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(56) Documents Cited
GB 2367756 A **GB 1338254 A**
US 5683361 A **US 4645487 A**

(58) Field of Search
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(54) Abstract Title
Dispensing device for a powdered product

(57) The present invention relates to a dispensing device for dispensing a powdered product comprising:

a housing 1, having a first end and a second end defining a first outlet 31;

a plunger 3 slidably received in the first end of the housing;

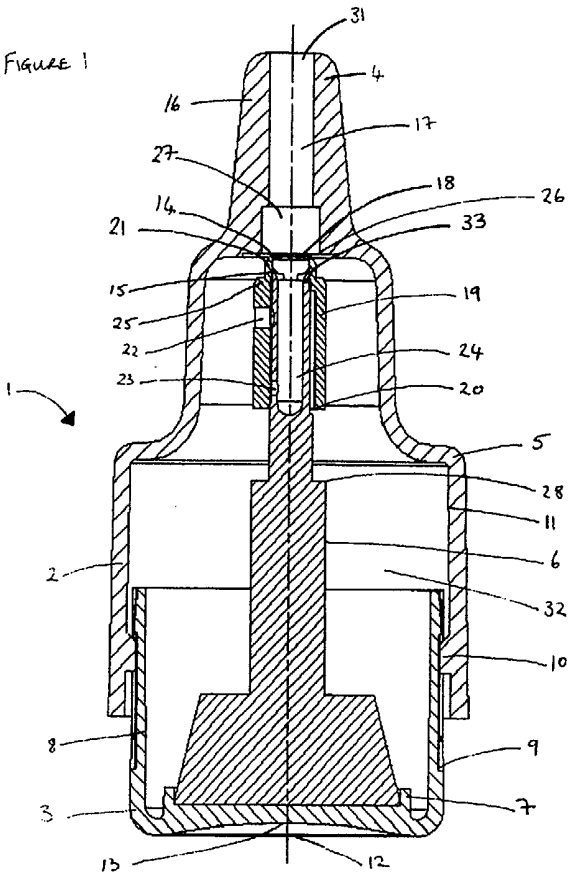
the housing 1 and plunger 3 together defining an interior 32 of the dispensing device which is open to atmosphere;

a chamber located within said plunger for housing a powdered product;

a sheathing means 19 slidably mounted on an end of the plunger 3 proximate the second end of the housing, and having an inlet and a second outlet closed by a frangible membrane 18;

and the plunger 3 comprising a perforating element 14 for puncturing the frangible membrane 18 when the plunger 3 is moved towards the second end of the housing.

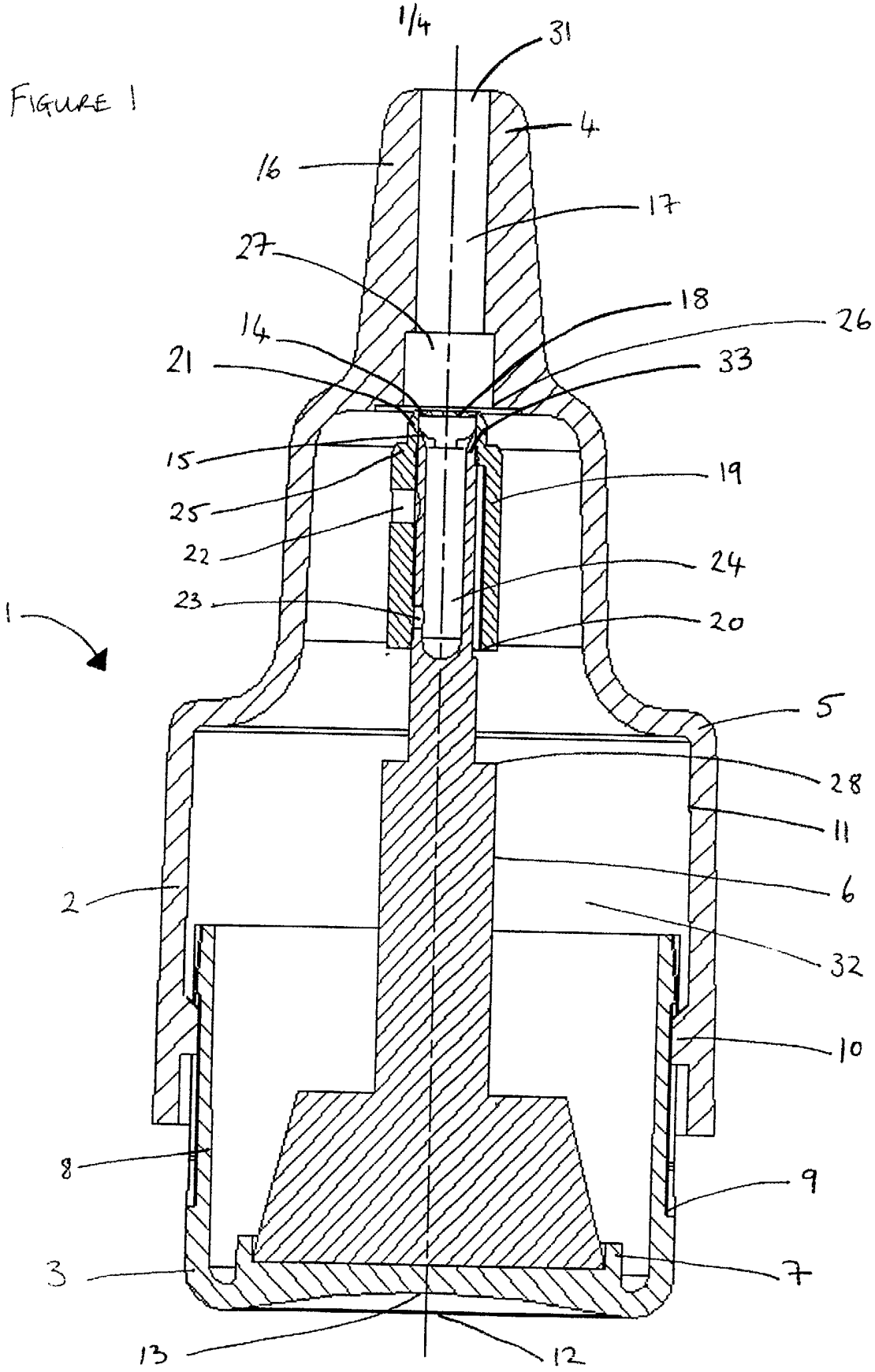
FIGURE 1



PRE-ACTUATION POSITION (STORAGE)

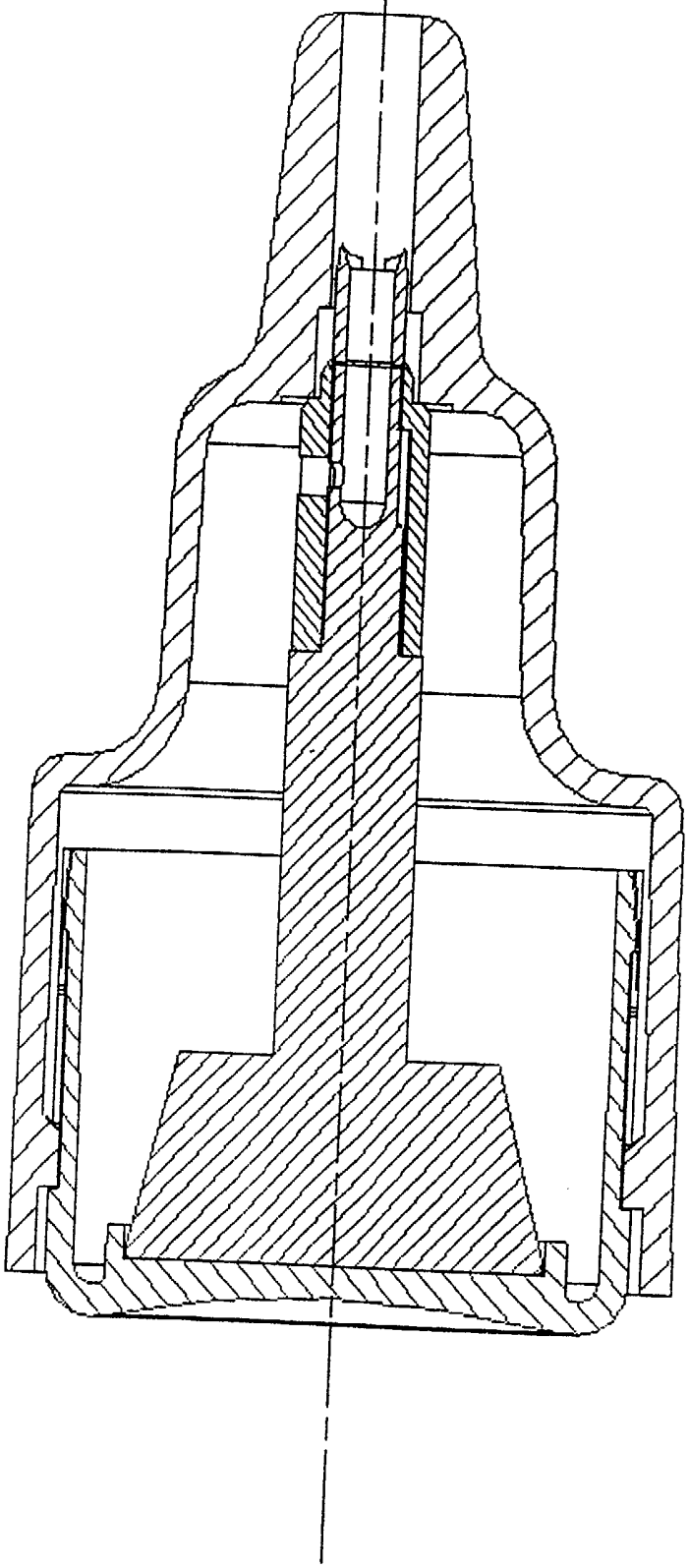
GB 2 384 190 A

FIGURE 1



PRE-ACTUATION
POSITION
(STORAGE)

FIGURE 2



ACTUATION
POSITION

(DISPENSING)

FIGURE 3a

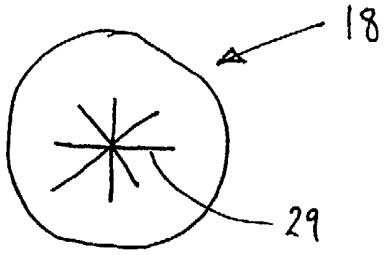


FIGURE 3b

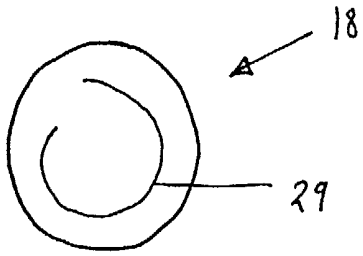


FIGURE 3c

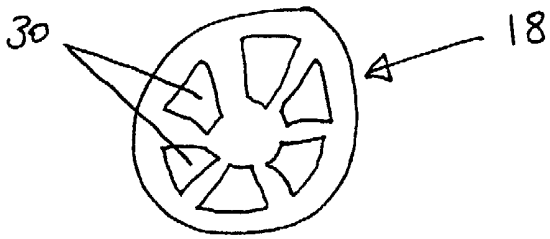


FIGURE 4

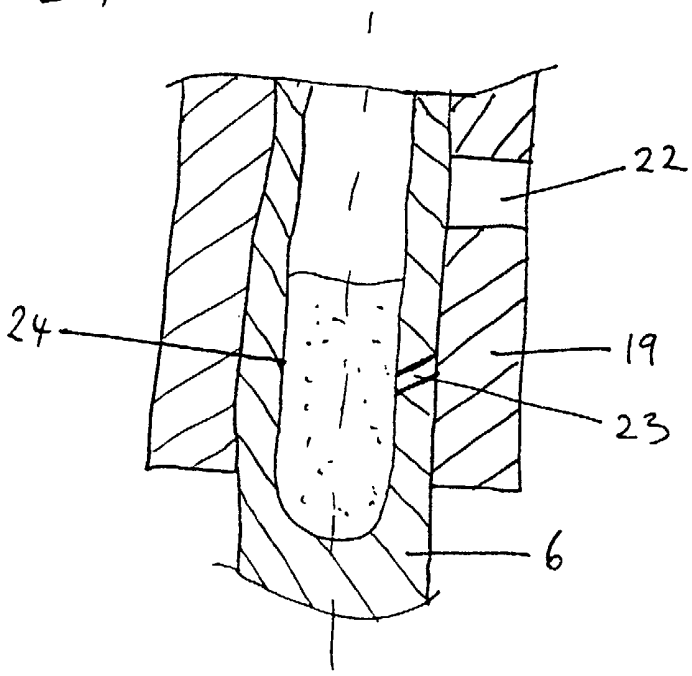
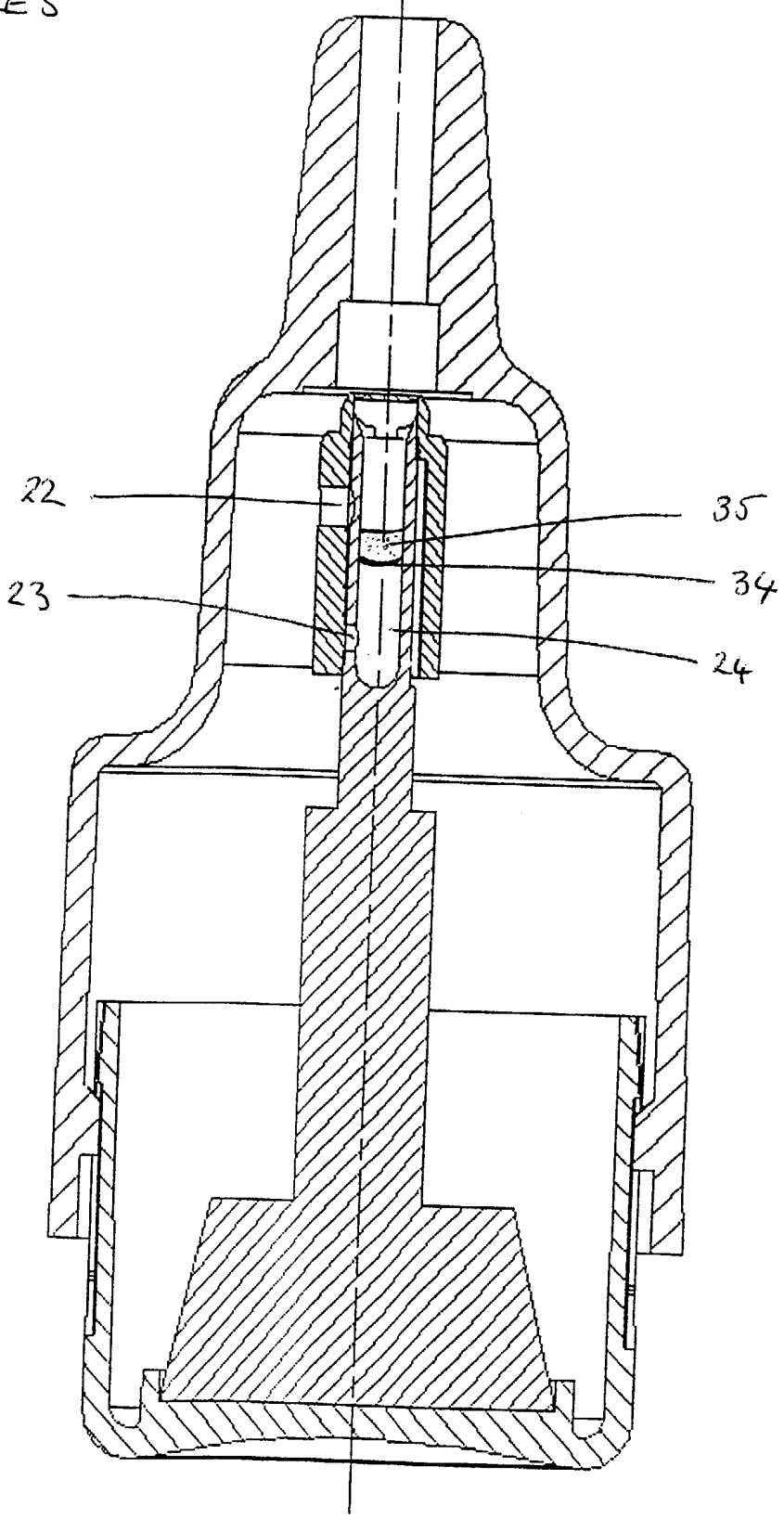


FIGURE 5



PRE-ACTUATION
POSITION
(STORAGE)

Dispensing Device

The present invention relates to a disposable dispensing apparatus for delivering a powdered product nasally or orally. More specifically, but not exclusively, there is provided a single use dry powder medicament inhaler which can be used by persons who have not had medical training.

Such dispensing devices are well known in the art and are of particular use for the dispensing of drugs which can easily be absorbed through the nasal or pulmonary passages, especially for drugs which only need to be dispensed occasionally.

A dispensing device is known from US 5,683,361 which dispenses a single dosage of a powdery drug which is stored in a cylindrical storage chamber within the sealed main body of the device until dispensation of the drug is required. The chamber is located in an axially displacable piston, which is mounted in the main body of the device between an end wall of the main body and a plunger for releasing the drug. The chamber is sealed with breakable membranes at either end of the cylinder which are, upon activation of the dispensing device, punctured by one or more perforating elements. An outlet duct is provided at the end of the main body remote from the plunger for dispensation of the drug to the user. The perforating element is provided at the end of the outlet duct nearest to the piston to puncture at least the outermost membrane of the drug chamber.

Both embodiments of the device described in US 5,683,361 involve pressurisation of the air inside the device prior to dispensation of the powdered medicament. When the plunger is pressed by the user

into the main body of the device a pocket of air, which is trapped inside the main body of the device between the piston and the plunger, is compressed and the pressure inside the device increases. This increase in pressure causes the piston to move towards the outlet duct of the dispensing device, thereby causing the outermost membrane to be punctured by the perforating element. The remaining intact membrane is then punctured in one of two possible ways: by the penetrating element provided at the inner end of the outlet duct as the plunger, and therefore also the piston, is pushed further into the main body of the device, or by a second perforating element which is optionally provided at the inner end of the plunger.

A disadvantage with the devices described in US 5,683,361 is that they do not always dispense the whole drug dose to the patient. As the outermost membrane is punctured, pieces of the perforated membrane are pushed into the chamber in the opposite direction to movement of the plunger and the desired drug flow path. This results in some of the powdered drug particles being trapped between pieces of the perforated membrane and the wall of the chamber as the drug is forced out of the dispensing device via the outlet duct. Furthermore, as the patient inhales, the pieces of the perforated membrane are drawn in the direction of the outlet duct and thereby interfere with the dispensing of the drug as the powder can no longer flow freely out of the drug chamber. In this way, the dose dispensed by the device is often incomplete, which can mean that the drug is not wholly effective.

Another single-use dispensing device is described in the applicant's co-pending application, GB 0025027.4, which device comprises a bellows unit for pressurising

the interior of the device and for propelling the powdered drug out of the dispensing apparatus.

A single-use dispensing device needs to be simple and cheap to manufacture. The known devices described above require a sealed main body to enable the device to be pressurised.

According to the present invention there is provided a dispensing device for dispensing a powdered product comprising a housing, having a first end and a second end defining a first outlet, a plunger slidably received in the first end of the housing, the housing and plunger together defining an interior of the dispensing device which is open to atmosphere, a chamber located within said plunger for housing a powdered product, a sheathing means slidably mounted on an end of the plunger proximate the second end of the housing, and having an inlet and a second outlet closed by a frangible membrane, and the plunger comprising a perforating element for puncturing the frangible membrane when the plunger is moved towards the second end of the housing.

A preferred embodiment of the present invention will now be described by way of example only and with reference to the accompanying drawings, in which:

Figure 1 is a cross-sectional view of a first embodiment of a dispensing apparatus according to the present invention in a 'storage' condition;

Figure 2 is a cross-sectional view of the apparatus of Figure 1 in a 'dispensing' condition;

Figure 3a, 3b and 3c show plan views of three variants of frangible membranes for use in the

dispensing device of the present invention;

Figure 4 is a cross-sectional view of a part of the dispensing device of the present invention showing a variant storage chamber inlet aperture; and

Figure 5 is a cross-sectional view of a second embodiment of a dispensing apparatus according to the present invention in a 'storage' condition.

As shown in Figures 1 and 2, the apparatus of the present invention comprises a housing 1, a plunger 3 and a sheath 19. The housing 1 comprises a generally tubular body 2 of varying diameter having an open second end forming a first outlet 31 in a tip 4 and an open first end in which the plunger 3 is slidably received. The housing 1 is provided with an external shoulder 5 for use as a finger rest. Alternatively, the housing 1 may be provided with a protruding lip to act as a finger rest.

The tip 4 comprises an outer wall 16 which defines an outlet duct 17 through which medicament may be dispensed. An innermost end of the outlet duct 17 is provided with an enlarged duct 27 which has a larger cross-sectional diameter than the outlet duct 17. The innermost end of the enlarged duct 27 is provided with a shoulder 26.

The tip 4 is frusto-conically shaped so as to form a nozzle which is inserted, in use, into a patient's nostril. However, the tip 4 may also be shaped into a substantially cylindrical shape or similar, suitable for insertion, in use, into a patient's mouth.

The plunger 3 comprises a substantially

cylindrical body 8 and a probe 6. The body 8 is closed at one end to form an end face 12. The opposite end is left open. The probe 6 is coupled or joined to an inner surface of the end face 12 and projects therefrom. The probe 6 is coupled to the end face 12 by means of a retaining lip 7, although in an alternative embodiment the probe 6 and plunger 3 may be moulded as one piece, therefore avoiding the need for a retaining lip 7. With the plunger 3 received in the housing 1, the probe 3 projects towards the first outlet 31 of the tip 4. Together, the plunger 3 and housing 1 define an interior 32 of the apparatus.

The probe 6 is substantially cylindrical in shape and is provided with an inwardly directed shoulder 28. Alternatively, the inwardly directed shoulder 28 could be replaced by a flange. An end 33 of the probe 6 remote from the end face 12 is provided with a piercing tip 14. The piercing tip 14 is provided with a sharpened cutting edge 15.

A portion of the probe 6, at the end 33 of the probe 6, is provided with a hollow bore forming a storage chamber 24. The storage chamber extends upwardly to the piercing tip 14. A radially directed aperture 23 is provided through the thickness of the wall of the probe 6 communicating with a lower end of the storage chamber 24.

The storage chamber 24 is substantially cylindrical in shape and is large enough to contain a single dose of powdered medicament which is to be dispensed. The powdered medicament is located in an end of the storage chamber 24 remote from the tip 4. Likewise, the aperture 23 is located at the end of the storage chamber 24 remote from the tip 4.

An external surface of the body 8 of the plunger 3 is provided with at least one axially oriented channel 9. Each channel 9 receives a lug 10 which is located on an inner surface 11 of the housing 1. The lug 10 and channel 9 arrangement prevents the plunger 3 from being withdrawn fully from the housing 1. The channel 9 also allows for air from atmosphere to pass between the plunger 3 and the housing 1, since the interference fit is not air tight.

The end face 12 of the plunger 3 is provided with an indentation 13 which is suitable for use as a thumb rest.

A sheath 19, which is substantially cylindrical in shape, is slidably received over the end 33 of the probe 6 remote from the end face 12. The sheath 19 comprises an open end 20 for receiving the probe 6 and an opposite closed end 21, which is closed by a frangible membrane 18. An aperture 22 is provided in the sheath 19. The aperture 22 is in the form of a radially directed inlet which passes through the wall thickness of the sheath 19. An outwardly directed shoulder 25 is provided on the sheath 19 in the vicinity of the closed end 21.

Typically, the thickness of the frangible membrane 18 is between 0.03 and 0.20mm. Furthermore, as shown in Figures 3a and 3b, the membrane 18 is provided with one or more pre-formed lines of weakness 29 to aid the rupturing of the membrane by the piercing tip 14. Figure 3a depicts a 'star' pattern of weaknesses and Figure 3b depicts a 'half-moon' pattern of weaknesses. Alternatively, the frangible membrane 18 may comprise a plurality of castellations 30 which are of a reduced thickness compared to the rest of the frangible membrane 18 as shown in figure

3C.

In a 'storage' position, as shown in Figure 1, the sheath 19 is mounted on the probe 6 with the piercing tip 14 in close proximity but not quite abutting against the frangible membrane 18. In this position, the radial apertures 22 and 23 are out of alignment and there is consequently no open flow path between the interior 32 of the housing 1 and the storage chamber 24. Thus, the apertures 22 and 23, which together form an inlet valve are in a 'closed' position. However, there is an open flow path from the interior 32 of the housing 1 to the outlet duct 17, via the duct 27.

In use, a user holds the apparatus typically by means of two or more fingers positioned on the external shoulder 5 and a thumb positioned on the end face 12. The tip 4 is then inserted into the nose (or mouth if the apparatus is for pulmonary use). Inhalation at this stage is possible freely but is ineffective since air is drawn from the interior 32 of the housing 1 through the enlarged duct 27 and out via the outlet duct 17. Pressure in the interior 32 is equalised by air flow into the interior 32 between the plunger 3 and the housing 1.

The user depresses the end face 12 of the plunger 3 relative to the housing 1 so as to move the probe 6 and sheath 19 axially in the direction of the tip 4. Initially, the probe 6 and the sheath 19 are free to move unhindered into the enlarged duct 27.

Further movement of the probe 6 and sheath 19 brings the outwardly directed shoulder 25 of the sheath 19 into contact with the internal shoulder 26 of the enlarged duct 27. At this point, further

movement of the sheath 19 towards the tip 4 is prevented. The abutment of the outwardly directed shoulder 25 of the sheath 19 against the internal shoulder 26 also closes the flow path from the interior 32 of the housing 1 to the outlet duct 17. Continued movement of the probe 6 towards the tip 4 causes the probe 6 to slide relative to the sheath 19 and the piercing tip 14 of the probe 6 to pierce and break the frangible membrane 18.

Advantageously, the frangible membrane 18 is ruptured from below with the piercing tip 14 moving relative to the membrane 18 in the direction of tip 4. As a result the 'flap' of the membrane 18 which is left after rupture is positioned above the membrane periphery such that as powdered medicament particles pass the membrane 18 the 'flap' tends to be moved away from the hole formed in the membrane so as not to block the flow path.

Subsequent inward movement of the probe 6 causes the storage chamber 24 to be moved into the outlet duct 17. During this stage of actuation, air within the housing 1 can escape between the plunger 3 and the housing 1. Further relative axial movement of the sheath 19 and probe 6 causes the apertures 22 and 23 to come into alignment, opening the inlet valve of the storage chamber 24. The apparatus is now in the 'dispensing' position, as shown in Figure 2.

In the 'dispensing' position the inlet valve is open and the frangible membrane 18 is ruptured. Thus a continuous flow path is established between the interior 32 of the housing 1, and the outlet duct 17 via the storage chamber 24. As a result, upon inhalation air is displaced from the interior 32 of the housing 1, through the inlet valve formed by the

apertures 22 and 23 and into the storage chamber 24 where it entrains the powdered product. The air and entrained product is then displaced through the piercing tip 14, and outlet duct 17 where it exits the apparatus and is inhaled.

Movement of the probe 6 is finally limited by abutment of the inwardly directed shoulder 28, against the open end 20 of the sheath 19.

In an alternative embodiment of the invention, shown in Figure 5, a second porous membrane 34 is provided in the storage chamber 24, between the aperture 23 and the piercing tip 14, on which a single dose of powdered medicament 35 is located. During use of this alternative embodiment, the tip 4 is placed into the nose or mouth and the end face 12 is depressed relative to the housing 1 so that the apparatus is in a 'dispensing' position. During subsequent inhalation by the user, air is displaced from the interior 32 of the housing 1 through the apertures 22, 23 into the storage chamber 24. Due to the porosity of the second membrane 34, the air travels through the membrane 34, thus entraining the powdered medicament 35 such that air and powdered medicament 35 exit the apparatus via the first outlet 31 and are inhaled. The second membrane 34 may be made of a porous paper, sintered plastic or similar material, provided that the pore size of the material is large enough to allow air through but small enough not to allow the powdered medicament 35 through.

The dispensing device is described above as being placed in the nose, or mouth as the case may be, before the device is actuated. However, the dispensing device may also be actuated prior to insertion of the tip 4 into the nose or mouth, as long

as the device is maintained in an upright position to avoid spillage of the powdered medicament prior to insertion of the device in the nose or mouth.

The dispensing apparatus may be provided in a sterile package such as a foil packet in order to prevent moisture from affecting the apparatus, and also for reasons of hygiene. The apparatus will not function adequately if the powdered drug becomes damp. Alternatively, a cover may be provided to encase and close tip 4 before use.

Figure 4 shows a variant of the aperture 23 wherein the aperture is directed so as to have a component in the axial direction as well as the radial direction. In this way the air entering the storage chamber 24 is directed towards the closed lower end of the chamber 24 so as to more efficiently entrain the powdered product. Alternatively, the inlet aperture 23 may be angled so as to have components in the radial, axial and circumferential directions such that air entering the storage chamber 24 is directed towards the lower end of the chamber 24 with a 'spiralling' motion. In any of these arrangements the inlet aperture 23 may be positioned so as to be covered or uncovered by the powdered product in the storage condition. More than one aperture 23 may be provided.

Alternatively, the inlet aperture 23 may be positioned in the lower end of the storage chamber 24 such that air entering the chamber enters underneath the powdered product and is directed axially along the chamber 24 towards the piercing tip 14. In a yet further alternative, the powdered product may be suspended on a mesh within the storage chamber 24 such that air entering the storage chamber 24 enters below

the mesh and entrains the powdered product as it passes through the mesh.

Optionally, the storage chamber 24 may be provided with rifling grooves or similar along its length to impart a 'spiralling' motion to the air and entrained product as it passes along the chamber towards the piercing tip 14.

In the above description, item 19 is described as a "sheath". This item may be in the form of a cap, case or similar.

The housing 1, plunger 3, probe 6 and sheath 19 are manufactured from polyethylene, polypropylene, polyester, any engineering plastic or a similar material. Similarly, the frangible membrane 18 is manufactured from polyethylene or polypropylene or a similar material. Alternatively, the probe 6 may be manufactured from a metal such as stainless steel.

The variants described above may be combined with the described embodiments in any combination as will be obvious to the skilled person.

Advantageously, the materials of the dispensing apparatus lend themselves to easy and ready recycling. In the preferred embodiment, the absence of any metallic or ceramic components reduces the cost of processing the recycled material.

Advantageously, the components of the dispensing apparatus are moulded. This leads to low levels of material waste. The current design allows for a low number of individual parts which reduce the assembly time and cost. In a preferred embodiment of the invention, the whole apparatus may be formed from only

three components, the first component being the housing 1 including the tip 4, the second component being the plunger 8 and probe 6 and the third component being the sheath 19 including the frangible membrane 18.

Claims:

1. A dispensing device for dispensing a powdered product comprising:

a housing, having a first end and a second end defining a first outlet;

a plunger slidably received in the first end of the housing;

the housing and plunger together defining an interior of the dispensing device which is open to atmosphere;

a chamber located within said plunger for housing a powdered product;

a sheathing means slidably mounted on an end of the plunger proximate the second end of the housing, and having an inlet and a second outlet closed by a frangible membrane;

and the plunger comprising a perforating element for puncturing the frangible membrane when the plunger is moved towards the second end of the housing.

2. A dispensing device as claimed in claim 1, wherein the interior of the dispensing device is open to atmosphere by means of a gap between the plunger and the housing.

3. A dispensing device as claimed in claim 1, wherein the interior of the dispensing device is open to atmosphere via the first outlet.

4. A dispensing device as claimed in any one of the preceding claims, wherein the frangible membrane is between 0.03 and 0.20mm in thickness.

5. A dispensing device as claimed in any one of the preceding claims, wherein the frangible membrane

comprises one or more castellations to aid rupture of said membrane.

6. A dispensing device as claimed in claims 1 to 4, wherein the frangible membrane comprises one or more pre-formed lines of weakness.

7. A dispensing device as claimed in claim 6, wherein the one or more pre-formed lines of weakness form a star pattern.

8. A dispensing device as claimed in claim 6, wherein the one or more pre-formed lines of weakness form a half-moon pattern.

9. A dispensing device as claimed in any one of the preceding claims, wherein the powdered product is located on a porous membrane which porous membrane is provided in the chamber.

10. A dispensing device as claimed in claim 9, wherein the porous membrane has a pore size which is large enough to allow air through but not large enough to allow the powdered product through.

11. A dispensing device as claimed in claims 9 or 10, wherein the porous membrane is made of porous paper or sintered plastic.

12. A dispensing device as claimed in any one of the preceding claims, wherein the housing further comprises a finger rest.

13. A dispensing device as claimed in any one of the preceding claims, wherein the plunger comprises a thumb rest.

14. A dispensing device as claimed in any one of the preceding claims, wherein the plunger is prevented from being removed from the housing by co-operating means.

15. A dispensing device as claimed in claim 14, wherein the co-operating means comprises at least one lug provided on an inner wall of the housing which co-operates with a channel provided on an outer wall of the plunger.

16. A dispensing device as claimed in any one of the preceding claims, wherein the housing is provided with an inwardly directed shoulder against which, in use, the sheathing means abuts.

17. A dispensing device as claimed in claim 16, wherein the sheathing means comprises an outwardly directed shoulder which, in use, abuts the inwardly directed shoulder of the housing.

18. A dispensing device as claimed in any one of the preceding claims, wherein the inlet of the sheathing means is radially directed and the chamber comprises a radially directed aperture.

19. A dispensing device as claimed in claim 18, wherein the inlet of the sheathing means and the chamber aperture are movable into alignment when the dispensing device is actuated.

20. A dispensing device as claimed in claim 18, wherein the radially directed aperture is located at an end of the chamber remote from the first outlet.

21. A dispensing device as claimed in any one of the preceding claims, wherein at least the housing is a

moulded component.

22. A dispensing device as claimed in any one of the preceding claims, wherein the plunger is a moulded component.

23. A dispensing device as claimed in any one of the preceding claims wherein the sheathing means is a moulded component.

24. A dispensing device as claimed in any one of the preceding claims, formed from one or more of polyethylene, polypropylene, polyester or a thermoplastic elastomer.

25. A dispensing device as claimed in any one of the preceding claims wherein the first outlet is adapted for nasal delivery of powdered products.

26. A dispensing device as claimed in any one of claims 1 to 21 wherein the first outlet is adapted for oral delivery of powdered products.

27. A dispensing device substantially as hereinbefore described with reference to or as shown in the accompanying drawings.

Application No: GB 0201409.0
Claims searched: 1-27

Examiner: Darren Williams
Date of search: 11 July 2002

Patents Act 1977
Search Report under Section 17

Databases searched:

UK Patent Office collections, including GB, EP, WO & US patent specifications, in:

UK Cl (Ed.T): A5T (TBD, TBE)

Int Cl (Ed.7): A61M 11/00, 15/00, 15/08

Other: Online: EPODOC, WPI, JAPIO

Documents considered to be relevant:

Category	Identity of document and relevant passage		Relevant to claims
X, E	GB 2367756 A	(BESPAK) see whole document, especially figs 1, 2 & 4	1, 3-8, 12-14, 16-26
A	GB 1338254	(FISONS)	
A	US 5683361	(ELK)	
A	US 4645487	(SHISHOV)	

X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art.
Y	Document indicating lack of inventive step if combined with one or more other documents of same category.	P	Document published on or after the declared priority date but before the filing date of this invention.
&	Member of the same patent family	E	Patent document published on or after, but with priority date earlier than, the filing date of this application.