

[54] **CAPSULE**
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 [58] **Field of Search** 128/260, 270, 271, 128

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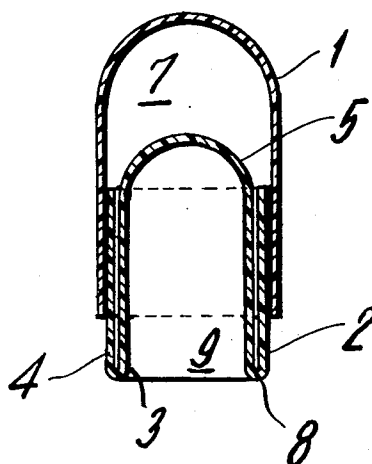
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[57]

ABSTRACT

A two piece capsule comprising a first, tubular open ended half and a second tubular open ended half in which the side wall is folded over externally on itself to form an annular outer wall, the closed end of the second half being inserted into the open end of the first half, is particularly suitable for intravaginal use.

7 Claims, 4 Drawing Figures



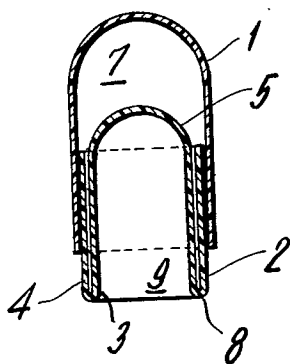


FIG. 1

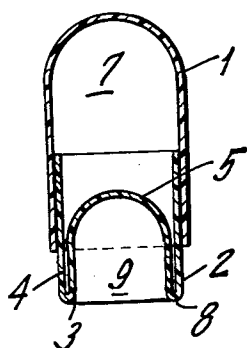


FIG. 3

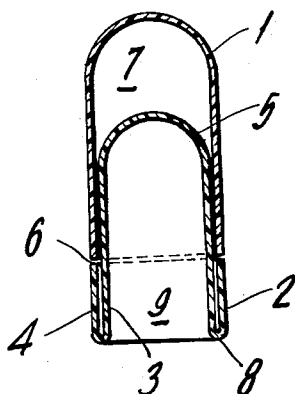


FIG. 2

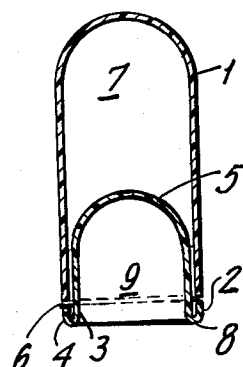


FIG. 4

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CAPSULE

BACKGROUND AND SUMMARY OF THE INVENTION

When medicaments are applied intravaginally, the therapeutic result depends upon inserting the medicament as deeply as possible into the vagina. Introduction with a finger of conventional therapeutic forms for the intravaginal application of medicines, namely vaginal tablets, vaginal ovules or even vaginal suppositories, often leads to difficulties, since the finger can slip past them and the medicament is not pushed forward to the desired place of application. There are also applicators which may be used repeatedly over a period of time. Experience has shown, however, that these applicators are often not sufficiently cleaned by the patient and above all not disinfected or sterilized so that in the case of infections of the vagina the danger of reinfection remains.

It has now been found that these difficulties may be overcome by means of a new form for these medicaments. This comprises a two piece capsule, which when assembled with the medicament therein, may be generally characterized as thimble shaped. The open end provides a receptacle in which the tip of a finger may be inserted so that the capsule may be easily and accurately introduced to the right place. Upon withdrawal of the finger, the capsule remains where placed and the rim resists the natural tendency for the capsule to be expelled.

THE DRAWING

FIG. 1 shows a cross section of the two piece capsule wherein the second half is inserted into the first half with the external wall also within the first half.

FIG. 2 shows a cross section of the two piece capsule wherein the rim of the external wall of the second half abuts the rim of the first half.

FIG. 3 shows a modification of the capsule shown in FIG. 1 in which the external walls extend beyond the closed end of the second half.

FIG. 4 shows a modification of the capsule shown in FIG. 2 in which the second half has smaller proportions.

DETAILED DESCRIPTION OF THE INVENTION

The capsule of this invention, particularly adapted for intravaginal use comprises two parts which, for the sake of convenience of reference, are termed here the top cap portion and the bottom closure portion. These are designated in the Figures as 1 and 2, respectively.

Both parts are tubular in shape, hollow and open ended somewhat similarly to the conventional two piece dry-fill gelatin capsule for oral administration. The bottom, closure portion differs, however, in that it is twin walled over some or all of its length. That is, the wall of this part is folded over or reversed on itself externally so as to form an annular, outside side wall about one-fourth to three-fourths of the length of this closure portion as in FIGS. 1, 2 and 4 or even longer as in FIG. 3. The external side wall is a continuation of the internal side wall of the capsule through a U-shaped bend which provides a smoothly curved rim 8 rather than a sharp edge.

The interior side wall is designated 3 and the annular external side wall is designated 4 in each of the Figures.

As a second departure from the conventional, the closed end 5 of the second part of the capsule is inserted into the open end of the first, cap portion 1 thus leaving the open end of the second half as an aperture or receptacle into which the tip of a finger may be inserted.

In the embodiment shown in FIG. 1, the bottom portion 2 is telescopically inserted into the cap portion 1, so that the external side wall 4 extends partially within the cap forming a tight, friction-fit closure.

In the embodiment shown in FIG. 2, the external side wall 4 extends only part way along the inside wall of the capsule as indicated in that figure. In this case, the internal side wall of the bottom part is telescopically inserted into the cap and forms the tight closure by friction fit. The external side wall does not extend into the cap and its rim 6 abuts the rim of the cap.

In another embodiment shown in FIG. 3, the external side wall 4 extends beyond the closed end 5 shortening the aperture 9 in this instance to about one-fourth to one-half the length of the external wall. A shortened aperture 9 is also shown in the modification of FIG. 4.

The diameter of the bottom, portion 2 is suitably adjusted in size in the respective modifications so that a tight closure, sealing and protecting the contents, is made.

The medicament to be carried by the capsule, and any vehicle or excipient conventionally formulated with such medicament is contained within the space formed between the closed ends of the two parts of the capsule, i.e., the chamber 7.

The medicament carried by the capsule may be liquid, semi-solid or solid as in the conventional capsule for oral administration. Any agent intended for intravaginal use may be administered in this form, e.g., trichomonacides and other antimicrobial agents, anti-inflammatory agents, etc.

The capsule may be produced from conventional materials, i.e., hard or soft gelatin or other substances used for oral capsules, which melt or disintegrate at internal body temperature or in the presence of moisture or other secretions. The wall of the bottom, closure portion of the capsule is fabricated longer than the conventional capsule half so that a portion of this wall may be folded over itself to form the external wall of appropriate length. The external wall is a continuation of the internal wall and turned in such a fashion that the rim 8 forms a smooth curve. The smooth curve avoids a sharp edge which may injure the finger which is used to insert the capsule or, more importantly, the delicate internal tissues.

The capsules for intravaginal use are larger in overall size than capsules for oral administration i.e., somewhat larger than the 000 oral size and more of the order of veterinary 11 or 12 capsules.

The active medicament, either singly or a mixture, and any additional materials such as a solvent, vehicle, excipient or the like, normally formulated with it, is placed in the cap in appropriate dosage and proportions. Then the bottom part is inserted into the cap, closed end forward so that the therapeutic material is enclosed within the chamber formed between the two halves of the capsule. The capsules are so formed that the external wall in the modifications of FIGS. 1 and 3 or the internal wall in the modifications of FIGS. 2 and 4 provide a tight closure by friction fit encasing and protecting the material within the capsule. When the

two parts are fit together, the overall contours are suggestive of a thimble with a thickened end. This is further suggested in that the open end of the bottom half of the capsule provides an aperture 9 into which the tip of a finger may be inserted in order to introduce the capsule into the vagina. The two modifications shown particularly permit medicaments to be introduced deep into the vagina without difficulty. The capsule has the additional advantage over vaginal tablets and vaginal ovules frequently used in that the difficulties of disintegration in a dry inflammation of the vagina are overcome. Whereas vaginal tablets and ovules remain as solid bodies in the case of insufficient secretion, cause pressure pains and especially do not release the medicament, a gelatin capsule is softened by minimal fluid content and the power or fluid content of a capsule adjust to local conditions without producing undesirable pressure.

What is claimed is:

1. A two piece capsule comprising a first tubular half open at one end and a second tubular half open at one end, the side wall of said second half being folded over externally on itself at the open end, the second half fitting telescopically, closed end forward, into said first

half and forming a chamber between the closed ends of said halves.

2. A capsule as in claim 1 wherein the externally folded portion of the side wall extends about one-fourth to three-fourths of the length of the second half of the capsule.

3. A capsule as in claim 1 wherein the externally folded portion of the side wall extends beyond said closed end.

4. A capsule as in claim 1 wherein a part of the externally folded portion of the side wall of the second half extends into the first half to form a tight closure.

5. A capsule as in claim 1 wherein the rim of the externally folded portion of the side wall of the second half abuts the rim of the first half of the capsule in the closed position to form a tight closure.

6. A capsule as in claim 4 wherein a medicament is contained within the space formed between the two halves of the capsule.

7. A capsule as in claim 5 wherein a medicament is contained within the space formed between the two halves of the capsule.

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