Sept. 27, 1966 M. E. BOWEN 3,275,000

SINGLE DOSE FOAMED MEDICATION APPLICATOR

Filed May 20, 1963 2 Sheets-Sheet 1

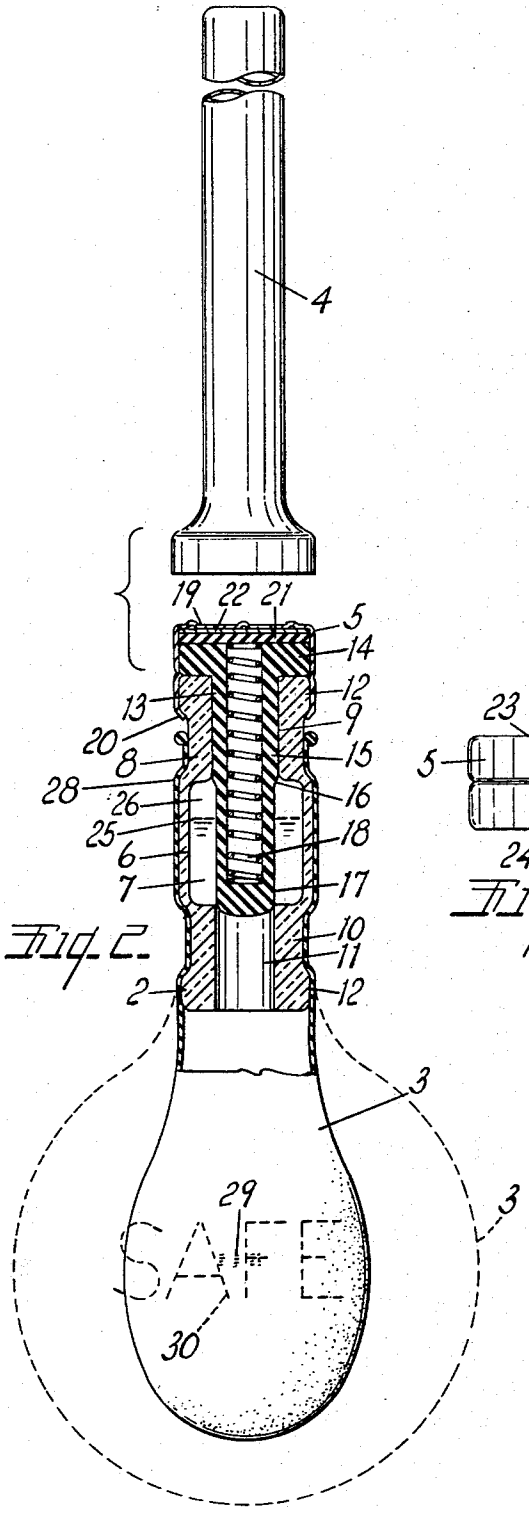


Fig. 2.

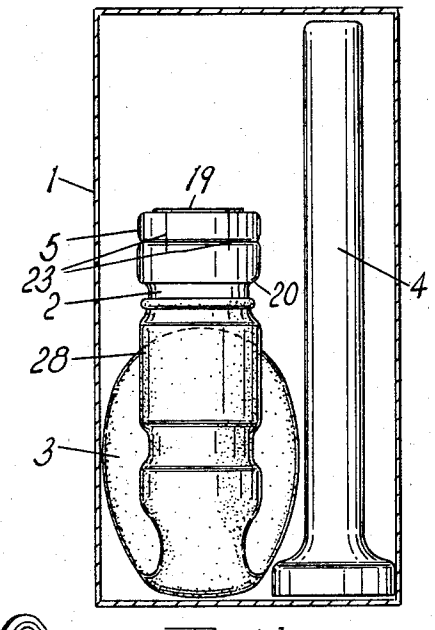


Fig. 1.

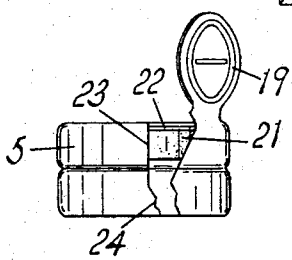


Fig. 4.

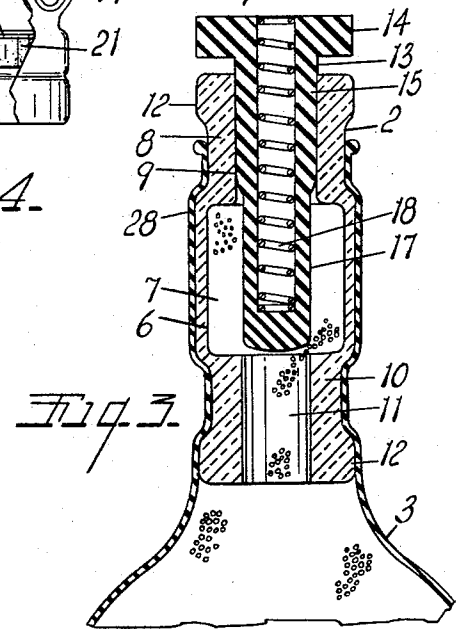


Fig. 3.

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SINGLE DOSE FOAMED MEDICATION APPLICATOR

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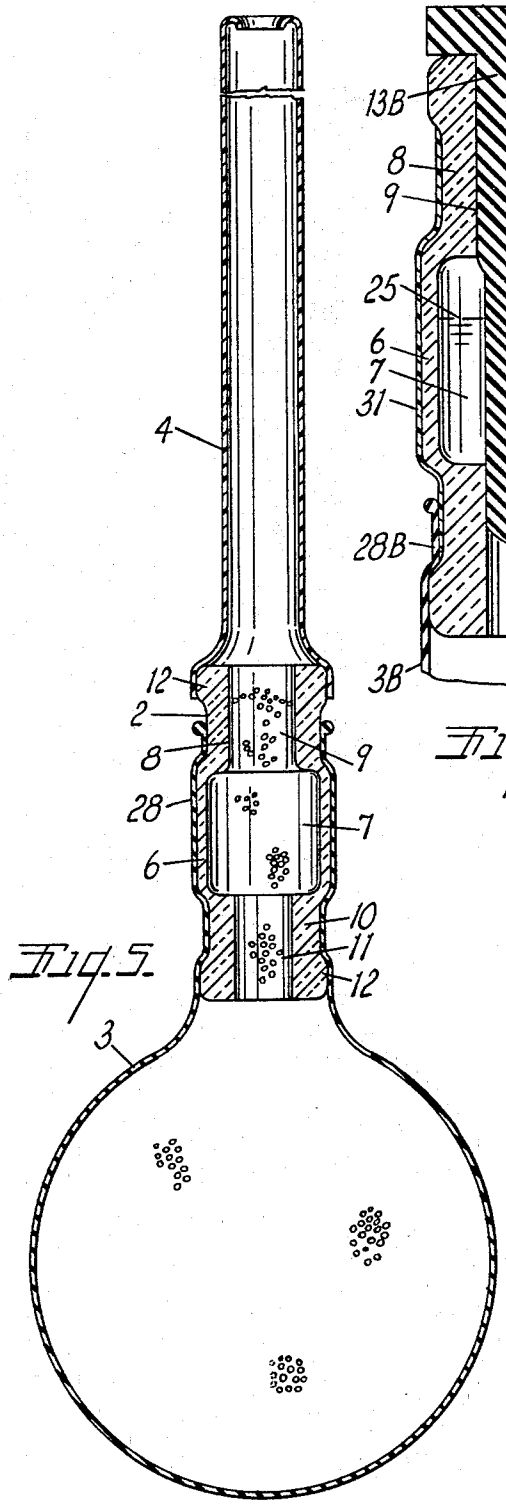


Fig. 5

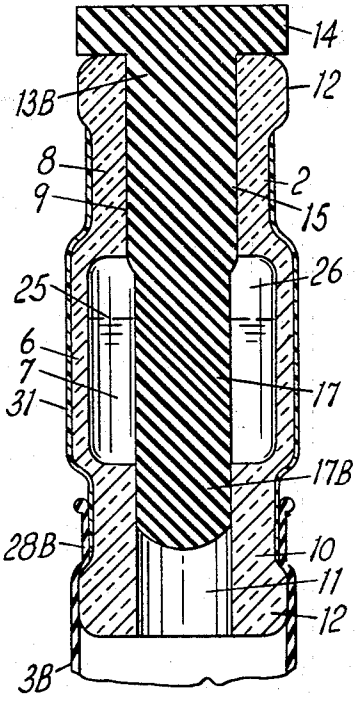


Fig. 6

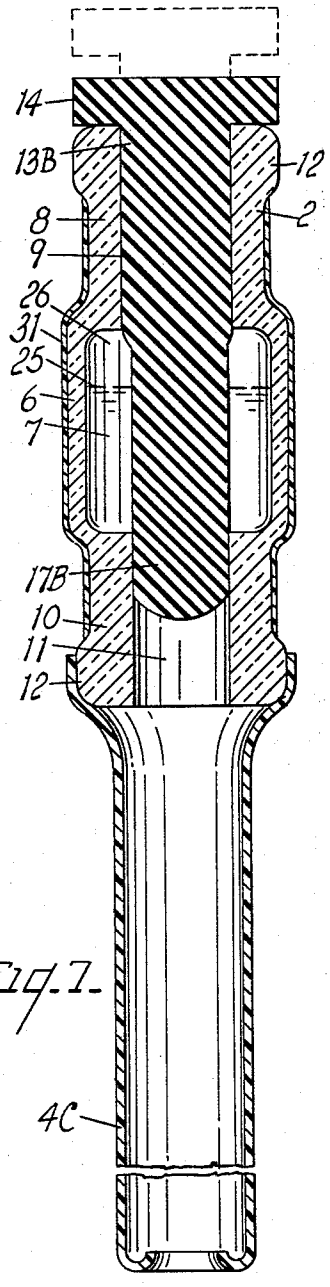


Fig. 7

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SINGLE DOSE FOAMED MEDICATION APPLICATOR

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8 Claims. (Cl. 128—272)

This invention relates to improvements in single dose foamed medication applicator.

The principal objects of this invention are:

First, to provide a sealed capsule holding a dose of medicinal material and a charge of an inert gas for expanding the material into a foam and with an expansible chamber for receiving the foamed dose and an elongated applicator probe and nozzle for discharging the foamed dose into vaginal or rectal passages under safe pressures by manually squeezing the expansible chamber.

Second, to provide a capsule and applying structure as described above which are inexpensive so that it is practical to supply and use a single sanitary capsule and applying structure which are discarded after use.

Third, to provide an inexpensive pressure retaining capsule and pressure releasing closure which can be assembled and charged under sterile conditions and packaged and sold with approved safety precautions for pressurized glass containers.

Fourth, to provide a medicinal container and applicator for a foamed medication which automatically and inherently indicates the loss or faulty charging of the foam forming pressure in the container.

Other objects and advantages of the invention will be apparent from a consideration of the following description and claims. The drawings, of which there are two sheets, illustrate a highly practical preferred form of the container and applicator of the invention and two modified forms thereof.

FIG. 1 is a cross sectional view through a shipping box or package with a preferred form of the applicator of the invention packed therein as it would be sold to the customer.

FIG. 2 is a fragmentary exploded elevational view, partially in section, showing details of the medication containing capsule and the dispensing or applying structures.

FIG. 3 is a fragmentary cross sectional view through the capsule showing an intermediate step or stage of conditioning the capsule for applying the medication.

FIG. 4 is an elevational view of the pressure retaining seal removed from the capsule.

FIG. 5 is a fragmentary longitudinal cross sectional view through the capsule and applicator in assembled condition ready for administering the medication.

FIG. 6 is a fragmentary cross sectional view through a first modified form of the capsule with the seal removed.

FIG. 7 is a fragmentary longitudinal cross sectional view through a second modified form of the capsule and applicator.

The applicator and dose capsule of the invention is designed primarily for single dose storage and application of a foamable medication to the vaginal or rectal passages of the human body. However, it will be apparent that by suitable changes in size and selection of the medication, the invention may be used to apply medication to the nose, throat or ear passages of humans or animals. Further, by elongation of the probe or dispensing nozzle, the invention may be used to medicate various internal organs of any body. Single dose application is contemplated but repeated or prolonged dose application is possible.

As shown in FIG. 1, the applicator may be packaged and sold in a convenient box or package 1 containing the dose retaining capsule 2 with attached dispensing balloon 3 and separate dose directing probe or nozzle 4. A tamper-proof seal 5 is attached to the capsule and the probe 4 is separately attachable, both to save shipping space and to permit operation of the closure of the capsule as will be described.

As appears more clearly in FIGS. 2 and 3 the capsule 2 is a short cylindrical tube preferably made of glass with a radially enlarged and relatively thin walled center portion 6 defining a dose chamber 7. A thick walled upper neck 8 defines a central bore 9 while a thick walled lower neck 10 defines a bore 11 aligned with the bore 9. Both necks and especially the upper neck 8 have enlarged exterior rims or beads 12. The lower bore 11 is smaller in diameter than the upper bore 9. A closure plug 13 made of rubber or other deformable material has a cap or collar 14 seated against the upper end of the capsule and an integral stem with a relatively larger upper end 15 fitting sealingly in the upper bore 9. The stem is reduced in diameter as at 16 within the dose chamber 7 and extends in a lower end 17 of reduced diameter into sealing engagement with the upper or inner end of bore 11.

The plug 13 and stem portions 15 and 17 are hollow and contain a spring 18 to assure sealing at the lower end 17 around the end of the bore 11. The reduction in size of the lower section 17 of the stem makes the stem easier to insert through the upper bore 9. The removable metal tamper-proof seal 5 is fitted over the cap 14 and crimped under the edge of the upper bead 12 at 20. The seal includes a rubber washer 21 and metal backing disk 22 that back up and retain the plug 13 and the spring 18 in the capsule. The seal, which is an old item in the drug and other arts has a partially separated pull tab 19 in its top wall. The side wall of the seal is split as at 23 part way down the sides of the seal from the edges of the tab. When the tab is pulled up and back as shown in FIG. 4 the remainder of the side wall tears away at 24 permitting removal of the seal.

The seal 5, when intact, backs up the stem 15, 17 and spring 18 and also indicates whether the capsule has been tampered with. While it is not the purpose of this invention to disclose the filling operation, it is pointed out that the capsule with the plug and seal assembled in sterile condition can be inverted on a suitable platform and a filling spout inserted through the bore 11 to deflect the end 17 and introduce a measured dose of liquid medication. A hollow needle may then be forced between the end 17 and the adjacent edge of the bore 11 to introduce an inert gas under pressure. The end 17 seals immediately on withdrawal of the needle and when the capsule is turned upright as in FIGS. 1 and 2 the liquid lies at the surface 25 under the pressure of the gas in the space 26.

The rubber or other expansible balloon 3 has its neck 28 stretched and drawn over the capsule from the lower end 10 and enlarged cavity forming center 6 and part way along the upper end 8 of the capsule. The neck 28 performs the double function of retaining the balloon on the capsule and satisfying interstate commerce safety requirements for a shatter-proof covering over glass containers with contents under pressure.

When the device is to be used, the seal 5 is removed as in FIGS. 3 and 4 and the plug 13 is partially pulled out or up unseating the lower end 17 of the closure plug from the bore 11 while maintaining a seal in the upper bore 9. The gas immediately expands forcing the liquid medicine through bore 11 into the balloon 3 while expanding and converting the liquid into a medicated foam. The balloon is of such size and resiliency as to permit complete expansion of the gas. The gas and medicine must of course be compatible and the gas must have no

damaging effect on human tissue. Gases and medications having these properties are know in the medical and pharmaceutical arts.

A feature and advantage of the applicator is here apparent. If the balloon does not expand, or only swells slightly, the user knows immediately that the capsule is defective for one reason or another and may immediately use or buy another. At least the patient will not have the false impression that he or she has used the expected medication. If desired, a very fine and small indicia may be printed on the balloon in collapsed condition as at **29** to swell into clearly readable print at **30** in FIG. 2.

After the pressure has equalized in the balloon **3**, the plug **13** is completely removed and the hollow probe or nozzle **4** is fitted over the upper bead **12** as in FIG. 5. The user inserts the probe into the body and squeezes the balloon manually to eject the medicated foam. The ejecting pressure is thus gentle and not dangerous to delicate body tissues. Also, the foam which is cooled by expansion of the gas has an opportunity to warm or be warmed by the user before use. The dose measured into the capsule is sufficient to permit discarding the foam that will remain in the capsule and the tube **4**.

The modified form of the applicator shown in FIG. 6 is essentially the same as the preferred first form except that the closure plug **13B** has no spring therein and has a longer lower stem portion **17B** that projects substantially into the lower neck **10** to seal more by side contact like a cork than by abutment with the end of the bore. The balloon **3B** has a shorter neck **28B** extended only over the bead or rim **12** on the lower end of the capsule. Since the balloon does not act as a guard for the pressurized capsule it is necessary to apply an acceptable plastic coating **31** over the thin center portion of the capsule and onto the thickened ends **8** and **10**. In other respects the capsule is charged, sealed and used in the same way as the first form of the capsule.

The third form of the applicator shown in FIG. 7 is in some respects the least desirable in that it ejects the medicated foam directly into the body cavity of the user under the pressure of the expanding gas which may be dangerous. The capsule **2** has the same plug **13B** and plastic coating **31** as in FIG. 6. The balloon of the first two forms of the applicator is entirely omitted as may be the tear-off seal **5**. The probe **4C** is sized to fit on the bead of the lower neck **10** and the dose is discharged directly to the probe by merely backing out the plug **13** until the lower end **17B** of the stem clears the bore **11**.

In each of the modified forms shown in FIGS. 6 and 7 the upper end or neck **8** of the capsule is longer than the lower end or neck **10** to assure that a seal and sufficient retaining friction will be maintained around the upper end **15** of the rubber stem to prevent the closure plug from blowing out of the top of the capsule before the closure at the lower bore is removed.

What is claimed as new is:

1. A single dose pressurized medicinal dispenser for use with an applicator nozzle comprising,

a pressure containing glass capsule having opposite first and second ends and a central cavity with aligned bores opening from the opposite ends of the capsule to said cavity,

the ends of the capsule having radially inwardly thickened walls forming said bores,

a radially thickened external bead on said first end of said capsule,

a deformable closure plug having a cap removably seated against the end of said thickened bead and having a connected stem in sealing engagement with the bore in said first end and extending in sealing relation through the bore in said first end of the capsule and through said cavity into sealing engagement in the inner end of the bore in said second end of said capsule,

a charge of liquid medicinal material partially filling said cavity,

a charge of a gas inert to said medicinal material retained under pressure in said cavity and adapted to expand said medicinal material into a large volume of foam when the pressure in said cavity is released,

a removable retaining seal fitted over said cap and crimped over said bead on said capsule,

and an expansible balloon having a neck stretched over and grippingly engaged over said second end of said capsule,

said balloon having sufficient capacity when extended to contain the foamed volume of said medicinal material when the stem on said closure plug is unsealed from the bore in said second end of the capsule.

2. A pressurized medicinal dispenser for use with an applicator nozzle comprising,

a pressure containing capsule having opposite first and second ends and a central cavity with aligned bores opening from the opposite ends of the capsule to said cavity,

the ends of the capsule having radically inwardly thickened walls forming said bores,

a deformable closure plug having a stem in sealing engagement with the bore in said first end and extending in sealing relation through the bore in said first end of the capsule and through said cavity into sealing engagement with the bore in said second end of said capsule,

a charge of medicinal material partially filling said cavity,

a charge of a gas retained under pressure in said cavity and adapted to expand said medicinal material into a large volume of foam when the pressure in said cavity is released,

expansible receiving means sealingly connected to the other end of said capsule and communicating with the bore therein and having sufficient capacity when extended to contain the foamed volume of said medicinal material and said gas.

3. A dispenser as defined in claim **3** in which said receiving means is an expansible balloon engaged over said second end of said capsule.

4. A dispenser as defined in claim **3** in which the stem of said plug projects into the bore in said second end of said capsule to a lesser extent than the length of the bore in said first end of the capsule.

5. A dispenser as defined in claim **3** in which the inner portion of said plug passing through said cavity and sealing said bore in said second end is of lesser diameter than the other end of the plug sealing the bore in said first end of the capsule.

6. A dispenser as defined in claim **3** in which the neck of said balloon extends over the central cavity forming portion of the capsule.

7. A dispenser as defined in claim **2** in which said plug is hollow with a spring therein and has a collar overlying the first end of the capsule with a removable seal crimped over the end of the capsule and backing said plug and said spring.

8. A medicinal dose capsule adapted to be used with an applicator comprising,

a double ended capsule having opposite first and second ends and openings formed in each end communicating with a central dose cavity containing a charge of medicating material under expansible gas pressure,

a common closure for said openings removable through the opening in said first end and extending in sealing relation through the opening in said first end and through said cavity into closing engagement in the inner end of the opening in said second end of said capsule,

said closure maintaining closing engagement within

said opening in said first end of said capulse until after the closing engagement with the opening in said second end of said capsule is broken upon removing movement of the closure,

and an expansible and contractable chamber forming member connected to said in said second end of said capsule and adapted to receive the fully expanded charge of said medicating material.

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