A medicament delivery device is provided having an oral tubular section for placement in the mouth of a user and a nasal tubular section for placement in the naris of a user. A medicament located in a corrugated, or flexible, section joining the oral tubular section and the nasal tubular section is dispersed into the nasal cavity of the user by blowing into the oral tubular section. A pinch valve or one way valve is used to prevent the user from accidentally inhaling the medicament. The medicament delivery device may also be used as a pulmonary delivery device into the mouth of a user.
before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))
MEDICAMENT DELIVERY DEVICE AND METHOD

FIELD OF THE INVENTION

The present invention is directed to a medicament delivery device and method for introducing a medicament into the oral or nasal cavity of a user.

SUMMARY

A medicament delivery device is provided having an oral tubular section for placement in the mouth of a user and a nasal tubular section for placement in the naris of a user. A medicament located in a corrugated, or flexible, section joining the oral tubular section and the nasal tubular section is dispersed into the nasal cavity of the user by blowing into the oral tubular section. A pinch valve or a one way valve is used to prevent the user from accidentally inhaling the medicament. The medicament delivery device may also be used as a pulmonary delivery device into the mouth of a user.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 depicts a side and perspective view of the medicament delivery device.

Figure 2 depicts a perspective view of the medicament delivery device with the sealing medium removed.

Figure 3 depicts a side view of the medicament delivery device with the cover removed.

Figure 4 depicts a side view of the medicament delivery device positioned at an optimal angle.

Figure 5 depicts a view of medicament delivery device placed in the naris and mouth of a user.

Figure 6 depicts a side view of the medicament delivery device showing the nasal fitting.

Figure 7 depicts a view of a pulmonary embodiment of the medicament delivery device.

Figure 8 depicts a view of the medicament delivery device having a one way valve.
Figure 9 depicts a view of the medicament delivery device of Figure 8 with the cover removed.

Figures 10-13 depicts various views of a one way valve compatible with the medicament delivery device.

Figures 14-15 depict views of a pulmonary embodiment of the medicament delivery device incorporating a one way valve.

Figures 16-17 depict an alternate configuration for the nasal tubular section.

Figure 18 depicts an alternate tip for the medicament delivery device.

Figure 19 depicts an alternate embodiment of the medicament delivery device with a squeeze bulb.

**DETAILED DESCRIPTION OF THE INVENTION**

Figure 1 depicts a side and a front view of medicament delivery device 100 in a closed position. The medicament delivery device 100 comprises oral tubular section 102, nasal tubular section 104, corrugated section 106, and cover 108. Oral tubular section 102, nasal tubular section 104, and corrugated section 106 are all preferably formed from a pliable, durable plastics such as polypropylene or polyethylene. Corrugated section 106 allows oral tubular section 102 and nasal tubular section 104 to be moved independently of each other. Nasal tubular section 104 further comprises nasal fitting 110 to form a seal with a user's naris as will be described later. Oral tubular section 102 further comprises markings 116 at which a pinch valve is formed.

Cap 108 comprises medicament chamber 112 which contains the medicament to be delivered to the user. In a preferred embodiment, the medicament is in a dry powder form. However, a liquid or any other granular medicament may be employed. A sealing medium 114 retains the medicament in medicament chamber 112 until medicament delivery device 100 is ready to be used by a user. Preferably, the sealing medium 114 resides within a slot in cap 108, with a portion extending from the cap 108 to act as a pull tab, allowing the sealing medium to be removed. The sealing medium slides out along grooves located on the sides of cover 108. In an alternate embodiment, sealing medium 114 may be a food-safe foil seal.

A top portion of oral tubular section 102 resides in cap 108 using a press fit connection and abuts sealing medium 114 in the closed configuration. A top portion of nasal tubular section 104, which extends beyond nasal fitting 110, similarly resides using in cap 108 a press fit connection.
To use medicament delivery device 100, the user first removes sealing medium 114 which causes the medicament contained in medicament chamber 112 to fall into corrugated section 106 through oral tubular section 102 as depicted by the downward arrow in Figure 2. Next, the user removes cover 108 from medicament delivery device 100 as depicted in Figure 3. The medicament delivery device 100 is now ready for use by the user.

The user next adjusts oral tubular section 102 and nasal tubular section 104 to an optimal angle as depicted in Figure 4. As previously described, corrugated section 106 allows oral tubular section 102 and nasal tubular section 104 to be adjusted independently of each other and maintains oral tubular section 102 and nasal tubular section 104 at their adjusted positions. In this embodiment, the user must maintain medicament delivery device in an upright position to prevent the medicament from falling out.

The user places nasal tubular section 104 into nares 118 as depicted in Figure 5. The user also places oral tubular section 102 into mouth 120. During placement of medicament delivery device 100, the user preferably pinches oral tubular section 102 at markings 116 to prevent accidental discharge of the medicament. The sidewalls or oral tubular section 102 may be made of a softer material than the rest of oral tubular section 102, allowing a pinch valve to be formed. Alternatively, the geometry of oral tubular section 102 near markings 116 may be modified to allow a user to easily squeeze the sidewalls together. Any such modifications of oral tubular section 102 which allow for easy deformation may be incorporated into oral tubular section 102. In some embodiments, for ease of manufacture, the markings 116 and the pinch valve may be omitted.

Nasal fitting 110 forms a seal with nares 118 to prevent any leakage. As depicted in Figures 3-6, nasal fitting 110 is preferably composed of multi-tiered, pliable rings 122 of increasing diameter. Rings 122 allow a seal to be formed with nares 118 of varying diameters. However, it should be apparent to one of ordinary skill in the art that nasal fitting 110 may be any shape (e.g., conical or without separations between rings 122) as long as it forms a seal with nares 118. For example, nasal fitting 110 may alternatively be cone shaped or flared.

When the user is ready, the user releases oral tubular section 102 at markings 116 and blows into oral tubular section 102. This forces the medicament from corrugated section 106 into nasal cavity 124 as depicted in Figure 6. Enhanced
dispersion of the medicament is achieved because of the sealing of naris 118 by nasal fitting 110. That is, nasal fitting 110 prevents any leakage of medicament of nares 118 and also ensures that the full force of the air is applied during medicament dispersal, ensuring complete dispersal of the medicament through nasal cavity 124.

An alternate pulmonary embodiment of medicament delivery device 100 is depicted in Figure 7. In this embodiment, the medicament delivery device 100 does not have nasal fitting 110 because the user instead inhales the medicament through oral tubular section 102. The method for using the pulmonary embodiment is substantially similar to that already described with respect to Figures 1-7. The user first removes sealing medium 114 (arrow 2) which causes the medicament in medicament chamber 112 to fall into corrugated section 106 (arrow 3). The cap 108 is then removed (arrow 4) and the oral tubular section 102 is placed in the mouth. However, the nasal tubular section 104 here remains open to the environment instead of being placed in nares 118 as shown in Figure 5.

In this embodiment, either oral tubular section 102 or nasal tubular section 104 may additionally comprise a pinch valve or markings 116 (not shown) to prevent dispersal of the medicament before placement of medicament delivery device 100 in mouth 120.

Referring next to Figure 8, depicted is an alternate nasal embodiment of medicament delivery device 100 incorporating a one way valve 802 instead of a manual pinch valve. This embodiment is useful for younger or elderly users that may lack the coordination or ability to use the pinch valve because it prevents accidental inhalation and does not require additional user intervention. The medicament chamber 112 is located in cap 108 above nasal tubular section 104 instead of above oral tubular section 102. Such a change is necessary to ensure that when sealing medium 114 is removed, that the medicament will fall into corrugated section 106. The one way valve 802 would prevent the medicament from entering corrugated section 106 if medicament chamber 112 was located above oral tubular section 102.

To use the medicament delivery device of Figure 8, a user removes sealing medium 114 which causes the medicament to fall into corrugated section 106 through nasal tubular section 104. Figure 9 depicts medicament delivery device 100 after sealing medium 114 has been removed and cap 108 has been lifted from oral tubular section 102 and nasal tubular section. The one way valve 802 is oriented such that it only allows airflow from oral tubular section 102 to nasal tubular section 104 and not
in the opposite direction. In order to be operated, a minimum cracking pressure must be applied to one way valve 802 through oral tubular section 102.

It is contemplated that many different types of check valves may be used for one way valve 802. Examples of check valves include, but are not limited to diaphragm check valves, swing check valves, stop-check valves, lift-check valves, in-line check valves, duckbill valves, ball valves, butterfly valves, ceramic Disc valves, clapper valves, choke valves, gate valves, globe valves, knife valves, needle valves, piston valves, plug valves, poppet valves, and pneumatic non-return valves. If additional safety is needed to ensure that the user does not inhale the medicament, one way valve 802 may incorporate two or more check valves in series.

An example of a one way valve 802 compatible with medicament delivery device 100 is depicted in more detail in Figures 10-13. As shown in the exploded view of Figure 10, one way valve 802 generally comprises air inlet section 1002, sealing gasket 1004, shaft 1006, spring 1008, and air outlet section 1010. The one way valve 802 can be incorporated anywhere downstream of the opening of oral tubular section 102 before corrugated section 106. A reversed view of air inlet section 1002 is depicted in Figure 11. In this view, the tapered valve seal 1012 is visible. The biasing force of spring 1008 (located over shaft 1006) against sealing gasket 1004 against valve seal 1012 prevents any reverse airflow through one way valve 1002. The scaffold construction of shaft 1006 allows the centering of sealing gasket 1004 against valve seal 1012 while minimizing obstruction of airflow once the cracking pressure of one way valve 802 has been reached.

Figure 13 depicts the components of one way valve 802 fully assembled. As shown in Figures 10-12, air inlet section 1002 further comprises locking mechanism 1014 which interlocks with a mating structure 1016 on air outlet section 1010. Preferably, the mating structure allows for a snap fit or threaded connection between air inlet section 1002 and air outlet section 1010. However, an adhesive or other material may also be used to hold the two parts using sonic welding or other mechanical techniques.

One way valve 802 features a widened body to prevent airflow restriction caused by the valve mechanism. For example, if one way valve were inserted without widening oral tubular section 102, airflow would be restricted which may lead to poor dispersal of the medicament. Outlet section 1010 gradually widens from
abutment surface 1018 to mating structure 1016. Similarly, air inlet section gradually widens from valve seal 1012 to locking mechanism 1014.

Air outlet section 101 further includes an abutment surface 1018 against which spring 1018 is biased when one way valve 802 is assembled. The opening in the center of abutment surface 1018 is chosen such that it is less than the diameter of spring 1008, but equal to or greater than the diameter of shaft 1006. Thus, when a user blows into air inlet section 1002, for example, spring 1008 compresses and shaft 1006 is free to move in the direction of the airflow. Then, when the airflow is removed, the biasing force of the compressed spring 1008 causes one way valve 802 to reseal (i.e., gasket 1004 contacts valve seal 1012 to prevent reverse airflow).

Figures 14 and 15 depict a pulmonary version of medicament delivery device 100 incorporating one way valve 802. This embodiment is substantially similar to that already described with respect to Figure 7, including the operation of the medicament delivery device 100. For clarity and conciseness, only the differences between the medicament delivery device 100 depicted in Figure 7 and the medicament delivery device 100 depicted in Figures 14-15 will be explained. As shown, nasal tubular section 104 here incorporates a one way valve 802 oriented such that air can only be inhaled through oral tubular section 102 and not in the other direction as depicted in Fig. 14. This ensures that the user does not accidentally exhale which would cause the medicament to be ejected through nasal tubular section 104 into the atmosphere. One way valve 802 prevents this from occurring.

Figures 16-17 depict an alternate shape for the proximal end of nasal tubular section 104. As shown, the proximal end of nasal tubular section 104 has a cone-shaped tip 1302 instead of a straight cut as depicted in Figures 1-13. Preferably, the cone-shaped tip 1302 has an angle of between 30-40 °, more preferably 38°. Cone-shaped tip 1302 causes the medicament to disperse into a plume as shown in Figure 16. This helps with the delivery of the medicament into naris 118. It should be apparent that other angles for cone-shaped tip 1302 are possible as long as a plume is formed by the medicament.

Figure 18 depicts an alternate shape for cone-shaped tip 1302. Optionally, cone-shaped tip 1302 may be narrowed to provide increased flow (venturi effect) and/or to accommodate users or animals with narrower nasal passages and/or for liquid, as well as powder delivery.
Figure 19 depicts a blowing device 1802 attached to oral tubular section 102. The blowing device 1802 may be a squeeze bulb or other pressure-generating device to accommodate infants, unconscious users, or users and animals otherwise incapable of blowing into the Medicament delivery device 100 with sufficient pressure to deliver the medicament.
CLAIMS

1. A medicament delivery device comprising:
a first tubular section;
a second tubular section;
a bendable section connecting the first tubular section to the second tubular section;
a cap having a compartment holding a medicament including a sealable opening,
wherein removal of the sealable opening causes the medicament to flow through the first or second tubular sections and into the bendable section; and
a nasal fitting located on the first tubular section or the second tubular section;
wherein the nasal fitting forms an airtight seal with the naris of a user when the nasal fitting is inserted into the naris.

2. The medicament delivery device according to claim 1, wherein the nasal fitting comprises a plurality of multi-tiered pliable rings of increasing diameter.

3. The medicament delivery device according to claim 1, wherein the nasal fitting is a conical shape having a smooth surface.

4. The medicament delivery device according to claim 1, further comprising:
a cone-shaped tip located at a proximal end of the second tubular section,
wherein the nasal fitting is located along the second tubular section, and
wherein the cone-shaped tip extends beyond the nasal fitting such that the cone-shaped tip is located completely within a nasal cavity of the user when the nasal fitting is inserted into the naris of the user.

5. The medicament delivery device according to claim 4, wherein sides of the proximal end of the second tubular section are angled inwards at 30-40° to form the cone-shaped tip.

6. The medicament delivery device according to claim 5, wherein the sides of the proximal end of the second tubular section are angled inwards at 38°.
7. The medicament delivery device according to claim 1, wherein the first tubular section comprises a pinch valve along its length and markings to indicate a location of the pinch valve.

8. The medicament delivery device according to claim 7, wherein the pinch valve comprises a softer material than that used to form the first tubular section.

9. A medicament delivery device comprising:
   a first tubular section;
   a second tubular section;
   a bendable section connecting the first tubular section to the second tubular section;
   a cap having a compartment holding a medicament including a sealable opening,
   wherein a proximal end of the second tubular section is located within the cap and abuts the sealable opening,
   wherein removal of the sealable opening causes the medicament to flow through the first or second tubular sections and into the bendable section; and
   a one way valve located along an interior of the first tubular member,
   wherein the one way valve allows airflow from the first tubular section to the second tubular section and restricts airflow from the second tubular section to the first tubular section.

10. The medicament delivery device according to claim 9, wherein the one way valve is a diaphragm check valve, a swing check valve, a stop-check valve, a lift-check valve, an in-line check valve, a duckbill valves, and a pneumatic non-return valve.

11. The medicament delivery device according to claim 9, further comprising:
   a second one way valve located in series with the one way valve along the interior of the first tubular member.

12. The medicament delivery device according to claim 9, wherein the one way valve comprises:
an air inlet section having a tapered valve seal, an air inlet, and a first mating portion;

an air outlet section having an abutment surface, an air outlet, and a second mating portion,

wherein the first mating portion is jointed to the second mating portion;

a shaft having a scaffold construction,

wherein the shaft has a proximal end and a distal end, and

wherein the proximal end of the shaft comprises a valve formed circumscribing the shaft; and

a spring surrounding the distal end of the shaft,

wherein a proximal end of the spring abuts the abutment surface and a distal end of the spring exerts a biasing force against the valve, causing the valve to form an airtight connection with the tapered valve seal to restrict airflow from the air outlet section to the air inlet section.

13. The medicament delivery device according to claim 12, wherein, when the air inlet receives an airflow force greater than the biasing force of the spring, the spring is compressed and the airtight connection is removed, allowing airflow from the air inlet to the air outlet.
INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2017/016706

A. CLASSIFICATION OF SUBJECT MATTER
A61M 15/00(2006.01)i, A61M 15/08(2006.01)i

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61M 15/00; A61M 31/00; A62B 7/00; A61M 15/08

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
Korean utility models and applications for utility models
Japanese utility models and applications for utility models

Electronic database consulted during the international search (name of database and, where practical, search terms used)
eKOMPASS(KIPO internal) & keywords: medicament, delivery, tubular, bendable, cap, nasal, oral, seal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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Further documents are listed in the continuation of Box C.

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