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2,864,368

FOIL ENVELOPE AND ENCLOSING TUBE DISPOSABLE APPLICATOR

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Fig. 1.

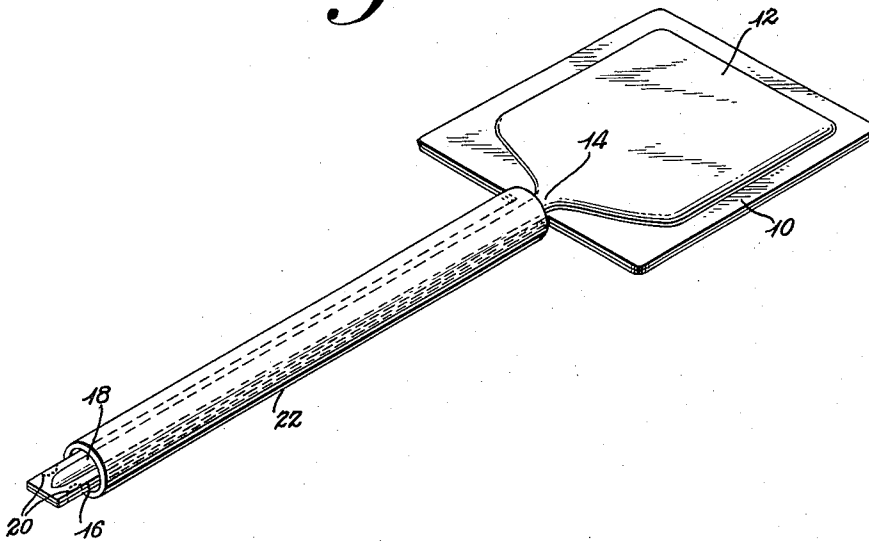
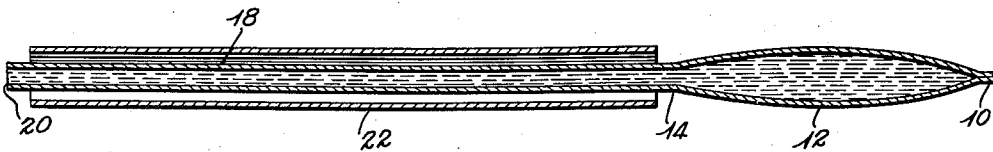


Fig. 2.



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**FOIL ENVELOPE AND ENCLOSING TUBE
DISPOSABLE APPLICATOR**

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Application April 3, 1957, Serial No. 650,449

4 Claims. (Cl. 128—261)

This invention relates to new and useful improvements in dispensers or applicators for pharmaceutical formulations in the nature of liquids, semi-liquids, and jellies, and particularly relates to dispensers or applicators adapted to the application of pharmaceutical formulations into the vagina. The invention is concerned especially with a dispenser which is convenient and highly satisfactory in use and which is capable of being produced economically whereby the dispenser may be employed on a single occasion and immediately thereafter destroyed.

Heretofore it has been the practice to introduce viscous liquid or jelly-like pharmaceutical formulations which are used for the treatment of vaginal infections or for contraception into the vagina by means of an applicator which has been filled with a pharmaceutical formulation from a large supply-storage tube of the collapsible type. It has been customary to use the same applicator repeatedly, and on each occasion it is necessary to fit the supply tube to the applicator, collapse the supply tube so as to discharge therefrom into the applicator the desired amount of formulation. It is then necessary to detach the supply tube from the applicator, close the supply tube and return it to the shelf. This procedure obviously has many disadvantages, among which is the mechanical unhandiness of the several abovementioned manipulations.

A serious disadvantage of the above described practice of the prior art entails re-use of the mechanical applicator. This disadvantage is readily appreciated in connection with instances where a vaginal infection is being treated since on each occasion the patient is subjected to the possibility of reinfection unless the applicator is adequately sterilized after each occasion of use. While adequate sterilization is entirely feasible and possible, it is a time consuming task; the trouble of doing so is objectionable. The combination of the applicator and a collapsible supply-storage tube containing the pharmaceutical composition to be introduced into the body cavity is bulky and not easily transportable; neither is the combination readily disposable when no longer to be used.

This invention seeks to overcome the disadvantages of the practices of the prior art by supplying a single-application dispenser, i. e., one adapted for use on only one occasion which, nevertheless, will provide all of the advantages of prior devices.

In providing a dispenser for immediate disposition after use the economic factor becomes paramount; such an article must possess many important characteristics and yet must be capable of being manufactured at a very low cost, objectively, of course, at the lowest possible cost. To overcome the disadvantages mentioned in preceding paragraphs, such a device must be capable of storing the pharmaceutical preparation over an extended period of time in a manner such that the formulation will not be attacked by the atmosphere or by the materials of fabrication of the dispenser itself. Similarly, the construction must be such that the water and alcohol content, or other volatile content, of the pharmaceutical

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formulation does not escape during the storage period between manufacture and use.

Further, such dispensers should be adapted to discharge substantially the entire content of the dispenser, leaving little or none in the dispenser; and further desirably, the device should be capable of delivering the entire quantity to the desired point of application within the body cavity.

It is essential that applicators or dispensers of the type here under consideration embody the utmost in appeal to the user, and it is highly desirable that any objectionable features such as difficulty of actual application be entirely overcome; otherwise they are likely to be unacceptable even though eminently satisfactory mechanically speaking.

Accordingly, an object of this invention is to provide a dispenser or applicator by means of which a liquid, semi-liquid, or jelly-like pharmaceutical composition may be neatly, quickly, and conveniently dispensed into a body cavity.

Another object is to provide a dispenser or applicator of simple and inexpensive construction which may be manufactured readily in large quantities and which may be discarded economically after a single occasion of use.

Another further object of this invention is to provide a dispenser or applicator which in addition to providing means for applying pharmaceutical compositions also serves to provide a holder or container for the composition prior to its being dispensed.

Still another object of this invention is to provide a dispenser or applicator of the class described, adapted to maintain its contents in a sterile and effective condition up to the time of use.

A further important object of this invention is to provide a dispenser or applicator of the class described which is not bulky and which is convenient to carry and use.

Other objects of this invention will appear from the following description and drawings, as well as in the appended claims.

According to this invention, it has been discovered that a dispenser or applicator may be provided having none of the disadvantages of the prior art yet accomplishing the foregoing stated objects. The dispenser or applicator of this invention comprises two parts as supplied by the manufacturer including an envelope having a depending delivery tube containing a quantity of formulation sufficient for use on a single occasion and a cooperating tubular member facilitating insertion of the delivery tube into the body cavity. The envelope and tubular member may be supplied by the manufacturer in assembled relation, but if they are not, they may be assembled very simply by the user with minimum annoyance as will be apparent from a more complete description of the invention hereinafter presented.

The accompanying drawings illustrate the structure that is designed to carry out the various objects of the invention, but it is to be understood that the invention is not confined to the exact features shown in the drawings and that various changes may be made in the specific embodiment of the invention described and illustrated herein within the scope of the claims which follow and without departing from the invention.

Figure 1 is a view in perspective of the applicator assembly of this invention illustrating the applicator as it may be packaged and at a time just prior to use.

Figure 2 is a longitudinal cross sectional view in side elevation showing the applicator with a portion of the dispensing end thereof torn away thus preparing the device for use.

Referring to the drawings, numeral 10 denotes generally an envelope having a centrally disposed pocket designated generally by numeral 12. Envelope 10 may

be formed in numerous ways, for example by sealing along edges of superimposed heat-sealable sheets. As may be seen in the drawings, envelope 12 is formed in such a fashion as to provide a restricted or neck portion 14 through which portion the contents of the envelope are dispensed.

Integral with envelope 10 and leading from the restricted or neck portion 14 is an elongated dispensing member designated by numeral 16. The member 16, as may be seen in dotted lines in Figure 1 and in cross section in Figure 2, is provided with a generally tubular passageway denoted by numeral 18. As can be best seen in Figure 2, the tubular portion of member 16 connects with neck 14 of the envelope thus providing a continuous passageway from the interior of the envelope to the point of extension of member 16.

Prior to the time of use, envelope 10 and member 16 are fully sealed from the atmosphere. However, at the time of use a portion of member 16 is torn away, cutting laterally across tubular portion 18 thereby providing an outlet for the envelope contents. In order to facilitate tearing away of the necessary portion, tear points 20 may be provided adjacent the end portion of member 16. These tear points may be formed in any suitable manner as by weakening or slightly cutting the edges of member 16 at the appropriate points, care being taken that the seal be maintained as regards tubular portion 18.

Numeral 22 denotes a generally tubular member surrounding the elongated portion of envelope 10. It has been found that tube 22 is desirable in using the device for the reason that greater comfort for the user is provided, and where the material from which envelope 10 and the extending portion 16 thereof is formed does not provide sufficient rigidity, tube 22 supplies this requisite.

Tube 22 preferably should be of a length approximately the same as member 16 after the end portion has been torn away. Suitably, tube 22 might be slightly longer in order to completely enclose the torn end of member 16 since if the torn end presents a ragged metallic-like edge the user should be protected against that portion of the device. As can be seen in Figure 2, tubular member 22 extends from a point just touching the edges of envelope 10 to a point adjacent the end of tubular portion 18.

It is contemplated that the general assembly shown in Figure 1 will be supplied by the manufacturer for use by the consumer already filled and sealed with a premeasured quantity of a suitable pharmaceutical formulation and that tubular portion 22 will be supplied the user at the same time, the afore-mentioned component parts forming the combination unit. Tube 22 may or may not be in place about member 16 as the supplier desires, although it is preferred that tube 10 be positioned about member 16 so as to facilitate packaging of the unit and to guard against damage to member 16 in handling.

As will be apparent from the foregoing, the applicator unit is employed by first tearing away the end of member 16 and, with tubular member 22 in place, the dispensing end of the applicator is inserted into the body cavity to whatever extent is necessary. Thereupon pressure is applied upon the walls of envelope 10 thereby discharging the contents therein through the tubular portion into the body cavity. The entire device may thereafter be disposed of in any desired manner.

Tube 22 may be formed of any suitable material such as a synthetic resin, for example polyethylene or polyvinyl chloride. However, for reasons of cost, comfort and the like paper providing sufficient rigidity is preferred.

Envelope 10 and extending member 16 likewise may be formed of various suitable materials, for example polyethylene, paper treated to be impervious to the contents of the package and to atmospheric effects, metal foil and the like. Metal foil is a common material for envelopes such as envelope 10 and the combined structure shown herein including the envelope; and extending member

16 may likewise be formed of metal foil, sealing taking place along the edges of the envelope and extending member 16 to provide a completely sealed package. The unit may be of various sizes although it is contemplated, preferably, that a size adapted to a single application of formulation will best serve the ends of the invention described herein; namely, that a single-use readily disposable applicator be provided.

Referring to the manufacture of envelope 10 and the depending dispensing member 16, an exceptionally suitable applicator may be provided by fabrication from very light gauge plastic or resinous material. For example, envelope 10 and dispensing member 16 may be formed as a unitary structure from substantially paper-thin polyethylene, the necessary rigidity in dispensing element 16 being achieved by the provision of rigid tubular member 22.

It is desired to point out that tubular portion of member 16 should be as small as is practicable, consistent with ease of dispensing the contents of envelope 10, so as to avoid unnecessary loss of formulation resulting from the amount remaining within the tubular portion.

It will be apparent to those skilled in the art that the principal objects of the invention have been accomplished and that numerous and various changes and modifications may be made in the embodiments of the invention herein described and that the invention is capable of use and has advantages not specifically described herein; it will, therefore, be appreciated that the hereinmade disclosures are to be construed in the nature of illustration only and that the invention is to be limited or delineated only by the appended claims.

What is claimed is:

1. A single-use applicator adapted to inject pharmaceutical formulations into body cavities, said applicator comprising a formulation-storage envelope, an elongated neck-like portion extending away from said envelope, said envelope and neck-like portion normally being sealed; a passageway within said neck-like portion extending substantially the entire length thereof and connecting with the interior of said envelope, said neck-like portion being adapted to be torn away thereby to open said passageway to the outside at a point remote from said envelope; and a straight tubular member fitting around said neck-like portion extending from said envelope to a point just short of the end of said elongated neck-like portion, the cross-section of said tubular member being about one-fourth the cross-section of said envelope and the length of said tubular member being about twice the length of said envelope.

2. An applicator as claimed in claim 1 wherein said envelope and neck-like portion are formed of a plastic material which is substantially paper-thin and the tubular member surrounding the said neck-like portion is formed to a rigid structure.

3. A pharmaceutical package comprising a single-use applicator adapted to inject pharmaceutical formulations into body cavities, said applicator comprising a formulation-storage envelope, an elongated neck-like portion extending away from said envelope, said envelope and neck-like portion normally being sealed; a passageway within said neck-like portion extending substantially the entire length thereof and connecting with the interior of said envelope, said neck-like portion being adapted to be torn away thereby to open said passageway to the outside at a point remote from said envelope; and a straight tubular member fitting around said neck-like portion extending from said envelope to a point just short of the end of said elongated neck-like portion, the cross-section of said tubular member being about one-fourth the cross-section of said envelope and the length of said tubular member being about twice the length of said envelope, and a pharmaceutical formulation in premeasured quantity contained in said applicator.

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4. A pharmaceutical package as claimed in claim 3 wherein said envelope and neck-like portion are formed of a plastic material which is substantially paper-thin and the tubular member surrounding the said neck-like portion is formed to a rigid structure.

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UNITED STATES PATENT OFFICE
CERTIFICATE OF CORRECTION

Patent No. 2,864,368

December 16, 1958

Frank A. Senger

It is hereby certified that error appears in the printed specification of the above numbered patent requiring correction and that the said Letters Patent should read as corrected below.

Column 4, line 59, for "neck-line" read -- neck-like --.

Signed and sealed this 10th day of March 1959.

(SEAL)
Attest:

KARL H. AXLINE
Attesting Officer

ROBERT C. WATSON
Commissioner of Patents