast

3-(ciclopropilmetoxi)-*N*-(3,5-dicloro-4-piridil)-4-(difluorometoxi)benzamida

**roxifibanum**

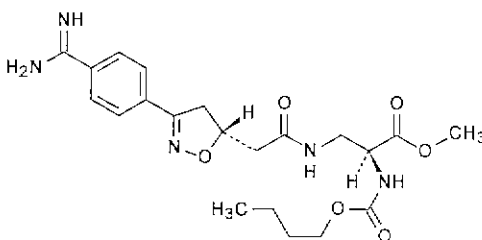
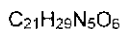
roxifiban

(2*S*)-3-[2-[(5*R*)-3-(*p*-amidinophényl)-2-isoxazolin-5-yl] acetamido]-2-(carboxyamino)propionic acid, 2-butyl methyl ester

roxifiban

(2*S*)-3-[[2-[[5*R*]-3-(4-carbamimidoylphényl)-4,5-dihydroisoxazol-5-yl]acétyl]amino]-2-[[butoxycarbonyl]amino]propanoate de méthyle

roxifibán

2-butil metil éster del ácido (2*S*)-3-[2-[(5*R*)-3-(*p*-amidinofenil)-2-isoxazolin-5-il]acetamido]-2-(carboxiamino)propiónico**sevelamerum**

sevelamer

allylamine polymer with 1-chloro-2,3-epoxypropane

sévélamer

copolymère de prop-2-én-1-amine et de 1,3-bis(prop-2-énylamino)propan-2-ol

sevelámero

copolimero de prop-2-en-1-amino y de 1,3-bis(prop-2-enilamino)propan-2-ol

sibrafibanum

sibrafiban

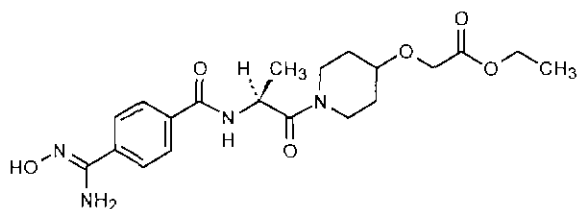
ethyl (Z)-[[1-[*N*-[(*p*-hydroxyamidino)benzoyl]-*L*-alanyl]-4-piperidyloxy] acetate

sibrafiban

[[1-[(2*S*)-2-[[4-[(*Z*)-amino(hydroxyimino)méthyl]benzoyl]amino]propanoyl]=piperidin-4-yl]oxy]acétate d'éthyle

sibrafibán

(Z)-[[1-[*N*-[(*p*-hidroxiamidino)benzoi]-*L*-alanil]-4-piperidil]oxi] acetato de etilo

C₂₀H₂₉N₄O₆**tazomelinum**

tazomeline

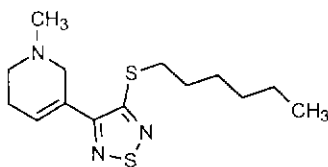
tazoméline

tazomelina

3-[4-(hexylthio)-1,2,5-thiadiazol-3-yl]1,2,5,6-tetrahydro-1-methylpyridine

3-[4-(hexylsulfanyl)-1,2,5-thiadiazol-3-yl]-1-méthyl-1,2,5,6-tétrahydropyridine

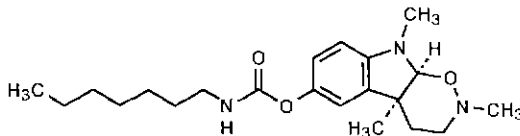
3-[4-(hexyltio)-1,2,5-tiadiazol-3-yl]1,2,5,6-tetrahydro-1-metilpiridina

C₁₄H₂₃N₃S₂**terestigminum**

terestigmine

térestigmine

terestigmina

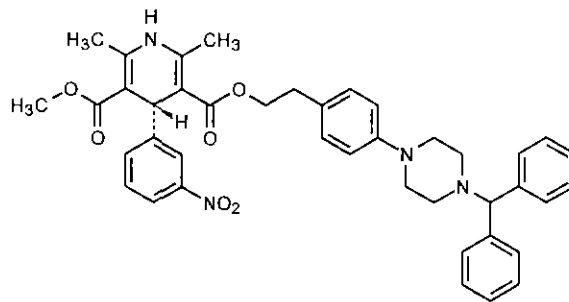
(4a*S*,9a*S*)-2,3,4,4a,9,9a-hexahydro-2,4a,9-triméthyl-1,2-oxazino[6,5-*b*]indol-6-yl heptylcarbamateheptylcarbamate de (4a*S*,9a*S*)-2,4a,9-triméthyl-2,3,4,4a,9,9a-hexahydro-1,2-oxazino[6,5-*b*]indol-6-yleheptilcarbamato de (4a*S*,9a*S*)-2,3,4,4a,9,9a-hexahidro-2,4a,9-trimetil-1,2-oxazino[6,5-*b*]indol-6-iloC₂₁H₃₃N₃O₃

urokinasum alfa

urokinase alfa	urokinase (enzyme-activating) (human clone pA3/pD2/pF1 high-molecular-weight isoenzyme protein moiety)
urokinase alfa	activateur du plasminogène (partie protéique de l'isoenzyme de masse moléculaire élevée fournie par le clone humain pA3/pD2/pF1)
urokinasa alfa	uroquinasa, activador del plasminógeno (fracción proteica de la isoenzima de masa molecular elevada producida por el clon humano pA3/pD2/pF1)

vatanidipinum

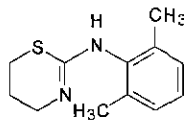
vatanidipine	(±)- <i>p</i> -[4-(diphenylmethyl)-1-piperazinyl]phenethyl methyl 1,4-dihydro-2,6-dimethyl-4-(<i>m</i> -nitrophenyl)-3,5-pyridinedicarboxylate
vatanidipine	(4 <i>RS</i>)-2,6-diméthyl-4-(3-nitrophényl)-1,4-dihydropyridine-3,5-dicarboxylate de 2-[4-[4-(diphénylméthyl)pipérazin-1-yl]phényl]éthyle et de méthyle
vatanidipino	1,4-dihidro-2,6-dimetil-4-(<i>m</i> -nitrofenil)-3,5-piridinadicarboxilato de (±)- <i>p</i> -[4-(difenilmetil)-1-piperazinil]fenetilo y metilo C ₄₁ H ₄₂ N ₄ O ₆



and enantiomer
et l'énantiomère
y enantiómero

xylazinum

xylazine	5,6-dihydro-2-(2,6-xylidino)-4 <i>H</i> -1,3-thiazine
xylazine	2-(2,6-xylidino)-5,6-dihydro-4 <i>H</i> -1,3-thiazine
xylazina	2-(2,6-xilidino)-5,6-dihidro-4 <i>H</i> -1,3-tiazina C ₁₂ H ₁₆ N ₂ S



**AMENDMENTS TO PREVIOUS LISTS
MODIFICATIONS APPORTÉES AUX LISTES ANTÉRIEURES
MODIFICACIONES A LAS LISTAS ANTERIORES**

Recommended International Nonproprietary Names (Rec. INN): List 31

(WHO Drug Information, Vol. 5, No. 3, 1991)

p. 4 dalteparinum natricum

dalteparin sodium

replace the definition by the following.

Sodium salt of a low molecular mass heparin that is obtained by nitrous acid depolymerization of heparin from porcine intestinal mucosa; the majority of the components have a 2-O-sulfo- α -L-idopyranosuronic acid structure at the non-reducing end and a 6-O-sulfo-2,5-anhydro-D-mannitol structure at the reducing end of their chain, the mass-average molecular mass ranges between 5600 and 6400 with a characteristic value of about 6000; the degree of sulfatation is 2.0 to 2.5 per disaccharidic unit

p. 10 parnaparinum natricum

parnaparin sodium

replace the definition by the following.

Sodium salt of a low molecular mass heparin that is obtained by radical-catalyzed depolymerization, with hydrogen peroxide and with a cupric salt, of heparin from bovine or pork intestinal mucosa; the majority of the components have a 2-O-sulfo- α -L-idopyranosuronic acid structure at the non-reducing end and a 2-N,6-O-disulfo-D-glucosamine structure at the reducing end of their chain; the mass-average molecular mass ranges between 4000 and 6000 with a characteristic value of about 5000, the degree of sulfatation is 2.0 to 2.6 per disaccharidic unit

p. 11 reviparinum natricum

reviparin sodium

replace the definition by the following

Sodium salt of a low molecular mass heparin that is obtained by nitrous acid depolymerization of heparin from porcine intestinal mucosa, the majority of the components have a 2-O-sulfo- α -L-idopyranosuronic acid structure at the non-reducing end and a 6-O-sulfo-2,5-anhydro-D-mannitol structure at the reducing end of their chain; the mass-average molecular mass ranges between 3150 and 5150, with a characteristic value of about 4150; the degree of sulfatation is about 2.1 per disaccharidic unit.

p 16 **enoxaparinum natricum**
enoxaparin sodium

replace the definition by the following:

Sodium salt of a low molecular mass heparin that is obtained by alkaline depolymerization of the benzyl ester derivative of heparin from porcine intestinal mucosa, the majority of the components have a 2-O-sulfo-4-desoxy-4- α -L-threo-hex-4-enopyranosuronic acid structure at the non-reducing end of their chain, the mass-average molecular mass ranges between 3500 and 5500 with a characteristic value of about 4500, the degree of sulfatation is about 2 per disaccharidic unit.

Recommended International Nonproprietary Names (Rec. INN): List 32
(WHO Drug Information, Vol. 6, No. 3, 1992)

p 10 **tinzaparinum natricum**
tinzaparin sodium

replace the definition by the following:

Sodium salt of a low molecular mass heparin that is obtained by controlled enzymatic depolymerization of heparin from porcine intestinal mucosa using heparinase from *Flavobacterium heparinum*, the majority of the components have a 2-O-sulfo-4-desoxy-4- α -L-threo-hex-4-enopyranosuronic acid structure at the non-reducing end and a 2-N,6-O-disulfo-D-glucosamine structure at the reducing end of their chain; the mass-average molecular mass ranges between 5500 and 7500 with a characteristic value of about 6500; the degree of sulfatation is 1.8 to 2.5 per disaccharidic unit

Recommended International Nonproprietary Names (Rec. INN): List 35

Dénominations communes internationales recommandées (DCI Rec.): Liste 35

Denominaciones Comunes Internacionales Recomendadas (DCI Rec.): Lista 35

(WHO Drug Information, Vol. 9, No. 3, 1995)

p. 14 **itamelinum**
itameline

replace the chemical name by the following:

(E)-p-chlorophenyl 3-formyl-5,6-dihydro-1(2H)-pyridinecarboxylate, O-methyloxime

itamelina

sustituyase el nombre químico por lo siguiente:

3-formil-5,6-dihidro-1(2H)-pindinacarboxilato de (E)- p-clorofenilo, O-metiloxima

p 11 **eptacogum alfa (activatum)**
eptacog alfa (activated)
eptacog alfa (activé)
eptacog alfa (activado)

replace the molecular formula by the following:

remplacer la formule brute par.

sustituyase la fórmula empírica por.

C₁₉H₃₀N₅O₆S₂

Recommended International Nonproprietary Names (Rec. INN): List 36**Dénominations communes internationales recommandées (DCI Rec.): Liste 36****Denominaciones Comunes Internacionales Recomendadas (DCI Rec.): Lista 36***(WHO Drug Information, Vol. 10, No. 3, 1996)***p. 148 igovomabum**

igovomab

*replace the description by the following:*immunoglobulin G 1 (mouse monoclonal OC125 F(ab')₂ F(ab')₂ fragment anti-human ovarian cancer antigen CA 125), disulfide with mouse monoclonal OC125 F(ab')₂ light chain

igovomab

*remplacer la description par la suivante:*fragment F(ab')₂ de l'anticorps monoclonal OC 125 F(ab')₂ dirigé contre l'antigène CA 125 associé à certaines tumeurs ovariennes

igovomab

*sustituyase la descripción por la siguiente:*fragmento F(ab')₂ del anticuerpo monoclonal OC 125 F(ab')₂ anti-antígeno CA 125 asociado a ciertos tumores ováricos**p. 160 thymalfasinum**

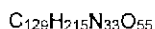
thymalfasin

replace the molecular formula by the following:

thymalfasine

remplacer la formule brute par la suivante:

timalfasina

sustituyase la fórmula empírica por:**p. 154 palonosetronum**

palonosetron

replace the chemical name and the molecular formula by the following.

(3aS)-2,3,3a,4,5,6-hexahydro-2-[(3S)-3-quinuclidinyl]-1H-benz[de]isoquinolin-1-one

palonosétron

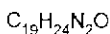
remplacer le nom chimique et la formule brute par :

(3aS)-2-[(3S)-1-azabicyclo[2.2.2]oct-3-yl]-2,3,3a,4,5,6-hexahydro-1H-benzo[de]isoquinolein-1-one

palonosetrón

sustituyase el nombre químico y la fórmula empírica por

(3aS)-2,3,3a,4,5,6-tetrahydro-2-[(3S)-3-quinuclidinil]-1H-benz[de]isoquinolin-1-ona



Dénominations communes internationales recommandées (DCI Rec.): Liste 31*(Informations pharmaceutiques OMS, Vol. 5, No. 3, 1991)*

p. 5 **dalteparinum natricum**
daltéparine sodique

remplacer la description par

Sel sodique d'une héparine de basse masse moléculaire obtenue par depolymerisation, au moyen d'acide nitreux, d'heparine de muqueuse intestinale de porc, la majorité des composants de la daltéparine sodique possèdent une structure acide 2-O-sulfo- α -L-idopyranosurionique à l'extrémité non reductrice de leur chaîne et une structure 6-O-sulfo-2,5-anhydro-D-mannitol à l'extrémité réductrice de leur chaîne, la masse moleculaire relative moyenne est de 5600 à 6400, avec une valeur caractéristique de 6000 environ; le degré de sulfatation est de 2.0 à 2.5 par unité disaccharidique.

p 10 **parnaparinum natricum**
parnaparine sodique

remplacer la description par

Sel sodique d'une héparine de basse masse moléculaire obtenue par dépolymérisation, à catalyse radicalaire, au moyen de peroxyde d'hydrogene et d'un sel de cuivre, d'héparine de muqueuse intestinale de boeuf ou de porc, la majorité des composants de la parnaparine sodique possèdent une structure acide 2-O-sulfo- α -L-idopyranosurionique à l'extrémité non réductrice de leur chaîne et une structure 2N,6-N,6-O-disulfo-D-glucosamine à l'extrémité réductrice de leur chaîne; la masse moléculaire relative moyenne est de 4000 à 6000, avec une valeur caractéristique de 5000 environ, le degré de sulfatation est de 2.0 à 2.6 par unité disaccharidique

p 17 **enoxaparinum natricum**
énoxaparine sodique

remplacer la description par

Sel sodique d'une héparine de basse masse moléculaire obtenue par dépolymérisation alcaline de l'ester benzylque d'héparine de muqueuse intestinale de porc; la majorité des composants de l'enoxaparine sodique possèdent une structure acide 2-O-sulfo-4-désoxy-4- α -L-thréo-hex-4-énopyranosurionique à l'extrémité non réductrice de leur chaîne, la masse moléculaire relative moyenne est de 3500 à 5500, avec une valeur caractéristique de 4500 environ; le degré de sulfatation est de 2 par unité disaccharidique.

p. 12 **reviparinum natricum**
réviparine sodique

remplacer la description suivante

Sel sodique d'une héparine de basse masse moléculaire obtenue par dépolymérisation, au moyen d'acide nitreux, d'héparine de muqueuse intestinale de porc; la majorité des composants de la réviparine sodique possèdent une structure acide 2-O-sulfo- α -L-idopyranosurionique à l'extrémité non réductrice de leur chaîne et une structure 6-O-sulfo-2,5-anhydro-D-mannitol à l'extrémité réductrice de leur chaîne, la masse moléculaire relative moyenne est de 3150 à 5150, avec une valeur caractéristique de 4150 environ, le degré de sulfatation est 2.1 environ par unité disaccharidique

Dénominations communes internationales recommandées (DCI Rec.): Liste 32
(Informations pharmaceutiques OMS, Vol. 6, No. 3, 1992)

p. 10 **tinzaparinum natricum**
 tinzaparine sodique

remplacer la description par:

Sel sodique d'une héparine de basse masse moléculaire obtenue par dépolymérisation enzymatique contrôlée, au moyen de l'héparinase de *Flavobacterium heparinum*, d'héparine de muqueuse intestinale de porc; la majorité des composants de la tinzaparine sodique possèdent une structure acide 2-O-sulfo-4-désoxy-4- α -L-thréo-hex-4-énopyranosuronique à l'extrémité non réductrice de leur chaîne et une structure 6-N,6-O-disulfo-D-glucosamine à l'extrémité réductrice de leur chaîne; la masse moléculaire relative moyenne est de 5500 à 7500, avec une valeur caractéristique de 6500 environ; le degré de sulfatation est de 1.8 à 2.5 par unité disaccharidique

Denominaciones Comunes Internacionales Recomendadas (DCI Rec.): Lista 31
(Información Farmacéutica, OMS, Vol. 5, No. 3, 1991)

p. 4 **dalteparinum natricum**
 dalteparina sódica

sustituyase la descripción por la siguiente:

Sal sódica de una heparina de baja masa molecular obtenida por despolimerización con ácido nitroso de la heparina de la mucosa intestinal de cerdo, la mayoría de los componentes tienen una estructura de ácido 2-O-sulfo- α -L-idopiranosurónico en el extremo no reductor y una estructura de 6-O-sulfo-2,5-anhidro-D-mannitol en el extremo reductor de la cadena, la masa molecular relativa media es de 5600 a 6400, con un valor característico de 6000 aproximadamente; el grado de sulfatación es de 2.0 a 2.5 por unidad de disacárido.

p. 10 **parnaparinum natricum**
 parnaparina sódica

sustituyase la descripción por la siguiente:

Sal sódica de una heparina de baja masa molecular obtenida por despolimerización con peróxido de hidrógeno y un sal de cobre de la heparina de la mucosa intestinal de buey o de cerdo, la mayoría de los componentes tienen una estructura de ácido 2-O-sulfo- α -L-idopiranosurónico en el extremo no reductor y una estructura de 6-O-6-N-disulfo-D-glucosamina en el extremo reductor de la cadena, la masa molecular relativa media es de 4000 a 6000, con un valor característico de 5000 aproximadamente; el grado de sulfatación es de 2.0 a 2.6 por unidad de disacárido.

- p. 16 **enoxaparinum natricum**
enoxaparina sódica
- sustituyase la descripción por la siguiente*
Sal sódica de una heparina de baja masa molecular obtenida por despolimerización alcalina del éster bencilico de la heparina de la mucosa intestinal de cerdo, la mayoría de los componentes tienen una estructura de ácido 2-O-sulfo-4-desoxi-4- α -L-*treo*-hex-4-enopiranosurónico en el extremo no reductor en el extremo reductor de la cadena; la masa molecular relativa media es de 3500 a 5500, con un valor característico de 4500 aproximadamente, el grado de sulfatación es de 2 por unidad de disacárido.
- p. 11 **reviparinum natricum**
reviparina sódica
- sustituyase la descripción por la siguiente*
Sal sódica de una heparina de baja masa molecular obtenida por despolimerización con ácido nítrico de la heparina de la mucosa intestinal del cerdo; la mayoría de los compuestos tienen una estructura de ácido 2-O-sulfo- α -L-idopiranosurónico en el extremo no reductor y una estructura de 6-O-sulfo-2,5-anhidro-D-manitol en el extremo reductor de la cadena, la masa molecular relativa media está entre 3150 y 5150, un valor característico de 4150 aproximadamente, el grado de sulfatación es de 2.1 por unidad de disacárido.

Denominaciones Comunes Internacionales Recomendadas (DCI Rec.): Lista 32
(*Información Farmacéutica, OMS, Vol. 6, No. 3, 1992*)

- p. 9 **tinzaparinum natricum**
tinzaparina sódica
- sustituyase la descripción por la siguiente*
Sal sódica de una heparina de baja masa molecular obtenida por despolimerización enzimática controlada con heparinasa de *Flavobacterium heparinum* de la heparina de la mucosa intestinal de cerdo; la mayoría de los componentes tienen una estructura de ácido 2-O-sulfo-4-desoxy-4- α -L-*treo*-hex-4-enopiranosurónico en el extremo no reductor y una estructura de 6-O-6-N-disulfo-D-glucosamina en el extremo reductor de la cadena, la masa molecular relativa media es de 5500 a 7500, con un valor característico de 6500 aproximadamente; el grado de sulfatación es de 1.8 a 2.5 por unidad de disacárido

Proposed International Nonproprietary Names (Rec. INN): List 35

Dénominations communes internationales proposées (DCI Rec.): Liste 35

Denominaciones Comunes Internacionales Propuestas (DCI Rec.): Lista 35

(*WHO Drug Information, Vol. 9, No. 3, 1995*)

- p. 25 **teverelixum**
teverelix
- replace the chemical name by the following:*
N-acetyl-3-(2-naphthyl)-D-alanyl-p-chloro-D-phenylalanyl-3-(3-pyridyl)-D-alanyl-L-seryl-L-tyrosyl-N⁶-carbamoyl-D-lysyl-L-leucyl-N⁶-isopropyl-L-lysyl-L-prolyl-D-alaninamide

tévérélix	<i>remplacer le nom chimique par</i> [N-acétyl-3-(naphthalén-2-yl)-D-alanyl]-(4-chloro-D-phénylalanil)-[3-(pyridin-3-yl)-D-alanyl]-L-séryl-L-tyrosyl-[N ⁶ -(carbamoyl)-D-lysyl]-L-leucyl-[N ⁶ -(1-méthyléthyl)-L-lysyl]-L-prolyl-D-alaninamide
teverelix	<i>sustituyase el nombre quimico por</i> [N-acetil-3-(naftalen-2-il)-D-alanil]-(4-cloro-D-fenilalanil)-[3-(piridin-3-il)-D-alanil]-L-seril-L-tirosil-[N ⁶ -(carbamoil)-D-lisil]-L-leucil-[N ⁶ -(1-metiletil)-L-lisil]-L-proli-D-alaninamida

Proposed International Nonproprietary Names (Rec. INN): List 38**Dénominations communes internationales proposées (DCI Rec.): Liste 38****Denominaciones Comunes Internacionales Propuestas (DCI Rec.): Liste 38***(WHO Drug Information, Vol. 11, No. 3, 1997)*

p 162 bimoclomolum bimoclomol	<i>replace the chemical name by the following</i> (±)-N-(2-hydroxy-3-piperidinopropoxy)nicotinimidoyl chloride
p 175 opratonii iodidum opratonium iodide ioduro de opratonio	<i>replace the chemical name by the following:</i> trimethyl[3-(10-undecenamido)propyl]ammonium iodide <i>sustituyase el nombre quimico por la siguiente:</i> ioduro de trimetil[3-(10-undecenamido)propil]amonio
p 178 tasonerminum tasonermin tasonermine tasonermina	<i>replace the graphic formula by the following.</i> <i>remplacer la formule développée par la suivante:</i> <i>sustituyase la fórmula desarrollada por la siguiente.</i>

VRSSRTPSD	KPVAHVVANP	QABGQLQWLN	RRANALLANG
VELRDNQLVV	PSEGLYLIYS	QVLFKQGQCP	STHVLLTHTI
SRIAVSYQTK	VNLLSAIKSP	CQRETPEGAE	AKPWYEPYYL
GGVFQLEKGD	RLSAEINRPD	YLDFAESGQV	YFCIIAL

Procedure and Guiding Principles / Procédure et Directives / Procedimientos y principios generales

The text of the *Procedures for the Selection of Recommended International Nonproprietary Names for Pharmaceutical Substances* and *General Principles for Guidance in Devising International Nonproprietary Names for Pharmaceutical Substances* will be reproduced in uneven numbers of proposed INN lists only

Les textes de la *Procédure à suivre en vue du choix de dénominations communes internationales recommandées pour les substances pharmaceutiques* et des *Directives générales pour la formation de dénominations communes internationales applicables aux substances pharmaceutiques* ont été publiés avec la liste 77 des DCI proposées et seront, à nouveau, publiés avec la prochaine liste.

El texto de los *Procedimientos de selección de denominaciones comunes internacionales recomendadas para las sustancias farmacéuticas* y de los *Principios generales de orientación para formar denominaciones comunes internacionales para sustancias farmacéuticas* aparece solamente en los números impares de las listas de DCI propuestas.