

[54] **VAGINAL CAPSULE**

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[58] Field of Search .... **128/271, 272, 270, 261;  
424/37, 14**

[56] **References Cited**

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[57]

**ABSTRACT**

A water soluble cylindrically shaped vaginal capsule is described comprising a sealed elongated large diameter portion containing a medicament and an elongated small diameter portion located at the distal end of the large diameter portion. This capsule is useful in treating vaginal infections such as vaginal moniliasis in pediatric patients.

**3 Claims, 2 Drawing Figures**

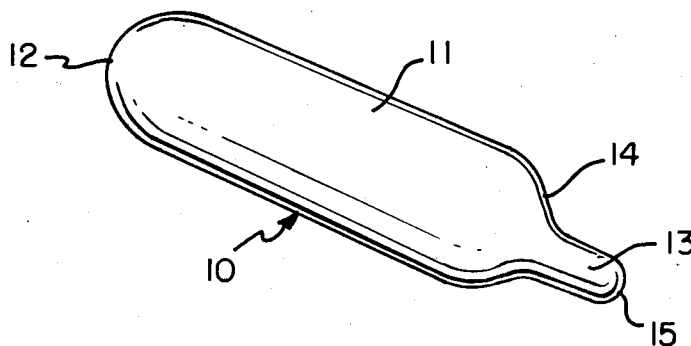


FIG. 1

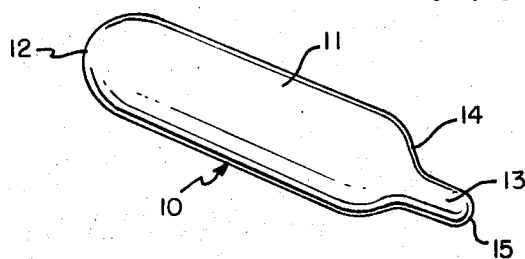
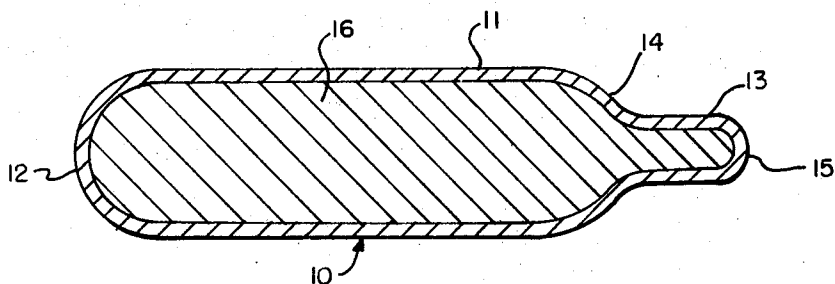


FIG. 2



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## VAGINAL CAPSULE

This invention relates to a novel medicament containing vaginal capsule.

In pediatric patients who not infrequently incur vaginal infections such as caused by *Candida albicans*, it has been difficult to effectively treat such infections where the patient retains her hymen. This membrane acts as a barrier against the passage of the medicament to the situs of the infection. Therefore, in many instances it is necessary to rupture the hymen to treat the patient.

The present invention provides a medicament containing water soluble capsule that is designed for use in treating vaginal infections without requiring rupture of the hymen.

Accordingly, one aspect of the present invention is to provide a vaginal capsule containing a premeasured quantity of medicament for use in treatment of vaginal infections such as *Candida albicans*.

Another aspect of the present invention is to provide a vaginal capsule that has deformable walls so that the medicament content may be squeezed from the capsule.

A still further aspect of the present invention is to provide a vaginal capsule that is conveniently used in pregnant or gravid patients without the use of an applicator.

An additional aspect of the present invention is to provide a vaginal capsule that contains the medicament candididin.

These and other aspects of the present invention will be apparent from the following description and drawings in which

FIG. 1 is a perspective view of a capsule according to the present invention; and

FIG. 2 is a sectional view of the capsule of the present invention.

Turning now to the drawings, FIG. 1 shows a vaginal capsule 10 generally cylindrical in shape having an elongated deformable large diameter body portion 11, a large diameter hemisphere-shaped end portion 12 integrally connected to the proximal end of body portion 11 and an elongated deformable small diameter portion 13 connected at the distal end of large diameter portion 11 by an integrally formed slope portion 14 and having a small diameter hemisphere-shaped end portion 15. Both large diameter portion 11 and small diameter portion 13 contain medicament 16. The length of small diameter portion 13 is substantially less than that of large diameter portion 11.

The vaginal capsule is dimensioned so that it can conveniently hold the desired quantity of medicament and be comfortably inserted in the vaginal tract. The dimensions of elongated small diameter portion 13 are such that this portion of the capsule can be inserted through the imperfections in the wall of the hymen located at the vagina orifice without damaging the hymen. The preferred outside circumference of small diameter portion 13 is about three sixteenths of an inch. The overall length of capsule 10 is about 2½ inches with the large diameter portion having a length of about 2 inches.

The vaginal capsule is preferably manufactured from a

gelatin containing composition that is water soluble.

The walls of the capsule are deformable so that medicament may be squeezed out after the hemisphere portion 15 of small diameter portion 13 is cut off.

5 The capsule provides an air tight encasement for medicament 16 (e.g., 3 mg. of candididin in a petrolatum base) which is necessary in order to maintain the potency and stability of this material during storage.

10 The vaginal capsule may be used either by inserting it in the vaginal area and permitting the capsule to dissolve or the medicament may be squeezed from the capsule as previously indicated. This latter technique is particularly desirable in the treatment of vaginal infections in pediatric patients who still retain their hymen.

15 The following example describes the manufacture of the vaginal capsule of the present invention containing three mg. of candididin in a petrolatum base which is used to treat infections caused by *Candida albicans*.

Candididin ointment (Petrolatum base) is melted at 53° to 20 55° C. and evacuated in the fluid state. The ointment is then cooled to approximately 33° to 35° C. prior to encapsulation. The ointment is injected into a standard gelatin mold composed principally of gelatin and glycerin with minor quantities of methyl and propyl parabenzoate to form the capsule by 25 means of a positive displacement pump. During the encapsulation the ointment is kept well mixed and the positive displacement pump is set to deliver 5,000 mg. of ointment containing 3 mg. candididin. The encapsulation procedure is carried out at a temperature between 32° and 34° C.

30 The foregoing capsule provides a unit does form which eliminates the use of an applicator. The medicament may be any material that is used locally to treat vaginal infections such as antifungal agents (e.g., nystatin, amphotericin B); antibacterial agents (e.g., 9 aminoacridine, nitrofurazone, oxytetracycline), etc.

What is claimed is:

1. As an article of manufacture a medicament containing water soluble capsule for use in treating vaginal infections, said capsule being cylindrical in shape and having an elongated deformable large diameter body portion containing a 40 premeasured quantity of medicament useful in the treatment of vaginal infections, and an elongated deformable small diameter portion located at the distal end of said large diameter portion and integrally connected to said large diameter portion by a sloped portion, said small diameter portion being of substantially less length than said large diameter portion and the opposed ends of said capsule being hemispherical in shape.

45 2. An article of manufacture according to claim 1 wherein said medicament is candididin.

3. An article of manufacture according to claim 2 wherein said large diameter portion and said small diameter portions are composed of gelatin.

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