My invention relates to single dose vaginal applicators for water-base medicaments. Essentially, my applicator involves a cylinder containing a jelly-like, water-base medicament, a piston to eject the medicament, a removable cap or cover for the cylinder, and means for effectively sealing against the loss of the volatile constituents of the medicament. A fundamental problem confronting a device of this type is that the water and alcohol content or other volatile content of the medicament is substantially lost or greatly reduced during the storage period between manufacture and use. This storage period may extend over a number of months, and thus vary greatly in duration. If the vaginal applicator is not dependably volatile-solvent or water-vapor tight, there is an indeterminable loss of volatile content of the jelly-like base between manufacture and use so that the physical properties of the jelly-like water base medicament become unpredictable. This uncertainty of moisture or volatile solvent content at the time of use has heretofore rendered it impossible to provide a single dose piston and cylinder-type applicator acceptable to doctors or their patients.

Not only is the loss of moisture or solvent content and consequent change in physical properties a problem, but also the absorption of moisture into the material comprising the container over the possibly long storage period, often so weakens the container as to make it unstable. Thus, prior attempts to use wax impregnated paper or water soluble materials, such as polyvinyl alcohol, do not permit use of water or alcohol base jelly-like medicaments for vaginal applicators. The problem of a suitable container would be improved, were it possible to make cheaply a tubular container in one piece, such as an extrusion. However, such is not the case. It is much cheaper to form a tube by multiples of spiral wrappings, but this increases the problem of making it moisture or vapor proof. Even if the problem of the container per se is solved, there remains the problem of a seal around the removable cap and a seal around the plunger.

Attempts to circumvent this whole problem involves the use of nondrying chemicals in the medicament. This nondrying property itself often renders the resulting medicament unsatisfactory for use. The result has been that jelly-type water base medicaments have been sold sealed in collapsible metal tubes. The user is then required to transfer a dose as needed from the container to an applicator. This technique is at best inconvenient and messy, and at worst can be a source of serious contamination, whereas, were it possible to provide a medicament in a sealed cartridge unit which required only the removal of a cap, these disadvantages would be overcome.

Thus, it may be seen that to provide a piston and cylinder type dispenser which also meets the severe requirement that it be moisture or water-vapor proof and still hold the manufacturing cost low enough to permit it to be used once and then discarded, poses no small problem. Bearing this in mind, the objects of my invention include:

First, to provide a single dose dispenser for water or alcohol base jelly-like medicaments involving a piston and a capped cylinder construction which is sufficiently economical of manufacture that it may be discarded after a single use yet insures retention of the volatile solvent content even after several months of storage.

Second, to provide a dispenser or applicator of this class wherein means are employed to effect a vapor proof seal for the cylinder, cap and piston.

With the above and other object in view as may appear hereinafter, reference is directed to the accompanying drawings in which:

Figure 1 is a side elevational view of my applicator prior to use.

Figure 2 is a fragmentary longitudinal and essentially diagrammatical sectional view wherein the thickness of the various laminations comprising the container are exaggerated to aid the illustration.

Figure 3 is a similar fragmentary sectional view showing a modified construction.

Figure 4 is an essentially diagrammatical sectional view taken through 4—4 of Figure 1 showing the container cap and piston.

Figure 5 is a diagrammatical sectional view similar to Figure 4 illustrating a modified form of the piston.

Figure 6 is a fragmentary elevational view showing a modified form of removable cap.

Figure 7 is a fragmentary sectional view thereof through 7—7 of Figure 6.

One form of my applicator, shown in Figures 1 and 2, includes a cylindrical tube 1. The tube comprises an inner lamination of metal or plastic foil 2 backed by paper 3 and a sealant adhesive 4. This is helically wound on a mandrel with adjacent convolutions overlapping. Over the adhesive are wrapped one or more laminations of paper 5. The convolutions of these laminations are preferably in abutting relation. Over these laminations may be wrapped an outer lamination 6.
After manufacture, the tube 1 is dipped in a paraffin-wax mixture 7, for example, one-half paraffin and one-half microcrystalline wax. This mixture impregnates the paper laminations, and in particular, not only coats the metal foil 5 but also the edge of its backing paper 3. This is of primary importance for even the exposed edge of the backing paper as occurs normally in the spiral wrapping of the foil is sufficient to permit by capillary action the moisture content of a water base jelly to decrease by loss of water through the paper layer sandwiched between the overlapped foil layers.

Alternatively, as shown in Figure 3, a heavier foil 8 of either metal or water-impervious plastic such as polyethylene may constitute the inner lamination, and is not backed with paper. On metal foil, a sealant adhesive 9, preferably a heat sealing type is used. An aluminum foil of about .001 inch thickness may be used. This construction eliminates the need of the paraffin-wax mixture 1 as the overlapping margins are sealed together. The outer plies 5 and 8 may be similar to the construction shown in Figure 2.

The tube 1, whether constructed as in Figure 2 or 3, is covered at one end by a cap 10 which may be a section of a laminated paper tube identical, except for size, to the tube 1. This short tube of tube is rolled at one end and fitted with a disk 11 having a metal foil surface 12. Prior to placing the cap 10 on the cylinder 1, the end of the cylinder, or the interior of the cap is coated with a sealant 13. It has been found that melted petroleum jelly forms a particularly satisfactory sealant as well as facilitating its later removal.

The tube 1 is fitted with a thin flexible plunger 14 which may be formed of polyethylene. Secured to the plunger is a handle 15 which also may be formed of polyethylene. The handle or stem 15 may be initially folded upon itself as indicated by 16 in Figure 1 to shorten the length of the package and also to aid in maintaining the plunger in position.

As shown in Figure 4, the handle side of the plunger is covered with a sealant 13, identical to the sealant used between the cap and cylinder. Alternatively, as shown in Figure 5, a metal or plastic foil cup 17 is provided with a heat sealable coating 18. The cup is initially sealed in place by its flange to the inner surface of the tube 1, and is backed by the plunger 14. On forward movement of the plunger, the heat sealed connection between the flange of the cup and the walls of the tube, is ruptured.

The section of the cylinder between the cap 10 and plunger 14 is filled with a water or alcohol base jelly-type medicament. The filling may be done by first positioning the piston, then filling to the end of the cylinder, then placing the cap in position, or the cap may be first positioned then the medicament introduced from the other end of the cylinder and the plunger moved into positioning. In either case, the sealant 13 may be introduced around the plunger after the medicament has been introduced. This is done to minimize contact between the sealant and the medicament. In either case, the sealant 13 or 16 is rupturable or yieldable on movement of the plunger.

In place of the laminated paper cap 18, a plastic cap 19 formed, for example, of polyethylene may be employed. Such cap is indicated in Figures 6 and 7. If a cap of this type is used, it is sealed with the sealant 13 as in the first described structure. However, the extremity of skirt of the cap is provided with one or more slits 20 so as to provide tabs 21 which permit the cap to be torn off.

It is, of course, contemplated that the entire applicator is sterilized at the place of manufacture and wrapped in a sterile covering.

The importance of completely sealing water or alcohol base jelly-like medicaments can be illustrated by the following test. A medicament composition containing 5 weight percent alcohol, 89 weight percent water as volatile solvents and approximately 5 grams of active medicament per dosage was used. A tube (A) was constructed as shown in Figure 2 except that the foil ply 2 was omitted. However, the tube was impregnated and coated with 50 weight percent paraffin-wax and 50 weight percent microcrystalline wax. A polyethylene piston and waxed cap were used. The weight loss of solvent after one month's storage at room temperature was 68%.

A tube (B) was constructed in accordance with Figure 2 in which the paper backing 3 was 30-pound paper water resistantly adhesively bonded to 0.00085 inch thick aluminum foil and the paper likewise bonded to the outer laminations. No wax impregnation was used. The cap 10 and plunger 14 and a petroleum jelly sealant 13 was used. The weight loss of solvent after one month's storage at room temperature was 13%.

A tube (C) was constructed as in Figure 2 including the wax impregnation and coating 7; i.e. the same as tube (B) with the addition of the wax impregnation and coating. The cap and plunger was scaled with a petroleum jelly sealant 13. The weight loss of solvent after one month's storage at room temperature was 0%.

The metal foil employed may be formed of aluminum, silver or tin. The plastic, while preferably polyethylene, may also be: natural or synthetic rubber, polyvinylidene dichloride, butyl methacrylate, plasticized vinyl chloride-vinyl acetate copolymer, polyvinylidene chloride or polyvinyl alcohol as with similar properties. While petroleum jelly has been found satisfactory as the sealant 13, silicone jelly or wax compositions may be used.

Having fully described my invention, it is to be understood that I do not wish to be limited to the details herein set forth, but my invention is of the full scope of the appended claims.

I claim:

1. A single use vaginal applicator for water-base medicaments, comprising: a multiple-ply tubular body member having a plurality of paper plies and an inner water-impervious foil ply, said foil being water-imperviously adhesively bonded to the paper plies; a removable water-impervious cap for one end of said body member; a piston movable within said body member; a handle for said piston protruding from the end of said body member opposite from said cap; a water-impervious rupturable sealant member securing said cap to said body member; a second water-impervious rupturable sealant member securing said piston to the inner water-impervious ply of the body member; whereby a completely water-impervious chamber is formed within said body member to contain a water-base medicament.

2. A single use vaginal applicator for water-base medicaments, comprising: a multiple-ply tubular body member having an outer ply of paper and an inner metal foil ply; a water-im-
5. A single use vaginal applicator for water-base medicaments as set forth in claim 1, wherein: said foil is a metal foil.

6. A single use vaginal applicator for water-base medicaments as set forth in claim 1, wherein: said foil is a water-imperious plastic foil.

7. A single use vaginal applicator for water-base medicaments as set forth in claim 1, wherein: said sealant member for said cap and piston is formed of nondrying water-imperious jelly-like material.

8. A single use vaginal applicator for water-base medicaments as set forth in claim 1, wherein: said sealant member for said piston is a rupturable foil sealed to the inner surface of said body member.

9. A single use vaginal applicator for water-base medicaments as set forth in claim 4, wherein: said foil is backed by paper and the edges of said paper at the overlapping margins of said foil are impregnated by said sealing means.

10. A single use vaginal applicator for water-base medicaments as set forth in claim 4, wherein: the overlapping margins of said foil are impregnated with and sealed by said sealing means.

11. A single use vaginal applicator for water-base medicaments as set forth in claim 4, wherein: said foil is a metal foil.

12. A single use vaginal applicator for water-base medicaments as set forth in claim 4, wherein: said foil is a water-imperious plastic foil.

13. A single use vaginal applicator for water-base medicaments as set forth in claim 4, wherein: said sealant member for said cap and piston is formed of a nondrying water-imperious jelly-like material.

14. A single use vaginal applicator for water-base medicaments as set forth in claim 4, wherein: said sealant member for said piston is a rupturable foil sealed to the inner surface of said body member.

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