A pharmaceutical product in the form of an anti-snoring substance includes a container (220) containing the anti-snoring substance, the anti-snoring substance being in the form of a solution pre-concentrate. The container (220) is made by a blow-fill-seal technology, wherein the container material is Polyethylene or Polypropylene. The container (220) includes a body portion (104) containing the anti-snoring substance and a fluid outlet portion (106) configured to deliver the anti-snoring substance.
NASAL SPRAY APPARATUS

BACKGROUND OF THE INVENTION

[0001] The present disclosure generally relates to administering a substance to the throat. More particularly, the aspects of the disclosed embodiments relate to administering a substance to the throat via the nose using a blow-fill-mold style bottle.

[0002] Devices are available for administering active substances or substances to the body, particularly through the throat, lungs or sinuses. These devices generally include containers that have a main chamber holding the desired contents and a head portion that is inserted into the nose or mouth. By squeezing the container, the substance is released into the nose or mouth. In some cases, the device has a tab or seal that must be broken in order to release the substance. A relatively narrow neck on the device can form the outlet channel from the main chamber into the head portion. This outlet channel can sealed by a frangible membrane that is typically formed by placing a crimp, tab or seal across the head portion during the molding and sealing process. At the time of use, the head portion is broken away from the main chamber portion, thus opening the outlet channel and allowing removal or dispensing of the contents. When the substance is being administered orally, the user will typically inhale at roughly the same time as the substance is released in order to force the medicine into, or further into, the sinus cavity, throat or lungs.

[0003] The blow-fill-seal process (BFS process), also referred to herein as blow-fill-mold, is a single operation which produces sterile containers. Bottles or vials made
from materials such as from thermoplastic, are blown to a desired shape and immediately on cooling are filled aseptically with a desired fluid and hermetically sealed. The containers that are produced by the blow-fill-seal process are generally referred to herein as "BFS containers." The blow-fill seal process generally produces compact, easy-to-use substance dispensing devices that can be used to deliver substance to the throat, lungs or sinuses.

[0004] Snoring is a serious problem for a large segment of the population. Snoring is a sleep disorder that can range from mild to severe in humans. Mild cases may result in no more than fitful sleep by the sufferer, while severe cases can cause disturbance of the sleep of others, and may result in insufficient inhalation of oxygen by the sufferer, apnea and, in extreme cases, death.

[0005] Remedies to alleviate the symptoms of snoring can range from surgery to a variety of substances. Although surgery has been proven to be somewhat effective, it is a radical and expensive approach that is subject to all the usual risks associated with surgery. Drugs are available by prescription for the treatment of the symptoms of snoring. Other snoring management techniques can include for example, mechanical aids, nasal strips and anti-snoring sprays. Anti-snoring sprays can tend to be ineffective unless applied repeatedly during the night. Additionally, device sterilization is a concern when administering anti-snoring sprays due to the potential for infection since the sprays are introduced directly into the lungs in a manner that at least partially bypasses the patient's natural defense mechanisms.
Accordingly, it would be desirable to provide a system that addresses at least some of the problems identified above.
BRIEF DESCRIPTION OF THE INVENTION

[0007] As described herein, the exemplary embodiments of the present invention overcome one or more of the above or other disadvantages known in the art.

[0008] In one aspect, the disclosed embodiments are directed to a pharmaceutical product in the form of an anti-snoring substance. In one embodiment, the product includes a container containing the anti-snoring substance; the anti-snoring substance being in the form of a solution pre-concentrate; the container being made by a blow-fill-seal technology, wherein the container material is Polyethylene or Polypropylene; the container including a body portion containing the anti-snoring substance and a fluid outlet portion configured to deliver the anti-snoring substance.

[0009] In another aspect, the disclosed embodiments are directed to a method for administering an anti-snoring substance. In one embodiment, the method includes sealing a unit dose of the anti-snoring substance in a container made by a blow-fill-seal technology; opening the unit dose; administering the anti-snoring substance to a nasal passage of a patient while a head of the patient is in a substantially backward tilted position in order for the substance to reach a throat of the patient, wherein the anti-snoring substance is delivered into the nasal passage in the form of a jet stream.

[00010] In a further aspect, the disclosed embodiments are directed to a nasal spray apparatus. In one embodiment, the apparatus includes a nasal preparation containing an anti-snoring substance; a container having an opening that provides access to an interior cavity, which container is operable to hold the anti-snoring substance within the
interior cavity; a pump dispenser mounted on the container in a manner that closes the opening; wherein the container and pump dispenser are manufactured by a blow-fill-mold process.

[00011] These and other aspects and advantages of the disclosed embodiments will become apparent from the following detailed description considered in conjunction with the accompanying drawings. It is to be understood, however, that the drawings are designed solely for purposes of illustration and not as a definition of the limits of the invention, for which reference should be made to the appended claims. Moreover, the drawings are not necessarily drawn to scale and that, unless otherwise indicated, they are merely intended to conceptually illustrate the structures and procedures described herein.
BRIEF DESCRIPTION OF THE DRAWINGS

[00012] In the drawings:

[00013] Fig. 1 illustrates an exemplary dispensing device incorporating aspects of the present disclosure.

[00014] Fig. 2 illustrates a use application of the dispensing device incorporating aspects of the disclosed embodiments.
DETAILED DESCRIPTION OF THE EXEMPLARY EMBODIMENTS OF THE INVENTION

[00015] Referring now to Fig. 1, a device 102 for the nasal or oral delivery of a substance is shown. The aspects of the disclosed embodiments are generally directed to the administration of an anti-snoring substance or medicament to a patient with a device manufactured using blow-fill-seal or blow-fill-mold technology. The device 102 shown in Fig. 1 is part of an ampule pack 100. In one embodiment, the device 102 comprises a sealed flexible container or body portion 104 containing the substance or medicament. The device 102 is typically manufactured using a blow-fill-seal or blow-fill-mold technique.

[00016] As shown in Fig. 1, the device 102 generally comprises a body portion 104 and a fluid outlet portion 106. The body portion 104 is configured to hold the nasal preparation, also referred to herein as the anti-snoring substance. In one embodiment, the device 102 includes a tab portion 108, which is generally configured to be of a twist off type. A frangible member 110 can be included on the fluid outlet portion 106 near or as part of the tab portion 108, to allow the tab portion 108 to be easily removed.

[00017] During the blow-fill-seal process, the device 102 is substantially filled with the anti-snoring substance when oriented in the vertical plane and sealed. When the tab 108 is removed, the substance can be dispensed, such as shown in Fig. 2. In this embodiment, the substance is generally dispensed by allowing the substance to exit from the fluid outlet portion 106 as the device 102 is positioned with the fluid outlet portion 106 oriented in a substantially downward direction. In this example, the body
portion 104 can be compressed to force or urge the substance from the body portion 104 and out of the fluid outlet portion 106 in the form of a jet stream, rather than a spray or atomization.

[00018] In one embodiment, the substance comprises an anti-snoring solution named ASONOR® and manufactured by TannerMedico A/S, Denmark. The solution contains Sodium Chloride, Glycerol, Polysorbate and Edetatesodium. Potassium sorbate can be added as preservative. During the manufacturing process, the solution is filled into the body portion 104 as part of the Blow-Fill-Seal process, as otherwise known in the art. In one embodiment, the containers 102 are plastic Polypropylene or Polyethylene containers. In alternate embodiments, the containers 102 can comprise any suitable container for use in the Blow-Fill-Seal process. Each container forms a single unit dose.

[00019] A method of administering the substance according to one aspect of the disclosed embodiments is described with respect to Fig. 2. As shown in Fig. 2, the head 200 of the user is generally tilted in a backwards or rearwards direction, such as the direction A shown in Fig. 2, from a substantially upright position, so that the nose 202 is in a substantially horizontal or slightly backward tilted position relative to the ground 204. Generally, the head 200 needs to be tilted backwards far enough, for a period of time, to allow the substance to travel through the nasal passages 206 to the throat area 208. By tilting the head 200 backwards, gravity will assist in delivering the liquid substance to the throat area 208 through the nasal passages 206.
[00020] Once the head 200 is in the tilted back position as is shown in Fig. 2, the end 106 of device 100 being used is placed in or near the opening of the nostril 210. The container 220 is then squeezed to deliver the substance into the nasal passage 206 and to the throat passage 208. The container 220 is squeezed a sufficient number of times until the substance is felt in the throat passage 208 or the entire substance is expended. The process is repeated for each of the nasal passages 206. Generally, three to four pumps into each nostril 210 is sufficient.

[00021] The liquid substance is not intended to remain in the nasal passages 206, as the benefits of this anti-snoring substance are primarily realized from the substance reaching the throat passage 208.

[00022] The aspects of the disclosed embodiments provide an effective treatment against snoring. An anti-snoring substance, and in particular ASONOR®, is administered into the nasal passages using a blow-fill mold style bottle. By incorporating a jet-stream style outlet nozzle, rather than a spray or atomization, the substance does not stay in the nose, but is rather delivered to the throat. This advantageously allows the substance to begin working sooner.

[00023] Moreover, it is expressly intended that all combinations of those elements and/or method steps which perform substantially the same function in substantially the same way to achieve the same results are within the scope of the invention. Moreover, it should be recognized that structures and/or elements and/or method steps shown and/or described in connection with any disclosed form or embodiment of the invention
may be incorporated in any other disclosed or described or suggested form or embodiment as a general matter of design choice. It is the intention, therefore, to be limited only as indicated by the scope of the claims appended hereto.
Patent Claims:

1. A pharmaceutical product in the form of an anti-snoring substance comprising: a container containing the anti-snoring substance; the anti-snoring substance being in the form of a solution pre-concentrate; the container being made by a blow-fill-seal technology, wherein the container material is Polyethylene or Polypropylene; the container including a body portion containing the anti-snoring substance and a fluid outlet portion configured to deliver the anti-snoring substance.

2. The product according to claim 1 wherein the fluid outlet portion comprises a jet stream nozzle.

3. The product according to claim 1 or 2 wherein the container is a squeeze device.

4. The product according to claim 1, 2, or 3 wherein the anti-snoring substance is administered through a patient's nasal passage.

5. The product according to claim 4 wherein the anti-snoring substance is administered through the nasal passage to a throat of the patient.

6. The product according to any of claims 1-5 wherein the container includes a unit dose of the anti-snoring substance.

7. The product according to claim 6, wherein the unit dose is delivered in multiple delivery increments.

8. A method of administering an anti-snoring substance comprising: sealing a unit dose of the anti-snoring substance in a container made by a blow-fill-seal technology; opening the unit dose; administering the anti-snoring substance to a nasal passage of a patient while a head of the patient is in a substantially backward tilted position in order for the substance to reach a throat of the patient, wherein the anti-snoring substance is delivered into the nasal passage in the form of a jet stream.
9. The method of claim 8 wherein the anti-snoring substance is administered by squeezing the container.

10. A nasal spray apparatus comprising: a nasal preparation containing an anti-snoring substance; a container having an opening that provides access to an interior cavity, which container is operable to hold the anti-snoring substance within the interior cavity; the container being manufactured by a blow-fill-mold process.

11. The apparatus of claim 10 wherein the container further comprises a nozzle and nozzle tip, and wherein the nozzle tip delivers the anti-snoring substance in the form of a jet stream.

12. The apparatus of claim 10 or 11 wherein the substance is delivered by the jet stream through a nasal passage into a throat passage.

13. The apparatus of claim 10, 11, or 12 wherein the apparatus includes a single dose of the anti-snoring substance and is disposable.
This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claims Nos.: 8, 9 because they relate to subject matter not required to be searched by this Authority, namely:
   see FURTHER INFORMATION sheet PCT/ISA/210

2. Claims Nos.: because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

This International Searching Authority found multiple inventions in this international application, as follows:

1. As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:  

4. No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:  

Remark on Protest

- The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- No protest accompanied the payment of additional search fees.
**INTERNATIONAL SEARCH REPORT**

**A. CLASSIFICATION OF SUBJECT MATTER**

INV. A61M15/08
ADD. A61M11/00 A61M15/00

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

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)
A61M A61J

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

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<th>Category*</th>
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<th>Relevant to claim No.</th>
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Further documents are listed in the continuation of Box C.

See patent family annex.

* Special categories of cited documents:
  * "A" document defining the general state of the art which is not considered to be of particular relevance
  * "E" earlier document published on or after the international filing date
  * "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another document or other special reason (as specified)
  * "O" document referring to an oral disclosure, use, exhibition or other means
  * "P" document published prior to the international filing date but later than the priority date claimed
  * "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
  * "X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
  * "Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
  * "Z" document member of the same patent family

Date of the actual completion of the international search: 20 September 2011

Date of mailing of the international search report: 28/09/2011

Name and mailing address of the ISA:

European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016

Authorized officer: Zeinstra, Hilaire
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Continuation of Box II.1

Claims Nos.: 8, 9

Claims 8, 9 generally refer to method of administering a substance to a nasal passage of a patient. This method comprises within its scope also a method of treatment by therapy of the patient. In view of that the ISA is not required to perform a search of Article 17(2)(a)(i) and Rule 39(1)(iv) PCT (Method for treatment of the human or animal body by therapy).