

# Supplements Who needs them?

A Behind the Headlines report June 2011

# Foreword

Millions of us take vitamins and dietary supplements hoping to achieve good health, ease our illnesses or defy ageing. Recent years have seen a massive boom in supplement use as products that were once the preserve of specialist health food stores have become available alongside our groceries in the supermarket and on the internet. As availability has grown, so have sales. In 2009 the UK market for dietary supplements and vitamins was worth more than £670 million.

However, the huge range of dietary supplements now available makes the area something of a minefield for consumers. Take a browse through the stocks of the UK's leading supplement suppliers and you will find hundreds of products ranging from acai capsules to zinc, with everything from devil's claw to royal jelly between. Even individual supplements can come in a range of doses and a number of different formulations, making it hard to know what is worth taking and what isn't.

The Behind the Headlines team has tackled numerous studies on supplements and during our work it has become clear that the widely perceived benefits of certain supplements simply do not have enough robust evidence to support them. At times, these misconceptions appear to have been formed due to press coverage, at other times because of the way some products are marketed or because of the sheer volume of misinformation floating around on the internet.

So how do we know which dietary supplements we should take, whether they work and whether they're safe? Where should we be going for reliable information? In this report we hope to make sense of some of these issues surrounding dietary supplements, and also to look at a selection of evidence on some of the most popular supplements in use today.





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# **Overview**

In this report, NHS Choices and Bazian have attempted to examine both individual supplements and the culture that surrounds supplements as a whole. Given the breadth of the topic it shouldn't be seen as a definitive review of their merits, but we do hope that it will encourage people to be more discriminating in the way they choose supplements and, ultimately, look after their health.

The Behind the Headlines service reviews two health news stories each day, looking at whether media claims match the research, as well as the strengths and weaknesses of the scientific



# There is a huge range of supplements available

studies themselves. We have found that dietary supplements, which are used by millions of people each year, are a popular topic for news stories, but that the claims the media makes aren't always supported by the underlying research. Also, contradictory conclusions about a supplement will sometimes be published in the press within a short space of time, adding to the public's confusion.

Supplements are clearly popular, but it's hard to know what to believe. Are the claims made about supplements supported by robust evidence? Are we wasting our money? Are we putting our health at risk? The answers to these questions are not clear-cut, particularly as there are hundreds of different products on the market. However, in this report we have consulted some of the most robust evidence on some big-selling supplements to help consumers make their own minds up, as well as presenting some news coverage of research to illustrate the complexity of the messages they can be faced with.

"Dietary supplements contain vitamins, minerals, herbs or plant material. They can be found in pill, capsule, tablet or liquid form and are used to supplement (add to) the diet, but they should not be considered a substitute for food," **World Cancer Research Fund**<sup>1</sup>

We start with an overview of dietary supplements, covering what they are, whether we need them and how they're regulated. There you'll also find a summary of the size of the industry from data collected about the market in 2009. We then address some commonly used supplements: vitamins, weight-loss supplements, supplements for colds, supplements commonly used by the elderly, fish oils and body-building supplements. In each section we have tried to provide some background on each supplement, discuss any official recommendations on these products and highlight their market share. We have also alerted readers about the known side effects of supplementation and provide links to further reading and guidance if you are considering taking them.

Importantly, we highlight key pieces of evidence that have come to light through the Behind the Headlines projects. While this report is not based on our own systematic searches and appraisals of all available studies (a process that can take hundreds of hours for just a single supplement), we have tried to find pieces of evidence that have carried out this kind of systematic search and appraisal in the Cochrane Library – a well-respected repository of highquality systematic reviews.

# What are dietary supplements?

As their name implies, dietary or nutritional supplements include any consumed products that aim to supplement the diet and provide additional nutrients that may be missing from it, or aren't



Supplements can be expensive

being consumed in sufficient quantities. Today's supplements contain not just vitamins and minerals, but herbs, amino acids, enzymes, fibre and fatty acids. They also come in a variety of forms, including traditional tablets, capsules, powders, drinks and supplement bars. They can be found in supermarkets, pharmacies, health food shops and, of course, on the internet. Many supplements are actually classified as foods rather than medicines and so don't have to go through the usual checks and regulations a medicine would go through for safety and efficacy (how well it works) before being put on the market. They are covered by the Food Safety Act and should not be harmful to health.

Other supplements are classified and regulated as medicines because of their reported effects and methods of use. This means that different products that contain the same main 'active' ingredient may actually have different classifications, with some classed as foods and others as medicines.

#### What's the industry worth?

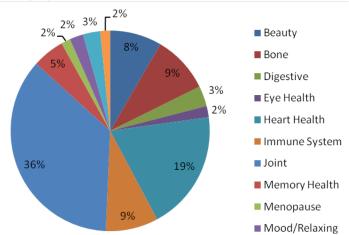
The supplements market is growing. In 2009, sales of vitamins and dietary supplements in the UK totalled £674.6 million, a growth of about 16% over the previous five years<sup>2</sup>, with the two biggest-selling areas being multivitamins (£138.6 million) and fish oils (£139.1 million). These figures relate to products specifically labelled 'dietary supplements' and 'vitamins'. They exclude the categories 'child-specific vitamins and dietary supplements' and 'nutritive drinks and tonics'. The graph overleaf uses the same figures to show the big sellers of 2009.

There's a large and bewildering range of products available, not just vitamins and minerals but substances as varied as bee pollen, ginseng, garlic, green tea, omega-3 fatty acids and resveratrol. Many supplements contain obscure, exotic substances that it's hard to find out about, and every so often newspapers will feature a story on some new wonder pill or ancient remedy that has now made its way to the UK market. According to industry reports, this growth in sales and new products is being driven by the UK's ageing population (15% of us are 65 or older), a more health-conscious public and easier availability due to the internet and the growing number of retail outlets stocking supplements.

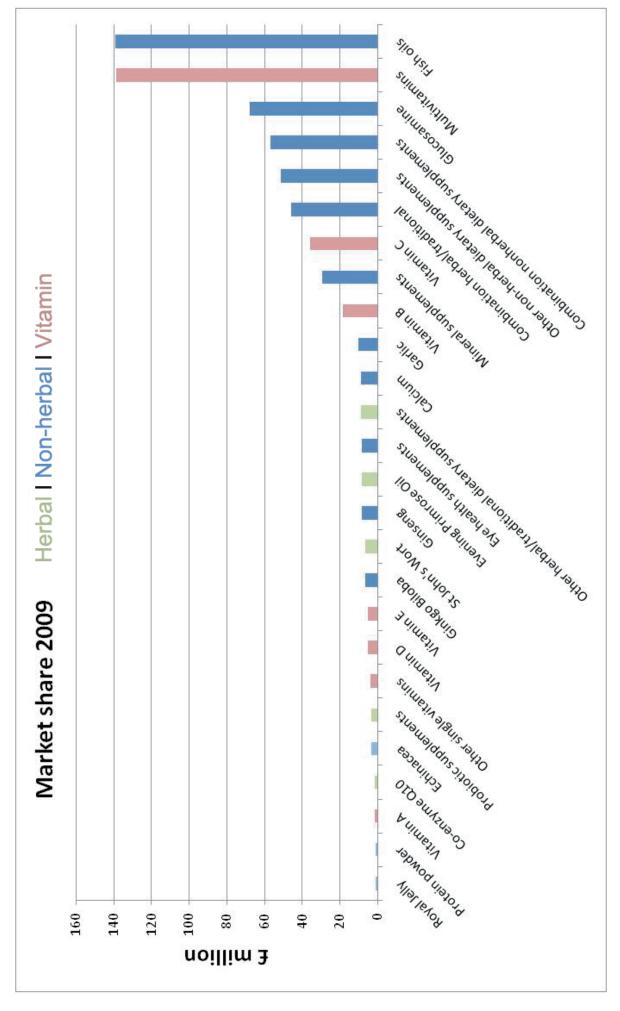
# Who takes supplements and why?

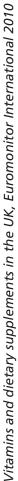
People take supplements for all kinds of reasons, usually relating to their health. They hope these will boost vitality, limit the signs of ageing, extend life, cut the risk of chronic disease such as cancer and treat specific ailments such as arthritis. According to research by the Food Standards Agency (FSA) in 2008<sup>3</sup>, nearly a third of people in the UK take some vitamin, mineral or dietary supplement on most days, and about 15% of us report having taken a "high dose" supplement in the last 12 months. The main reason we take supplements is for our general health and wellbeing.

Market data suggest that joint health is a major aspect of wellbeing, accounting for 36% of all supplements sales in 2009. Products that target health of the heart, bones and immune system are also popular, as shown below<sup>2</sup>.



Targets of supplement use (%age of 2009 retail value) Vitamins and dietary supplements in the UK, Euromonitor International 2010





FSA research<sup>3</sup> found the following:

- women are more likely than men to take supplements
- older people and people in poorer health are also more likely to take them
- the market is not exclusively for adults, with just over half of households with children (52%) saying they currently give them a vitamin or mineral supplement
- nearly a fifth of households giving their children supplements give them the adult version

# Should we be taking supplements?

There is not a straightforward yes or no answer to this question, both because of the range of products available and because an individual's circumstances will govern whether they would benefit from using a particular supplement.

For example, even with popular, well-known products such as multivitamins things are not

The British Nutrition Foundation advises anyone concerned about whether their diet is providing enough nutrients to discuss this with a health professional. It's always a good idea to talk to your GP or to a registered dietitian if you're considering supplementing your diet. They can give you advice about whether supplements will have health benefits for you in your particular circumstances

as clear-cut as you might imagine. There are, of course, certain vitamins, minerals and other nutrients that are essential for keeping the body functioning, but experts agree that most people can get enough of these nutrients from eating a balanced diet and, in the case of vitamin D, from getting enough sunlight. On the other hand, there is good evidence that certain vitamin supplements may be beneficial to the health of certain groups of people, such as the elderly, pregnant women and children between six months and five years old.

In other cases, people may be taking supplements for specific health reasons, for example, using glucosamine in a bid to protect their joints. In this particular case the most comprehensive evidence reviews to date suggest that there is no overall benefit, and bodies such as the National Institute for Health and Clinical Excellence (NICE) do not recommend its use. However, there are certainly still plenty of people buying glucosamine, and in these cases it's best that this personal choice is made in an informed way, with knowledge about what the evidence says and any potential harms.

At the other end of the scale some supplements sold over the internet, such as certain herbal weight-loss products, have been found to contain banned substances that carry a significant risk to health<sup>4</sup>. It's clear that in these cases nobody should be taking these dangerous products.

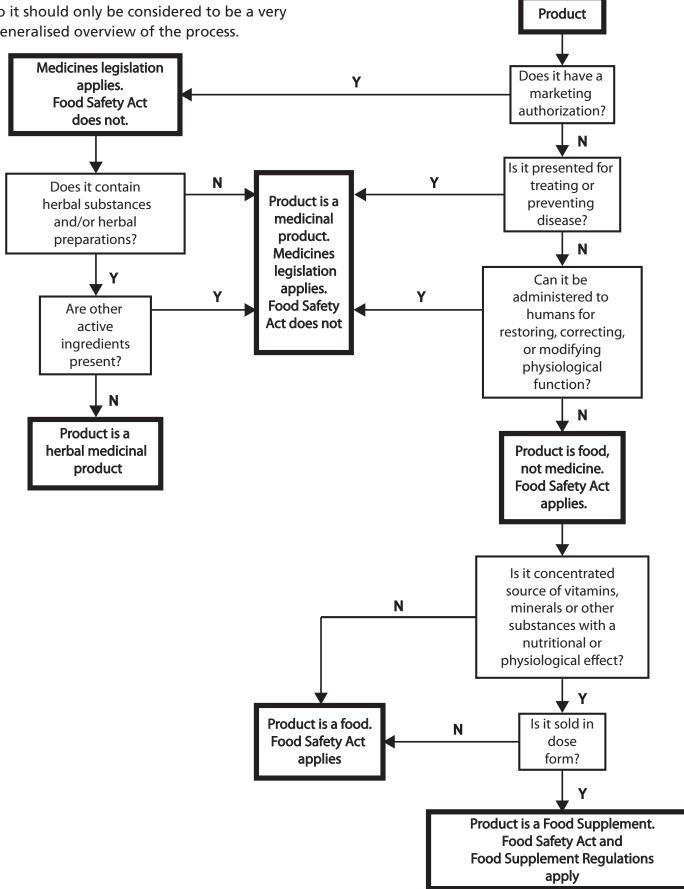
In short, there is no easy answer to the question of whether we should be taking supplements, but what is clear is the need for people to know what they are taking, to know whether it is likely to help and to know whether it is likely to harm.



If you take supplements, always read the label first

# How are supplements regulated?

Depending on how a supplement is classified it will be subject to different regulation. Below is a flowchart originally produced by the Government Chemist to show broadly how supplements will be classified<sup>5</sup>. There are numerous regulations and considerations behind classifying each supplement, so it should only be considered to be a very generalised overview of the process. The Government Chemist provides advice to Government and industry, applying sound analytical science in the public interest and acting as the referee in cases of dispute.



As illustrated in the chart, in the UK certain supplements are considered to be foods and will therefore be regulated under general food laws by the Food Standards Agency and Department of Health. Others will be regulated as a medicine by the Medicines and Healthcare Regulatory Agency (MHRA).

Before a medicinal product can be marketed it must be approved by the MHRA, which makes its decision based on the product's safety, quality and efficacy<sup>6</sup>.

If a supplement is considered to be a food, that does not mean it is unregulated, rather that it is subject to food safety laws, which are not as stringent as those for medicines.

There is also EU legislation that dictates which vitamins and minerals can be included in supplements<sup>7,8,9</sup>. Dietary supplements should only be made with vitamins or minerals that appear on an approved ingredient list. While such measures are an attempt to oversee which substances supplements contain, many also include other active ingredients that can have biological effects in the body. These may make them potentially unsafe as their ingredients can interact with licensed medicines or with other supplements. Ginkgo biloba, for example, interacts with antidepressant, anticonvulsant, antiviral and blood-thinning medications (e.g. warfarin). The effects can be undesirable and even dangerous.

# **Herbal medicines**

The way that some herbal products are regulated has recently changed. As of April 30 2011 all herbal medicines placed on the UK market must have a Traditional Herbal Registration (THR)<sup>10</sup> or a marketing authorisation (previously known as a product licence). The MHRA now defines individual herbal medicines as either registered traditional herbal medicines or licensed herbal medicines.

Registered traditional herbal medicines
 These products are required to meet
 specific standards of safety and quality and
 be accompanied by a list of 'indications'
 (medicinal uses). These agreed indications must
 be based on a history of traditional usage,
 and patients should also be provided with
 information on the safe use of the product.
 These products can be identified by a THR
 number on their label and a special logo.

- Licensed herbal medicines
  - Some herbal medicines in the UK hold a product licence or marketing authorisation just like any other medicine. These are required to demonstrate safety and quality, and they must be accompanied by the necessary information for safe usage. These products can be identified by a distinctive nine-digit product licence (PL) number on the product container or packaging which is prefixed by the letters PL.

Although this new legislation – the EU Traditional Herbal Medicines Products Directive (THMPD) – has come into force, consumers may still find unlicensed herbal medicines available for sale that do not feature written claims. This is due to legislation that stipulates a seven-year transitional period whereby products legally on the market prior to 2004 could continue to be placed on the market until 2011. These products will not be taken off the shelves, instead they can continue to be sold legally, although stock can no longer be replenished. The MHRA points out that the standards of these unlicensed medicines can vary widely, and that these products have not been assessed by the MHRA for quality and safety purposes<sup>11</sup>.

Herbal products and supplements marketed as foodstuffs will continue to be regulated as foods.

For more detailed information on the THR scheme, THR numbers and herbal medicines, see the MHRA website (www.mhra.gov.uk).



Different supplements are regulated in different ways

"I deal with many patients who are led by clever marketing or packaging to spend huge amounts of money on so-called 'health' supplements and products for which there is no evidence, and which do nothing at all," Michael Lean, professor of human nutrition, University of Glasgow.

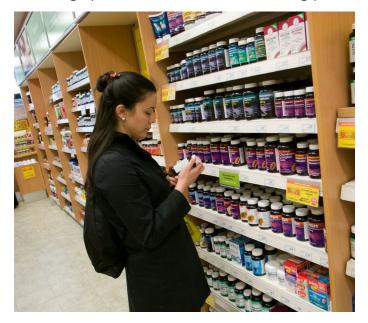
#### What claims can supplements make?

We've all seen the claims made by supplement manufacturers for products that "maintain the immune system" or "keep joints healthy". But how can we tell whether they are backed up by proper scientific research? If manufacturers of supplements claim that their product treats or cures conditions, they are generally considered to be medicinal and therefore subject to regulation by the MHRA. If a supplement has not been given marketing authorisation as a medicine by the MHRA, it should not be making claims that the product treats or cures conditions. However, they can make claims that their product only maintains a function (e.g. "maintains bone function") and still be governed by food laws.

Which?, the well-known consumer review association, is concerned that people are being "taken for a ride" by some claims made on supplement packaging and wants health claims about supplements to be backed up by evidence<sup>12</sup>. The reality is that, at present, the public can have great difficulty telling which, if any, of the health claims made by supplement manufacturers can be supported by firm evidence.

There is EU legislation controlling the use of nutrition and health claims, which requires all claims to be assessed and authorised at EU level. The European Food Safety Authority (EFSA) has looked at the science behind the health claims of thousands of different supplements, to see if they stand up. According to Which?<sup>12</sup>, out of the thousands that have been checked so far, it has turned down roughly 80% of these claims. No-one is able to act on the conclusions of this research yet, as the scientific assessments have to be voted on by EU member states, but, eventually, manufacturers will be forced to remove all unsupported health claims from their marketing.

There are, of course, advertising guidelines that apply to products such as supplements, and the Advertising Standards Authority (ASA) has taken action against false or misleading adverts in this area, asking companies to edit or remove inaccurate claims under its industry self-regulation scheme. The ASA can also report un-cooperative and persistently misleading advertisers to the Office of Fair Trading. However, misleading supplement advertising still occurs, with a 2008 audit of internet marketing conducted by the ASA finding that 28% of adverts for health and beauty products failed to satisfy guidelines<sup>13</sup>. The audit also found that when searching for the term "slimming", for example, one in three sponsored search engine results were in breach of regulations. The ASA said that users searching for the term "slimming" were likely to be presented with search results featuring "problematic claims for slimming pills".

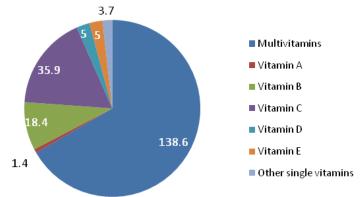


Buyers should be cautious when choosing supplements

# Vitamin supplements Vitamins are vital, but are vitamin pills?

The body needs vitamins in order to function properly and maintain health, but, despite their vital importance, the body only needs them in minute amounts. We need 13 vitamins to maintain health – vitamins A, C, D, E, K and the eight B vitamins. Each has specific functions in the body: vitamin C helps to keep cells healthy, vitamin A is good for eyesight and healthy skin, vitamin D helps to regulate calcium and is essential for strong bones and teeth, and vitamin E is needed to maintain cell structure. With a few exceptions (niacin and vitamin D), our bodies cannot make these substances, meaning we need to obtain them from other sources such as food. If you have low levels of certain vitamins, you may develop a deficiency disease. Too little vitamin D, for example, could lead to rickets in children.

# The UK vitamin market (£million) in 2009



# Vitamins and dietary supplements, Euromonitor International 2010

Vitamin pills are very popular. Along with fish oils, they dominate the supplements market, with consumers spending nearly £208 million on vitamin supplements in 2009<sup>2</sup>. Nearly £139 million of this amount was spent specifically on multivitamins, nearly £36 million on vitamin C products (the most popular single vitamin supplement on the market) and

Behind the Headlines stories on vitamins:

- <u>Vitamin D immune system boost?</u>, March 8 2010
- <u>Vitamin B12 and brain volume</u>, September 9 2008
- <u>Vitamin E linked to physical activity</u>, January 24 2008
- Vitamin C jabs and cancer, August 5 2008

more than £18 million on vitamin B products. There are clearly plenty of people buying vitamin supplements but, surprisingly, only certain groups are considered to benefit from taking them.

What's the best way to get enough vitamins?

The best way for most of us to get enough vitamins is to eat a varied and balanced diet. This includes plenty of fruit and vegetables; plenty of starchy foods, such as bread, rice, potatoes, and pasta; some milk and dairy foods; some meat, fish, eggs, and beans and other non-dairy sources of protein. Foods and drinks high in fat and/or sugar should be kept to a minimum. Vitamin D is an exception here. A small amount is obtained through diet but most of this vitamin is made under the skin when it is exposed to sunlight.

The Department of Health set Dietary Reference Values (DRVs) for the UK population (in 1991). DRVs provide information on the amount of energy and nutrients including vitamins and minerals that a group of people of a certain age range (and sometimes sex) needs for good health. DRVs only apply to healthy people.

Dietary supplements and certain foods therefore carry labels denoting the percentage of the Recommended Daily Allowance (RDA) contained in the product<sup>14</sup>. RDAs are based on the DRVs and are used across all European countries. RDAs have a few differences from DRVs and are used only for food labelling purposes.

Vitamins	RDA	Minerals	RDA
Vitamin A	800 µg	Calcium	800mg
Vitamin D	5 µg	Magnesium	375 mg
Vitamin E	12 mg α-TE	Iron	14 mg
Vitamin K	75 µg	Copper	1 mg
Vitamin B1	1.1 mg	lodine	150 µg
Vitamin B2	1.4 mg	Zinc	10 mg
Niacin	16 mg	Manganese	2 mg
Pantothenic acid	6 mg	Potassium	2000 mg
Vitamin B6	1.4 mg	Selenium	55 µg
Folic acid	200 µg	Chromium	40 µg
Vitamin B12	2.5 µg	Molybdenum	50 µg
Biotin	50 µg	Fluoride	3.5 mg
Vitamin C	80 mg	Chloride	800 mg
		Phosphorus	700 mg

RDAs for vitamins and minerals in the EU

# Who needs vitamin supplements?

Certain groups at risk of deficiencies should use supplements<sup>15</sup>:

• all pregnant and breastfeeding women should take vitamin D supplements

- women trying to conceive and women in the first 12 weeks of their pregnancy are recommended to take folic acid supplements, which reduce their child's risk of neural tube defects such as spina bifida.
- people aged 65 and over should take vitamin D supplements
- people with darker skin and people who are not exposed to much sun should take vitamin D supplements
- all children aged six months to five years should be given a supplement containing vitamins A, C and D
- Your GP may also recommend supplements if you need them for a medical condition

If you fall outside of these groups and buy vitamin pills then the chances are that you will be spending your money on surplus amounts of vitamins you've already gained through your diet.

#### Vitamins as antioxidants

While it has been known for some time that most people can meet their daily requirement of vitamins through their diet, in recent years there has been particular interest in supplements that will provide high doses of antioxidant vitamins. Antioxidants have become a bit of a buzzword in recent years, with all sorts of products proclaiming that they are a good source of antioxidants.

Of course, this raises the question 'what exactly is an antioxidant?' In basic terms an antioxidant is a substance that can interfere with the chemical process of oxidation, in which an atom or molecule gives electrons to another substance. While this



may sound a bit complicated, the basic theory is that unstable atoms or molecules called free radicals need extra electrons and will 'steal' these from other molecules in the cell, oxidising them and leaving them in need of extra electrons themselves. This can start off a chain reaction and damage cell components, and this damage accumulates with ageing. Antioxidants are capable of safely donating electrons to free radicals without becoming free radicals themselves. They can therefore fight the "oxidative stress" caused by excess free radicals, which has been implicated in diseases including cancer and heart disease<sup>16</sup>.

Several lab-based studies have indeed shown that certain vitamins can "mop up" these free radicals and fight oxidative damage. They include vitamins A, C and E (as well as selenium, a trace element). Several observational studies have also shown that a higher intake of antioxidant-rich fruit and vegetables is associated with a reduced risk of chronic disease. These findings have led to claims that antioxidant supplements can slow ageing, reduce the risk of chronic disease and reduce the risk of dying early.

#### What can vitamin supplements really do?

An extensive review by the respected Cochrane Library (published in 2008) assessed trials comparing the effects of a range of vitamins (as well as selenium) on death rates<sup>17</sup>. It was one of the biggest reviews of the effects of vitamin supplements on mortality to date, pulling in the results of 67 trials and data on more than 232,000 people. Despite the seemingly plausible mechanism, the results do not provide the reassurance that many taking antioxidant vitamins would wish to hear.

The study found no reduction in mortality in people who took antioxidant supplements, either in healthy people or in those with diseases. Separately, the results on vitamins A and E and beta-carotene suggest that they may even increase the risk of death (although these results only just reached statistical significance). On the basis of these results the reviewers call for further trials to be "closely monitored" for potential harmful effects.

The findings are also leading to a rethink about free radicals, with the Cochrane researchers saying that by eliminating free radicals from the body,

Pregnant women benefit from certain supplements

"Antioxidants need to be considered medicinal products and should undergo sufficient valuation before marketing," Goran Bjelakovic, lead author, Antioxidant supplements for prevention of mortality

we may be interfering with essential "defensive mechanisms". Indeed, the process of oxidation is part of numerous chemical reactions in the body, and there is some scientific debate over whether taking huge doses of antioxidants might upset the natural balance of these reactions. As with all research, there are important points to note about the scope of this review. It only looked at mortality, not effects on health, and most of the trials in the review used high-dose supplements, so the findings may not apply to low-dose vitamins or to the antioxidants found in food as part of a normal diet. Still, it does show that the antioxidant issue is complex and, given the results of this research, it would seem sensible for most of us to rely on a balanced diet for our intake of antioxidants.

# Vitamins for fertility

Then there is the question of fertility. There have been some theories that antioxidants can aid conception. Earlier this year the Cochrane subfertility group performed a review examining the effect of antioxidant supplements, such as vitamin E or zinc, on male subfertility<sup>18</sup>. The review, which included 34 studies in just over 2,800 couples, showed that a woman was more likely to have a pregnancy or live birth if her partner took an antioxidant supplement.

These results are certainly more positive, but it's important to put these results into perspective. The reviewers themselves said that more research is needed, particularly relating to the findings on live births, which came from only three trials featuring a total of 214 couples. We also don't know from this research which particular antioxidant, if any, might be most effective, or at what dose.

Can vitamin supplements be harmful? It could be construed that taking vitamins can't really do any harm. People may believe that at most they will lose some money. Although the doses of vitamins and minerals found in most supplements are thought to be safe, very high levels can be harmful and you are likely to experience some harms if you take vitamins in large amounts over long periods of time. For example, beta-carotene, which is turned into vitamin A by the body, has been found to increase the risk of lung cancer in heavy smokers and in people who have been heavily exposed to asbestos. High levels of niacin (vitamin B3) can cause skin flushes in some people. Too much vitamin B6 can lead to loss of feeling in the arms and legs. Levels of vitamin C above 1,000mg a day can cause abdominal pain and diarrhoea. Safe upper limits of many vitamins and minerals have been set by the Food Standards Agency and can be found in their 2003 report<sup>19</sup>.

It's also worth bearing in mind that vitamins are either water soluble or fat soluble. Those that are water soluble – the eight B vitamins and vitamin C – are used rapidly by the body, and the excess is excreted rather than stored. Highdose supplements containing water-soluble vitamins could well be a waste of money as you could literally end up flushing their expensive contents down the toilet.On the other hand, fat-soluble vitamins – A, D, E and K – are stored in the liver and fat tissues. Amounts in excess of what is needed are more likely to accumulate in the body and could lead to hypervitaminosis (vitamin poisoning). "Excessive amounts of vitamin A can have side effects such as abdominal pain, weight loss, vomiting, blurred vision, irritability and headache" says Emma Williams, nutritional scientist with the British Nutrition Foundation.

# Key points on vitamins

- Most of us can get all the vitamins we need from a balanced diet.
- Pregnant or breastfeeding women, children aged under five years and some adults do benefit from taking certain supplements. For more information, see <u>NHS Choices: Do I need vitamin</u> <u>supplements?</u>
- Vitamin supplements should not be used as a substitute for a balanced diet. If you do take them, make sure you do not exceed your daily requirement.

# Weight-loss supplements

# Shedding Ibs or shedding fs?

Obesity is one of the most serious health issues in the UK. In England alone, more than one-third of adults are overweight and nearly one-quarter obese, with obesity rates predicted to rise by 60% over the next 40 years<sup>20</sup>. It's widely recognised that obesity is linked to major health problems such as heart disease, type 2 diabetes and some cancers. Beyond the important health implications, being overweight can also be a source of unhappiness, particularly if nothing seems to help shift that extra weight.

Given the unfortunate fact that it's generally much easier to gain weight than it is to lose it, it's not surprising that growing numbers of people are turning to over-the-counter slimming supplements and internet wonder pills. There are dozens, if not hundreds, of heavily marketed weight-loss products that claim to contain herbs or natural substances that work by mechanisms such as speeding up the metabolism (the rate at which the body burns calories), blocking the absorption of dietary fat in the body ("fat magnets") or promoting feelings of fullness.

Even if you don't really believe the claims, it's easy to get drawn into the "Wow! I feel great!" captions, the celebrity endorsements and the before-and-after transformations showing how in just 60 days some glum, pale, overweight person has transformed into a trim, happy individual with a cheesy grin and a pair of jeans that are now 10 sizes too big.

The slimming products industry is vast: according to the British Nutrition Foundation sales of over-the-counter slimming products topped £900 million in 2009 in Western Europe alone.

And indeed, lots of us do end up taking the plunge, reasoning that for a small outlay we might transform our bodies and our lives, and that at worst we will lose a bit of money if our pills don't work. Well, unfortunately there is little evidence for some of the products sold by reputable retailers and, worse still, many of the "guaranteed, clinically proven, 100% natural weight-loss pills" sold over the internet come with no guarantees, have no evidence behind them and could be packed with potentially harmful substances.

# Am I overweight?

Adults are defined as being overweight or obese using a measure called the body mass index (BMI). It is a way of assessing whether your weight is appropriate for your height by calculating the ratio of your mass (your weight in kilograms) to your height (in metres squared). The following table categorises weight according to BMI:

Classification	BMI (kg/m <sup>2</sup> )
Healthy weight	18.5-24.9
Overweight	25-29.9
Obese	30+

Check your own BMI using the <u>BMI</u> <u>calculator</u> on the NHS Choices website

# So do they live up to their claims?

Manufacturers often cite 'clinical trials' to prove that their products work. However, many of these manufacturer-led studies are of poor quality, and independent research often finds that products simply don't live up to these claims. For example, a recent, well-conducted systematic review attempted to make an independent assessment of the evidence behind popular weight-loss supplements<sup>21</sup>. It gathered together all published reviews on individual weight-loss supplements, finding nine that had assessed popular products such as bitter orange, calcium, green tea, guar gum and chitosan. None of these existing systematic reviews had found good evidence that they offered clinically relevant effects without undue risks.

Even if much of the more reliable research out there suggests that many popular weight loss supplements are unlikely to work, people may be swayed by guarantees that they will get results from a particular product. For example, weightloss supplements are advertised on the internet with compelling guarantees, such as a full refund if you don't 'lose a stone in just 30 days' or 'get the fat-free stomach you've always wanted'.

Products marketed in this way appear to breach UK advertising guidelines. The Advertising Standards Agency has said that "marketing communications should not contain claims that people could lose precise amounts of weight within a stated period or that weight or fat could be lost from specific parts of the body".

Indeed, in 2005 the Advertising Standards Agency looked at the way a range of slimming products were marketed in regional papers and women's

"Manufacturers cherry-pick and only ever mention the positive trials ... they then also fail to mention the mostly poor quality of their studies. Desperate people are being misled to buy unproven treatments at considerable expense," Professor Edzard Ernst, professor of complementary medicine magazines<sup>13</sup>. Out of 48 adverts considered, 24 were found to be in breach of advertising regulations, including 10 relating to weight-loss pills and edible supplements.

# Are weight-loss pills safe?

Many ingredients in common weight-loss pills carry the potential of side effects, some of them serious. The table below lists common ingredients in popular weight-loss supplements along with their reported side effects.

Potential problems such as heart palpitations, stomach pain and throat blockage are not particularly pleasant, and these are just those associated with herbal products being sold legitimately. The Medicines and Healthcare Regulatory Agency (MHRA), which is responsible for ensuring that medicines work and are acceptably safe, frequently issues warnings about some products being sold on the internet as herbal slimming aids. These are often presented as "100% natural" or completely safe, but testing has revealed that some contain undeclared pharmaceuticals, banned substances or toxic ingredients that pose a serious risk to health<sup>4</sup>.

Purported mechanism of action	Ingredients in weight-loss supplements	Reported adverse side effects at recommended intakes
Enhance fat or carbohydrate metabolism	Hydroxycitric acid	Stomach pain
	Conjugated linoleic acid	Insulin resistance
	Green tea	Drug interactions, potential liver damage for green tea extract‡
	Licorice	Pseudoaldosteronism, hypertension and hypokalaemia
	Pyruvate	None to date
	Pantothenic acid (vitamin B5)	Excess pantothenic acid (vitamin B5) (e.g. 5-9 g) is widely known
		to cause nausea, headaches, diarrhoea and a lack of energy
	L-carnitine	None reported
	Chromium picolinate	None reported
	Calcium	None reported
	White kidney bean extract	None reported
lock dietary fat absorption	Chitosan (polyglucosamine)	Gastrointestinal symptoms
timulants or energy enhancers	Ephedra (ma huang)† or ephedrine	Increased heart palpitation, psychiatric,
		autonomic and gastrointestinal adverse effects
	Bitter orange	Increased blood pressure, possible drug interactions
	Caffeine, theophylline or theobromine	Irritibility, heart palpitations, anxiety and other
	(from kola nut, guarana or maté)	central nervous system events
Promotes satiety	Guar gum	Blockage of the throat, oesophagus or intestine if taken without
	Sodium alginate	~ 250ml of water or other fluid
	Glucomannan (Konjac extract)	
	Psyllium	
Reduce stress- or depression-related eating	St Johns Wort	Drug interactions, gastrointestinal symptoms,
		dizziness, confusion, tiredness and sedation
	Ginko biloba	Headaches, dizziness, possible increased risk of bleeding,
		gastrointestinal discomfort, nausea, vomiting, diarrhoea,
		heart palpitations and restlessness
Laxative	Cascara	Potential for usual laxative adverse effects (e.g. dehydration
	Rhubarb root	and electrolyte imbalance)
	Flaxseed	
Sale prohibited in the USA since April 2004.		
Sarma et al. (2008).		

Do slimming supplements work? Gibson-Moore H, Nutrition Bulletin (2010)<sup>20</sup>

For example, a banned substance called sibutramine was recently found in two Chinese herbal supplements, Paiyouji tea and Pai You Guo capsules<sup>22</sup>. Sibutramine was a prescription-only medicine until it was withdrawn from the market in January 2010 following a warning from the European Medicines Agency that it increased the risk of heart attacks and strokes. The MHRA has officially warned people not to use these products. Despite this, there are still weight-loss sites marketing these dangerous supplements in the UK.



Weight-loss wonder pills are unlikely to work

Herbal Flos Lonicerae (Herbal Xenicol) is another product that appears to be readily sold over the internet, even though the MHRA has warned against its use<sup>23</sup>. This Chinese "weight-loss oil" has been linked with side effects such as palpitations, and at least one patient has needed hospital treatment after ingesting it. Despite it being marketed as a 'herbal' product the MHRA says that the capsules are thought to contain an "as yet unknown pharmaceutical substance".

At least 60 other slimming products have been given official recalls and bans<sup>24</sup>, with consumers warned to stop taking them because they contain a variety of undeclared, active drugs that may pose a health risk. Many of these products continue to be available on the internet, illustrating how difficult it is to control the sale of potentially dangerous products.



Your GP can help you to lose weight

#### Safe, proven ways to lose weight

Rather than turning to weight-loss supplements, your GP should be your first port of call. They will be able to offer you a number of tried and tested approaches to weight management. What's more, visiting your GP is free through the NHS. Initially, GPs and other health professionals usually advise people to maintain a healthy weight by sticking to a balanced diet and increasing physical activity. To help you achieve these goals your doctor can give you specific advice on what you should be eating and ways to stay active.

Beyond this initial advice your GP may then offer you more comprehensive, 'multicomponent' interventions that feature not only activity programmes and dietary advice on healthy eating, but also behavioural interventions to help you achieve your weight-loss goals. Again, your GP can offer these free as part of your treatment by the NHS, and they may be able to tailor your plan to your preferences, fitness level and lifestyle.

Drug treatment with orlistat (see below) may be considered, but only after dietary, exercise and behavioural approaches have been started. It may be used if your target weight has not been reached or if your weight has reached a plateau. Your treatment will be carefully monitored and only continued if it is working. (Drug treatment is not recommended for children under 12 years of age.)

# Orlistat

It's worth pointing out the difference between slimming supplements and a licensed medicine to help weight loss, called orlistat. This medicine is available on prescription, with a lower dose version called Alli available over the counter. If a medicine is licensed, it has been through a strict process of rigorous clinical testing to show sufficient effectiveness and safety. Orlistat has been shown to work by stopping the body absorbing fat, so that it passes straight out in your stools. Research shows it can help some people lose weight, but even then it is not a wonder pill. In clinical trials, between one-third and one-half of participants achieved a 5% reduction in body mass. Side effects include diarrhoea and bloating. Read more about weight loss on the NHS Choices website.



Alli is a licensed weight-loss medicine

# Key points about weight-loss supplements

- There is very little evidence that most over-the-counter weight-loss supplements actually work.
- Your GP can offer a range of options both to help you lose weight and to maintain a healthy weight. These interventions will mostly be free, so speak to them first.
- If you are still thinking of trying a weightloss supplement be aware of the risks, particularly if you are shopping over the internet. You could be wasting your money or, more importantly, putting your health at risk.
- Don't buy weight-loss products on the internet because of the risk of side effects, but if you really want to buy a product, try searching for information on reputable sites such as the MHRA or US Food and Drug Administration (FDA) to check for known problems. Also, try internet searches with words such as "danger", "scam", "side effects", although don't assume it's safe if these don't return results.
- The MHRA provides regular updates on herbal safety and has a particular section alerting consumers to products that contain undeclared or banned pharmaceuticals<sup>25</sup>.

# **Supplements for colds** Vitamin C won't keep the doctor away

Vitamin C is the UK's most popular single vitamin supplement, with annual sales adding up to about £36 million. Other supplements that people often turn to when they have a cold include zinc and echinacea. All of these have been found to have antiviral properties in animal or laboratory studies, but do they work for people?

# Vitamin C

Researchers have been interested in using vitamin C to prevent and treat colds for more than 60 years. Some animal studies have found that vitamin C strengthens resistance to infections. One theory for this is that the vitamin protects cells against oxidative stress. However, the results from trials in people have so far had inconclusive results.

The latest position on vitamin C and colds comes from a systematic review from the Cochrane Library<sup>26</sup>, generally considered to be one of the most respected sources of systematic review evidence. The review concluded that there is little evidence that vitamin C supplementation (0.2g per day or more) is beneficial within the general community in terms of preventing infection. Even higher doses of 1g per day or more did not prevent colds in the general population.

The same review did find that regular high doses of vitamin C (1g per day or more) seem to reduce the duration of colds a little, by 8% in adults and 13% in children. The researchers also found that vitamin C supplements seemed to have a greater effect for people who were undergoing extreme physical stress, such as marathon runners. In these groups, the supplements halved the risk of getting a cold, and didn't necessarily need to be taken in high doses.

The researchers found no evidence that the vitamin could treat early cold symptoms, but they say that more studies are warranted, particularly among children, who get colds more often than adults.

Vitamin C is available through many foods we eat, such as citrus fruits, but do we get enough of it from the diet to fight colds? An orange contains about 70mg of vitamin C<sup>27</sup>, so to get as much as the high doses used in some of the trials (1,000mg or more) you would have to eat an awful lot of oranges.

The recommended daily allowance of vitamin C in the EU is 80mg and most people will achieve this by eating a sensible diet

In the doses that are available (generally up to 1,000mg daily) vitamin C is safe for most people. The exceptions are mentioned below. However, vitamin C is water-soluble, and the body cannot store excess amounts. What it doesn't need it will just get rid of when you go to the toilet, raising the question of whether these supplements are worth the expense.

Possible harms of vitamin C Vitamin C is not suitable for everyone. It can cause dangerous rises in the blood sugar levels of people with <u>diabetes</u>. It can also be dangerous for people with genetic conditions that cause an excessive build-up of iron in their body, such as <u>haemochromatosis</u>. Large doses may cause nausea, diarrhoea and stomach cramps. If you intend to take vitamin C supplements, it is best to discuss this with your doctor, particularly if you have any medically significant conditions.

An orange contains about 70mg of vitamin C



# Zinc

Zinc is a trace element that is essential for normal growth. The mineral has been promoted for many years as being able to boost the immune system. Laboratory studies have found that it can inhibit the replication of the rhinovirus, which is the most frequent cause of cold symptoms (Cochrane).

# Read more about zinc

• Zinc for the common cold, Behind the Headlines, February 2 2011

Until recently, trials investigating its potential for reducing cold symptoms have had mixed results, but now the evidence seems to be swinging in its favour. In 2011, the Cochrane Collaboration published a review on zinc and colds<sup>28</sup>. It found that taking zinc lozenges or syrup within 24 hours of symptoms starting may reduce the length of your cold symptoms by about a day. The severity of the symptoms may also be reduced. Regular zinc supplements (taken for at least five months) appear to protect people against catching colds, and children who take zinc are less likely to be absent from school or to be prescribed antibiotics when they are ill. The review was of 15 trials involving more than 1,300 people, and so is likely to be reliable. However, whether these small benefits are worth the expense (around £7 for 30 tablets) is an individual decision.



Taking zinc regularly may prevent you from catching a cold

The possible side effects of zinc If you decide to take zinc supplements, buy them from a reputable outlet and keep to the recommended dosages (available with the pack). The correct dose is important and there may be side effects including nausea and an unpleasant taste in the mouth, or more serious events such as vomiting, diarrhoea and abdominal pain.



Rest and plenty of fluids are the best treatment for colds

- "Take zinc to fight a cold, say scientists," The Daily Telegraph, February 16 2011
- "The body of evidence for zinc supplementation seems to be swinging in favour of its benefit," Behind the Headlines, February 16 2011

# **Echinacea**

Echinacea, a group of plants with pinkish-purple flowers, is a popular herbal remedy in the UK. Two echinacea products ranked in the top three supplements sold to support the immune system in 2009<sup>2</sup>. There are many echinacea preparations on the market, including tablets, drops, capsules, tincture and loose tea. The herb also comes in a wide range of doses – from 400 to 4,000mg.

As with vitamin C, laboratory studies have shown the plant contains substances that can affect the immune system, but the results from research in people have been mixed. One large systematic review undertaken by the Cochrane Collaboration in 2009 found 16 clinical trials that investigated different echinacea preparations for both preventing and treating the common cold<sup>29</sup>. The review found that echinacea did not prevent colds, but some preparations containing a particular species of echinacea plants (Echinacea purpurea) might reduce the duration and severity of colds in adults. The reviewers did add, however, that the results are "not consistent" and so should be treated with some caution.

Several echinacea formulations have been tested in studies. Different parts of the plant have been used, different methods have been used to process them and sometimes other herbs are added. Although systematic reviews are the best way to summarise the evidence, if trials use different methods, the findings from pooling them are less reliable than if the methods used had been similar.

A 2010 trial found that echinacea did not reduce the duration or severity of colds<sup>30</sup>. This large randomised controlled trial (RCT) in more than 700 participants found that people who took a standardised dose of echinacea had no significant improvement in either the duration or the severity of their colds compared with those taking a placebo.

"Herbal remedy really does cure a cold," The Times June 25 2007 "There is some evidence that preparations based on the aerial parts of E purpurea might be effective for the early treatment of colds in adults but the results are not fully consistent," Cochrane Library 2009

Possible side effects of echinacea Echinacea is thought to be safe when used in the short term, although some side effects have been reported, including fever, nausea and stomach pain<sup>31</sup>. There is not enough information to know if it is safe for long-term use. The Cochrane review recommended not taking echinacea for longer than eight weeks at a time. In trials, the herb has been well tolerated, with the only side effect being a rash in some children.



A flower from the Echinacea purpurea plant

# Key points about cold supplements

**Vitamin C** There is no conclusive evidence that regular vitamin C supplementation, at moderate or high doses, has any effect on reducing the general population's risk of getting a cold. In people who undergo extreme physical stress, such as marathon runners, there is some evidence that supplementation (not specifically with high doses) reduces the risk of getting a cold. Regular vitamin C may slightly reduce the length of a cold in some people.

**Zinc** There is evidence that taking zinc within a day of developing symptoms of a cold reduces the duration of the cold by about a day and that regular supplementation (for at least five months) protects people against catching colds. For many people, the limited benefit seen here may not seem worth the expense and possible side effects of taking zinc.

**Echinacea** There is a lack of evidence that echinacea in general can prevent or treat colds. There is some evidence that preparations from Echinacea purpurea might reduce the duration and severity of colds in adults. However, the reviewers that concluded this also added that results in this area are "not consistent".

# The ageing population Ginkgo, ginseng and glucosamine

According to the FSA, most people who buy supplements are over 55 years old, so it's not surprising that some of the most popular supplements are bought in the hope of preserving memory, joint health and general vitality. Here, we discuss three big sellers – ginkgo, ginseng and glucosamine. In 2009, consumers spent more than £82 million on these three supplements alone.

# Ginkgo

The leaves of the ginkgo biloba tree are used in traditional Chinese medicine, in particular for circulatory problems. Here in the West there are claims that ginkgo extracts help a range of conditions, including memory problems, sexual performance problems and eye disorders. Laboratory studies have suggested that some of the active compounds in ginkgo may dilate blood vessels, reduce blood viscosity (thickness), modify neurotransmitter systems and reduce free radicals<sup>32</sup>.



The leaves of the ginkgo biloba tree

In recent years, ginkgo has been marketed as being able to prevent the mental decline associated with ageing, and two ginkgo products are the top best-selling dietary supplements for memory health. There is a wide range of products available, including tablets, capsules and liquids, ranging in strength from 30 to 500mg.

However, the most recent research on ginkgo and cognitive decline suggests that many people could be wasting their money<sup>33</sup>. In November 2008 Behind the Headlines appraised a study that The Daily Telegraph had picked up which found that "ginkgo biloba does not prevent dementia". The trial tested whether ginkgo could prevent dementia in healthy, elderly people, but found limited usefulness of the supplement for this purpose. It was a large, good-quality study in 3,000 people, so we can be confident in the findings. There seemed to be a "small protective effect" for vascular dementia (caused by damaged blood vessels in the brain), a finding that would fit with the theory that ginkgo may widen blood vessels.

It wasn't the first time ginkgo had been in the news for this reason. In June 2008, a smaller study (including 176 people) also found that ginkgo didn't benefit people with existing dementia.

A systematic review published by the Cochrane Library in 2009 provides a robust round-up of the evidence<sup>34</sup>. It considered whether ginkgo had any effect on dementia and cognitive decline, and concluded that, although it appears to be safe, evidence that it has any benefit is "inconsistent and unreliable".



More than £6 million has been spent on ginkgo products every year since 2004.

Behind the Headlines has covered several ginkgo stories. Current research hasn't yet answered questions about its use to prevent stroke or slow the progression of a common eye disease called age-related macular degeneration. You can read the coverage of these claims here:

- <u>Ginkgo biloba and age-related</u> <u>macular degeneration</u>, March 17 2008
- <u>Ginkgo 'won't stop dementia'</u>, November 19 2008
- <u>Ginkgo 'no benefit' for dementia</u>, June 17 2008
- <u>Can ginkgo protect you from strokes?</u> October 10 2008
- <u>Ginkgo herb in seizure warning</u>, February 1 2010

The possible side effects of ginkgo Ginkgo supplements based on the leaf extract are thought to be safe for most people, although minor side effects have been reported, including stomach upset and headache<sup>35</sup>. Ginkgo is thought to thin the blood, so there is some concern it might increase the risk of bruising and bleeding. A few people have experienced bleeding in the eye and brain, and it may cause problems for people with certain disorders. People who are about to have surgery are advised to stop using it two weeks before. It may also interact with prescribed medications including anticoagulant drugs. It's best to consult your doctor before taking ginkgo, to find out if it's safe to do so.

# Ginseng

There are several different species of ginseng. They include Panax ginseng (also called Asian or Chinese ginseng), and Panax quinquefolius (American) ginseng. In alternative medicine, ginseng is often referred to as an "adaptogen", which implies a substance that increases resistance to physical, chemical and biological stress and builds up general vitality. The major active components (ginseng saponins, also called ginsenosides) supposedly work in several ways, including having possible antioxidant effects.

Ginseng is another supplement that is widely used for its reputed health benefits, including combating ageing. According to research, ginseng



products are often bought by consumers who believe they will experience both physical benefits and a positive effect on cognitive performance and wellbeing.

Panax ginseng is probably best known for claims that it aids memory and concentration, but it seems that there is no conclusive evidence for whether or not it works.

A recent systematic review by the Cochrane Collaboration that assessed the effects of ginseng supplements (containing ginseng or active agents of the Panax genus) concluded that although ginseng "appears to have some beneficial effects on cognition, behaviour and quality of life", "more rigorously designed studies are needed"<sup>36</sup>. At present, there is no convincing evidence that ginseng aids the brain or is of benefit to people with existing dementia or cognitive impairment.



In the UK, the market for ginseng-based products was worth £8.3 million in 2009.



Some people believe ginseng combats ageing

The possible side effects of ginseng Ginseng products can vary greatly in their content and quality. Some have been found to contain little or no actual ginseng, and some may contain other substances. Although the ingredient ginseng is generally considered safe to use on its own for most people, it can have side effects and may also interact with prescription medications and other supplements and herbs. In addition, some ginseng products have been associated with side effects, including high blood pressure and hormonal effects. Ginseng is also not suitable for people with certain conditions. If you wish to try ginseng, it is best to consult your GP first.

The ginseng root

# Glucosamine

Glucosamine and chondroitin sulphate are natural substances found in and around the cells of cartilage, the flexible connective tissue that protects our bones at the joints. Both are produced by the body. Glucosamine is one of the building blocks of cartilage and chondroitin sulphate is a substance that helps cartilage retain water.

In osteoarthritis, cartilage becomes thin and stiff, and the theory is that glucosamine supplements might help supply the materials needed to rebuild it. In animal and laboratory studies, glucosamine was found to "normalise" cartilage metabolism and rebuild damaged cartilage. Glucosamine supplements are often sold in combination with chondroitin, the idea being that both substances can slow down the progression of osteoarthritis. The glucosamine found in dietary supplements is usually harvested from the shells of shellfish.

There is a large and varied range of glucosamine products available. Holland & Barrett, the UK and Europe's largest health supplement retailer, sells 43 glucosamine-containing supplements, in different strengths and combined with other substances (such as omega-3, cod liver oil and rosehip). They come in different forms too, including gels, caplets and sprays.

Are the benefits of glucosamine worth the money spent on it? The latest research suggests not. A recent systematic review published in the British Medical Journal (BMJ) pooled 10 studies published up to 2009, involving 3,802 patients<sup>31</sup>. Neither glucosamine, chondroitin or a combination of the two were found to reduce joint pain or treat the narrowing of the joint space associated with osteoarthritis. The authors also say that the differences in effect between the supplements and placebo were "less pronounced" on average in independent trials than in those funded by industry. This review itself was well-conducted. However, it should be pointed out that the trials in this review were all small, potentially affecting the reliability of the review's findings.

Read Behind the Headlines stories about glucosamine

- Osteoarthritis supplement study, September 17 2010
- <u>Arthritis: herbs don't help</u>, February 11 2009

Possible side effects of glucosamine Glucosamine is thought to be safe for most people, although it may not be suitable for those with certain conditions, including asthma. It can interact with medications including warfarin. Reported side effects include wind, bloating and cramps<sup>38</sup>. Glucosamine may not be suitable for people who are planning to have surgery. Anyone taking glucosamine should stop at least two weeks before any surgery. Although there are no reports of this yet, there is some concern that glucosamine products may cause allergic reactions in people who are allergic to shellfish.



Glucosamine is found in the shells of shellfish

Sales of glucosamine in the UK rose from more than £36 million in 2004 to nearly £68 million in 2009, and in the non-vitamin market, sales are second only to fish oil supplements. Joint health is also the biggest area in the supplement market, comprising more than a third of its retail value.



Glucosamine is taken for osteoarthritis

NICE does not recommend glucosamine supplements either<sup>39</sup>. It says: "The use of glucosamine or chondroitin products is not recommended for the treatment of osteoarthritis. Many people take over-the-counter nutraceutical products and may benefit from clear, evidence-based information. It would be beneficial to advise people who wanted to trial over-the-counter glucosamine that the only potential benefits identified in early research are purely related to a reduction of pain (to some people, and to only a mild or modest degree) with glucosamine sulphate 1,500mg daily. Because only one glucosamine hydrochloride product is licensed, it would not be cost effective to prescribe glucosamine on the NHS"



Osteoarthritis causes pain in the joints

## Key points about ageing supplements:

- Ginkgo This supplement is generally thought to be safe for most people, but there is very little evidence that it actually does you any good. A recent large review found only inconsistent and unreliable evidence that it has any effect on the risk of dementia or cognitive decline.
- Ginseng The evidence for ginseng remains inconclusive and more highquality studies are needed to examine its effects. A recent review found that there may be some beneficial effects on cognition, behaviour and quality of life, but the level of evidence is not convincing and there is no evidence that it can prevent or treat dementia or cognitive decline. The quality of products on the market also varies greatly.
- Glucosamine NICE says that there is insufficient evidence to recommend the use of glucosamine in osteoarthritis.
   NICE advise that, if people choose to buy it, they should be aware that there is evidence for only minimal pain reduction in some people with the use of glucosamine sulphate, and no evidence that it has any effect on the joint space narrowing of osteoarthritis.

# **Fish oils** Brain food in a pill?

Omega-3 fatty acids (called polyunsaturated fatty acids, or PUFAs) are important for the maintenance of good health. They're found in oily fish such as fresh tuna, mackerel and herring (as well as in some plants). Omega-3 fats are essential fatty acids, meaning that the body can't make them and they must be obtained from the diet or other external sources.

Fish oil has been associated with numerous health benefits and often features in the press, with stories about its ability to help prevent heart problems, cancer, dementia, asthma, joint problems and psychosis. Some studies have looked at whether omega-3 can protect against heart disease and lower fats in the body (triglycerides). Others have looked at their use in people with established heart disease. It is recommended that <u>people who have had a heart attack</u> eat two-four portions of oily fish a week.

Media coverage related to fish oil over the last few years has focused on claims that fish oil may increase children's brainpower and concentration. This theory is based on the idea that the fatty acids found in fish oils are also major structural components of cell membranes throughout the body, and these are especially present in the brain<sup>40</sup>.

Fish oil supplements are big business. They are the best-selling product in the UK dietary supplements market, with sales worth just over £139 million in 2009 – a rise of nearly 40% since 2004<sup>2</sup>.



Fish oils are unlikely to affect behaviour

# Fish oils for adults

Two of the most important omega-3 fatty acids contained in fish oil are eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA). Several animal, laboratory and population studies have found an association between omega-3 fats and healthier cholesterol levels, a lower risk of dementia and reduced vascular risk, inflammation and oxidative damage.

Yet, so far, the evidence from clinical trials of omega-3 supplements in humans is far from conclusive. A 2006 Cochrane review that looked at all available trials up to 2005 found no evidence that omega-3 supplements reduce the risk of cognitive impairment or dementia<sup>41</sup>.



Herring and other oily fish contain omega-3 fatty acids

Another review of fish oil in 2002 found no evidence of any effect on mortality, "cardiovascular events" such a heart attack or stroke, or cancers, either in people at high risk of heart disease or in the general population, and regardless of whether obtained through supplements or from the diet<sup>42</sup>. The reviewers concluded that, although there is no evidence to suggest that people should stop taking rich sources of omega-3, further high-quality trials are needed to confirm suggestions of a "protective effect" on cardiovascular health.

## Fish oils for children

A substantial proportion of fish oils are sold with the promise of aiding or improving mental ability, making them attractive to parents hoping to boost their child's performance at school. Omega-3 supplements with catchy names, eyecatching packaging and chewable, fruit-flavoured capsules compete for market share. A growing number and variety of foods are now fortified with omega-3. Some, such as fish fingers and milk, are aimed specifically at children. In June 2006, Dairy Crest, which makes St Ivel Advance milk, was instructed by the Advertising Standards Authority to withdraw adverts claiming the milk could improve a child's intelligence<sup>43</sup>.

"Severely troubled boys 'soothed by fish oils'," *The Guardian*, October 12 2006

One of the biggest controversies about fish oil pills was the widely publicised "trial" of omega-3 using students planning to sit their GCSEs – a story that was taken up by *Guardian* journalist Ben Goldacre in his Bad Science blog (www.badscience.co.uk).

In 2006, County Durham announced a plan to give £1 million worth of omega-3 fish oil pills to 5,000 children approaching their GCSEs, to see whether the pills improved performance. Though the county reported that the fish oil was found to have a beneficial effect, Goldacre said that the design of the trial and its execution were flawed, and that its findings were 'meaningless'.

Despite all the media attention, there hasn't been much directly relevant research into how fish oil supplements affect cognition in children<sup>44</sup>. *The Observer* reported in June 2010 that "fish oil helps schoolchildren to concentrate". This was a small brain-imaging study in 33 children. One group got omega-3 supplements (not in fact from fish oil, but from omega-3 fatty acids derived from algae), another group got a smaller dose of omega-3 and a third group got nothing.

Researchers compared brain activity across the groups and found that certain types of activity increased in both groups taking the supplement, more so than in the group taking none. However, despite the increase in brain activity there were no actual differences in cognitive performance between the groups. This is an interesting result from a very small preliminary study, clearly showing that more research is needed before we can say that fish oil supplements help children concentrate.

The largest omega-3 supplement study in the UK yet was also published in 2010 and looked at omega-3 supplementation in 450 schoolchildren aged 8-10 years<sup>40</sup>. This study was one of the few randomised controlled trials (RCTs) to have used several different measures of the potential effects of fish oils in children, including biochemical measures of PUFA levels, measures of cognitive performance and measures of behaviour from both parents and teachers.

It found that, in terms of learning and performance measures, there were "very few significant differences" between children taking an omega-3 supplement and those in a placebo group. The researchers concluded that further work is required on the effect of different PUFAs and other micronutrients. They said this was needed in typically developing children and also children with developmental disorders, to help define who may benefit from supplements and the type, dose and ratios that work best.



Fish oil supplements are very popular in the UK

# The risks of fish oils

Omega-3 fats are generally regarded as safe when taken in low doses (3g or less a day)<sup>45</sup>. But fish liver oil tablets (such as cod liver oil) should not be taken by pregnant women as they also contain vitamin A, which can harm the unborn baby. Omega-3 supplements may also be unsuitable for people with certain conditions and may interact with some medicines including those that control high blood pressure. If you are thinking of taking a fish oil supplement, it's best to speak to your doctor.



Schoolchildren do not need to take fish oil supplements

# Key points about fish oils

- The omega-3 fatty acids found in fish oils are important for good health and cannot be made by the body – they must be obtained from the diet. Eat two portions of fish a week, one of which should be oily, such as fresh tuna, mackerel and herring.
- Studies have looked at their possible benefits in people with heart disease and high cholesterol, but government bodies advise that current evidence does not support the use of supplements to prevent cardiovascular disease. However, research continues into their use by people who have already had a heart attack. For such people, consumption of two to four portions of oily fish per week is ideal, though omega-3 may be recommended as a supplement.
- There is no compelling evidence that fish oils boost brainpower or memory in adults or children.
- Fish oil supplements are not suitable for everyone, and can be potentially harmful to pregnant women.

# **Body building** Getting ripped or getting ripped off?

Protein supplements are marketed as being able to promote your body's muscle growth, aid metabolism (helping with weight loss), reach peak physical performance, boost energy and fight the ageing process. The supplements are widely available and sold through magazines, gyms and personal trainers, and are available over the counter in many high-street stores and on internet sites. Some are ready mixed with water, milk, juice and flavouring to create a "shake", and the range of products includes protein bars, gels and capsules. These products are usually recommended to be taken before and after exercise.

Body-building products are growing in popularity and not just among athletes or body builders. Muscle supplements are also being bought by teenagers who want a buff body. A study of American teenagers found that about 5% of boys and 2% of girls, aged 12 to 18, used protein powders and shakes or other supplements to improve their appearance or strength<sup>46</sup>.

Stories also crop up in the newspapers about the supplements, *The Daily Mail* ran a story in October 2010 with a headline proclaiming that a body builder protein powder "could increase life expectancy by 10 years". The newspaper only mentioned some way into its article that the research behind these claims was in middle-aged mice. Mice fed a diet supplemented with certain amino acids lived longer (by about 95 days) than untreated control mice.

Body building has become a lifestyle trend, and the industry's value has grown to match it. According to Euromonitor, the retail value of sales of sports nutrition products grew by 14% in 2010 to reach £200 million in the UK<sup>47</sup>. Health food shops and pharmacies are the most popular sales outlets, but 6% of sales are now made via the internet<sup>48</sup>.

"We would generally not recommend protein shakes for athletes or people doing exercise as the body's protein needs can be met through a healthy varied diet," British Nutrition Foundation, Sept 2010

## Do the products work and are they safe?

So what's in these "sports nutrition supplements"? Protein powders are one of the most popular muscle building supplements. Whey protein is a by-product of cheese-making and sold as containing high levels of essential amino acids, the compounds that form protein.

Protein is a crucial element in our diets and is key to building and maintaining all types of body tissue, including muscle. Protein-rich foods such as meat, poultry, eggs, dairy, beans and tofu all supply amino acids, the building blocks used for muscle growth. We need a certain amount of protein to stay healthy, and serious athletes, such as endurance runners, may need more.



Eggs, milk and cheese are all high in protein

There are eight essential amino acids that cannot be made by the body and that need to be obtained from the diet. Most of us get the protein we need from our diets. In the UK, the recommended daily amount of protein for adults aged 19 to 50 is 55.5g for men and 45g for women (excluding pregnant and breastfeeding women)<sup>49</sup>. Most of us eat more than this, and the actual average adult daily intake has been estimated to be 88g for men and 64g for women (British Nutrition Foundation)<sup>50</sup>.

In the UK, enough protein is easily available from our diet. A chicken sandwich with about 65g of meat (about 2.3oz) contains about 20g of protein. If you also have a 150ml glass of milk (5g of protein) you have nearly half the amount needed for the average-weight man, and more than half of that required for a woman.

Athletes require slightly more protein than the rest of the population. According to the British Nutrition Foundation (BNF), endurance athletes require between 1.2 and 1.4g per kg of body weight daily, while those competing in strength and speed events need between 1.2 and 1.7g per kg of body weight. These intakes can easily be achieved by eating a normal balanced diet.

A search of the PubMed research database will turn up a lot of studies on protein supplementation and its effects on muscle mass and athletic performance. However, this research has had conflicting results, some studies finding it beneficial and others concluding it to have no effect. There are no Cochrane reviews that would go some way towards shedding some light on its usefulness in healthy, non-pregnant, non-elderly adults. The British Nutrition Foundation says that high-protein diets are "erroneously associated with fitness training because of the mistaken belief that this leads to greater strength, since muscle itself is protein".

Recent research on 15 protein powders by the US organisation Consumer Reports<sup>51</sup> also found that some of the drinks were contaminated with heavy metals such as arsenic, cadmium, lead and mercury. They point out that, while exposure to small amounts of heavy metals in the environment and food is inevitable, three products raised "particular concern" because consuming three servings a day could result in daily exposure that exceeded recommended limits of arsenic, cadmium and lead. Cadmium raises particular concern, they report, because it accumulates in, and can damage, the kidneys.



Even athletes can get the protein they need from their diet

The risks of protein supplements Consuming too much protein can have side effects, including diarrhoea. There is also evidence that, in the long term, excessive protein intake may contribute to bone demineralisation and an increased risk of osteoporosis, while for anyone with kidney problems, too much protein can lead to further complications. Instructions on packages should be clear about maximum daily amounts because of potential risks of harm. Supplements aren't always suitable for those aged under 18 and other groups such as pregnant women. The Department of Health advises adults to avoid consuming more than twice the recommended daily intake of protein<sup>49</sup> (55.5g for men and 45g for women).



Whey protein is a by-product of cheese-making

#### **Other products**

There are numerous other products on the market that claim to build muscle. They contain substances such as glutamine (an amino acid), essential fatty acids, creatinine (a naturally occurring organic acid that supplies energy to muscle cells), "thermogenic" products (any product that claims to increase body temperature, metabolism and the rate at which the body burns fat), naturally occurring "testosterone boosters" and "prohormones". Prohormones are reputedly converted by the body into natural hormones such as testosterone and are promoted as a safe alternative to anabolic steroids.

All of these products are widely available on the internet, but there is very little good research into their effectiveness or safety. The Food and Drug Administration (FDA), the US organisation that regulates the safety and quality of food and drugs, has issued several warnings about body-building products marketed as dietary supplements that have been found to contain synthetic steroid and steroid-like substances<sup>52</sup>. Although these are often promoted as being safe alternatives to anabolic steroids, the FDA says that these products are potentially harmful and there are reports of liver damage, stroke, kidney failure and pulmonary embolism (blockage of an artery in the lung) following their use.

One study that looked at the content of 634 nutritional supplements bought in shops from around the world and on the internet found that nearly 15% of them contained illegal anabolic steroids not declared on the label<sup>53</sup>. More than a fifth of supplements from the companies selling prohormones contained anabolic steroids that could lead to positive doping results. The sports community should be aware that some ingredients are not listed on the labels of these products.

Given the possible risks and the lack of any evidence for their effectiveness it seems wise to avoid these products and rely on something cheaper and far more enjoyable – decent food.



A healthy diet will provide all the protein you need

## Key points about body-building supplements

- The recommended daily protein intake is 55.5g for men and 45g for women and we can get this from our diet. In fact, most of us easily exceed this every day.
- Too much protein can carry some risks, and heavy metals in some supplements are of concern.
- Claims that protein supplements improve muscle mass and strength for athletes and others are largely unsubstantiated.
- The public are warned against any "bodybuilding supplements", which may be more likely to do harm than good.
- Some body-building supplements contain illegal anabolic steroids not declared on the label.

# Conclusion

While this report should not be taken as a definitive review of individual supplements, it is clear that the perceived benefits of many popular products have not been confirmed through robust research. In some cases these supplements may even be harmful. Overall, it is clear that we may be placing our hope in products that still require far more testing.

Of course, that's not to say that there aren't any supplements that work, or that all are harmful. There are some products that have been found to have clear benefits and many have been found to be generally safe for use. The key point is that we can't be certain that they are necessarily effective or safe until they have been put through robust testing.

# Why do we take supplements if they are unproven?

There are lots of reasons why someone might decide to start taking a supplement. They might do so based on recommendations from friends and family, opinions on the internet or having seen it displayed in a shop.

There can also be media flurries surrounding many supplements and, on occasions, newspapers have proclaimed that a supplement works based on the results of a single, flawed study, possibly alongside a photo of a celebrity fan or glowing reports from some new convert. That's not to say that the media is solely to blame, but it's certainly easier to fall into the trap of assuming a supplement works if magazines, newspapers and television keep telling us it does.

To their credit, newspapers do cover robust research, including studies that contradict the results of earlier trials. However, news articles don't always stress the scientific merits of each study, meaning that readers may not understand that the results of a well-conducted <u>systematic</u> <u>review</u> should be considered to be more reliable than those from an earlier <u>cohort study</u>. Without knowing that one set of results is more reliable than another a reader may assume that two studies are of equal weight, leading them to believe that they simply cancel each other out, that the results are unclear or that scientists just can't make their minds up. Also, given the time it takes to build up a decent body of evidence on a supplement it can be too late to change the public's opinion. Once a supplement is already taken by millions and sold everywhere from the chemist to the corner shop, are people going to be put off using it by the results of a robust scientific study? The fact that we may only study supplements once they are in use is in contrast to the development of licensed medicines, which have to provide evidence of being sufficiently safe and effective before people are allowed to use them.

"People should be able to buy supplements if they wish to. But they need good information to make an informed choice and they shouldn't be put at risk," Sue Davies, chief policy adviser, Which?

## Are supplements worth the money?

While different supplements can greatly vary in their effects, the one common effect they share is upon your wallet. Take zinc, for example – although it has been found to have some benefits you would need to take it for at least five months to reduce your chances of catching a cold, at a cost of around £35.

As we've said before, some supplements do have benefits and may be of use to you depending on your personal circumstances. We can't tell you how to spend your money, but we do recommend that you look at the evidence and seek reliable information, including your doctor's advice, before you splash the cash.



Pharmacists can offer advice about supplements

## Supplement your knowledge

The Behind the Headlines team firmly believes in the importance of evidence, and ideally people should be fully informed about what they are taking, whether it has proven benefits and whether it could harm them.

When considering using a supplement we think a little bit of scepticism is usually a good thing and, as consumers, we should get into the habit of asking some questions and doing some research before we even consider parting with our cash. You would do this if you were shopping for other products such as a mortgage or a mobile phone, and it is even more important when choosing products that may affect your health.

In the first instance, there are some simple questions you should ask yourself before buying a supplement, including the rather obvious one of "do I really need it?". The answer to this will depend on the product in question and what you hope it will do. It may also be useful to ask yourself:

- What do I think this product can actually do?
- Is there solid evidence suggesting it will work?
- Is it likely to cause me harm?
- What do reliable sources of information say about this product?
- Even if it could be of benefit, is it worth the money?
- Is this a problem my doctor can help me with instead?



Some internet sites are more reliable than others

Although we are probably a little biased, we would recommend initially turning to sources such as our Behind the Headlines service to help answer these questions. We have already covered news stories about dozens of supplements and will continue to do so whenever they appear in the news. There is also a great deal of reliable information available from the MHRA, the Department of Health and, most importantly, your GP.

# Good sources of information about supplements:

- NHS Choices: www.nhs.uk
- Behind the Headlines: <u>www.nhs.uk/</u> <u>news</u>
- MHRA: <u>www.mhra.gov.uk</u>
- Food Standards Agency: <u>www.food.</u> <u>gov.uk</u>
- US Food and Drug Administration: <u>www.fda.gov</u>

Science moves quickly and relevant studies are being published all the time, including systematic reviews by respected organisations such as the Cochrane Collaboration. Supplementation is likely to come up as a research topic time and time again, and as the body of evidence behind particular products evolves the balance of evidence may shift, meaning that a product that had appeared to have merit in initial research may eventually be found to be lacking when given a more robust analysis. We recommend reading not only the available research, but also information on the way that research itself is conducted, which can help you understand which types of results are more likely to be reliable.

Ultimately, though, before you do actually buy or use a product, you should consult your GP.

As a doctor they can offer you an informed opinion about whether a particular dietary supplement is necessary or advisable, making these recommendations based on your personal health circumstances. They will also be able to check your general health, make a professional diagnosis of any health problems you may have and offer you other forms of treatment.

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