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(54) IMPROVEMENTS IN AND RELATING TO FLUIDS ADMINISTRATION DEVICES

(71) We, IMS LIMITED, a Delaware corporation of the United States of America, of 408 South Spring Street, Suite 510, Los Angeles, California 90013, United States of America, do hereby declare the invention, for which we pray that a patent may be granted to us, and the method by which it is to be performed, to be particularly described in and by the following statement:—

This invention relates to fluids administration devices.

Heretofore various packaging devices and administration devices have been proposed for the administration of fluids such as creams, spermicides, and the like into the vagina. All of these devices have been characterized by various drawbacks including difficulty of manufacture, cumbersomeness in operation and general lack of acceptability.

The device of U.S. Patent No. 2,855,931 (Brown), although not intended for vaginal use, might, upon superficial examination, appear to be suited for vaginal use. However, the external recess at the closed end of the casing would retain medicament when in the vertical position, resulting in wastage of a portion of the medication which could be avoided, if at all, only by the use of the device while in the prone position. In general, administration in the prone position is ineffective to avoid waste of viscous materials and unacceptable because restrooms and lavatories are not provided with the facilities needed to assume such position. Further, the device disclosed in U.S. Patent No. 2,855,931 has external protuberances which would be objectionable in vaginal use. In addition, the device is too short to reach the area around the opening of the uterus. Also, it is not possible to change vials while the casing is within the vagina, so that administration of more than one vial re-

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quires complete withdrawal of the device from the vagina for each vial.

U.S. Patent No. 1,833,598 (Smith) discloses a device said to be useful for vaginal administration. However, it is clear that the device there described contains not only a fluid passage within the injector, but also a hollow tubular stem-like element protruding therefrom which terminates in a globular, bulbous-like knob. The medicinal contents are expelled by hydraulic pressure produced within the column of fluid which, in use, extends the length of both the fluid passage within the injector and the protruding element including the knob. In operation of the disclosed device, a significant amount of medicament would inevitably remain as a residual fluid column. This residual amount remaining would be wasted, since once the vial has been bottomed out in the injector, no further force is present to expel this fluid column.

The present invention provides a device for the administration of fluids into the vagina, comprising an elongated generally cylindrical hollow tubular member adapted to be inserted into the vagina and having an open end and a generally smooth rounded end which is closed apart from an aperture therein for the discharge of fluid, and a cylindrical vial which is capable of being received in the open end of said tubular member, said vial having a resilient stopper in an open end which seals on the inside walls of said vial and which has an imperforate central diaphragm portion, a thrust portion being provided within said tubular member, said thrust portion being substantially coextensive in length with said tubular member, said thrust portion having a fluid passage extending in a lengthwise direction with respect to the thrust portion, said fluid passage having a substantially uniform cross-section along its length, one end of

said passage terminating at the said aperture in said rounded end, the end of said thrust portion adjacent the other end of said passage having a sharp terminal portion having one or more holes therein communicating with the said other end of said passage, said thrust portion also having in proximity to the end adjacent the said other end of said passage stopping means for the vial stopper, the arrangement being such that, when in use said stopper is forced over said sharp terminal portion and said central diaphragm portion is punctured by said sharp terminal portion, said stopper is held by said stopping means and functions as a piston to expel the contents of the vial through said passage as said vial is moved into said tubular member.

The device of the invention can be easily made and loaded, is free of structure which might create physical or psychological objections, and is such that essentially all the medication contained in the vial can be administered to the host. More specifically, the device of the present invention provides an administration device which can be made of a minimum of parts, which parts can be readily fabricated from glass, rubber and plastics. The device, at least over the region which is to be inserted into the vagina, is free of external recesses and protuberances. Hence, it is tolerable to the user, and can be applied with the human body in virtually any position in which injection into the vagina is possible. Moreover, the device is such that the length of the injector is appropriate for vaginal use.

Advantageously, the tubular member is provided at the exterior of its open end with wings to aid in the handling and operation of the device. This facilitates the sequential administration of vials without the withdrawal of the tubular member from the vagina.

A fluids administration device constructed in accordance with the invention will now be described, by way of example, with reference to the accompanying drawings, in which:

Figure 1 shows a sectional view of the device prior to assembly;

Figure 2 is a sectional view of the device after assembly and administration has been completed;

Figure 3 is a perspective end view of one portion of the device;

Figure 4 is a perspective view showing how the device is held during insertion into the vagina; and

Figure 5 is a perspective view showing how vials are gripped for changing while the vial holder remains within the vagina.

Turning to the drawings in further detail, the device comprises a vial 10 in which the cream, spermicide, or any other desired

medication fluid is contained. The vial 10 has a resilient stopper 12 provided with a thin diaphragm portion 14 and sealing rings 16. The portion 14 is disposed flush with the external side or face of the stopper 12. The device also includes an elongated tubular holder or injector 18 having a thrust portion 20 therein. The tubular holder 18 has an open end for receiving the vial and a generally smooth rounded end 28 which is closed apart from an aperture 26 therein for the discharge of fluid. The thrust portion 20 is substantially coextensive in length with the holder 18 and has a passage 22 extending in a lengthwise direction with respect to the thrust portion and over substantially the entire length hereof. The passage 22 permits fluid to pass from holes 24, which are provided in a sharp terminal portion 32 of the thrust portion 20, to the aperture 26. The holder 18 is intended to be inserted in the vagina with the aperture 26 innermost. The external smooth curved surface 28 has a generally rounded tapering configuration with the degree of taper gradually increasing in the direction of the closed end, which facilitates the insertion of the device within the vagina. A disk-like member 30 at the upper end (as seen in the drawing) of the thrust portion 20 acts as a stop so that when the stopper 12 is punctured by a sharp end portion 32 of the thrust portion 20, the contents of vial 10 are discharged through the passage 22 as a result of the stopper 12 being held in place by the disk-like member 30. Wings 34 are for gripping of the device during insertion and operation.

In operation, when the vial 10 is inserted in the holder 18, the stopper 12 is restrained by the disk-like member 30 and the diaphragm portion 14 is punctured by the sharp portion 32 communicating the holes 24 on thrust portion 20 with the contents of vial 10, so that the stopper 12 functions as a piston in vial 10 and permits the discharge of the contents of the vial through aperture 26. Preferably, the tubular holder 18 is provided with openings 36 which are diametrically opposed to each other at the open end of the holder. These openings permit the changing of vials and the sequential administration of dosages without the removal of the holder 18 from the vagina. The empty vial is simply grasped at openings 36 and removed. A second vial can then be inserted in the holder.

As shown in the drawings, the thrust portion 20 is cylindrical in cross-section with a pointed tip at the upper end of the thrust portion, the end of the thrust portion being provided with a blunt surface which acts as a stop for the vial stopper. Many variations on this construction are possible. For example, the thrust portion may be

tapered in its longitudinal dimension to form a point at its upper end. In this case, wings or a collar or some other external protrusion is provided in proximity to the upper end of the thrust portion to act as a stop for the vial stopper.

While it will be understood that the vial may fit loosely within the holder, it is preferred that the vial fit snugly within the holder, that is, that the outside diameter of the vial be only slightly less than the inside diameter of the holder. This has been found to facilitate the alignment of the vial with the holder when changing vials while the holder is in place within the vagina. At this point in the operation, the configuration of holder and vial just described tends to automatically align the vial with the holder. The alignment can be readily accomplished by feel, thereby eliminating problems which can occur during alignment based upon visual observation.

The sealing rings 16 form a force or sealing fit with the interior of the vial. However, the amount of interference is such that the stopper 12 can be reciprocated within the vial 10 in piston-like fashion without undue force.

WHAT WE CLAIM IS:—

1. A device for the administration of fluids into the vagina, comprising an elongated generally cylindrical hollow tubular member adapted to be inserted into the vagina and having an open end and a generally smooth rounded end which is closed apart from an aperture therein for the discharge of fluid, and a cylindrical vial which is capable of being received in the open end of said tubular member, said vial having a resilient stopper in an open end which seals on the inside walls of said vial and which has an imperforate central diaphragm portion, a thrust portion being provided within said tubular member, said thrust portion being substantially coextensive in length with said tubular member, said thrust portion having a fluid passage extending in a lengthwise direction with respect to the thrust portion, said fluid passage having a substantially uniform cross-section along its length, one end of said passage terminating at the said aperture in

said rounded end, the end of said thrust portion adjacent the other end of said passage having a sharp terminal portion having one or more holes therein communicating with the said other end of said passage, said thrust portion also having in proximity to the end adjacent the said other end of said passage stopping means for the vial stopper, the arrangement being such that, when in use said stopper is forced over said sharp terminal portion and said central diaphragm portion is punctured by said sharp terminal portion, said stopper is held by said stopping means and functions as a piston to expel the contents of the vial through said passage as said vial is moved into said tubular member.

2. A device as claimed in claim 1, wherein the thrust portion is generally cylindrical.

3. A device as claimed in claim 1 or claim 2, wherein the stopper has a plurality of sealing rings thereon.

4. A device as claimed in any one of claims 1 to 3, wherein the tubular member is provided at the exterior of its open end with wings to aid in the handling and operation of the device.

5. A device as claimed in any one of claims 1 to 4, wherein the tubular member is provided at its open end with openings to facilitate removal of said vial therefrom.

6. A device as claimed in any one of claims 1 to 5, wherein the outside diameter of the vial is only slightly less than the inside diameter of the tubular member.

7. A device as claimed in any one of claims 1 to 6, wherein the exterior of the tubular member tapers in the vicinity of the rounded end with the degree of taper gradually increasing in the direction of the rounded end.

8. A device for the administration of fluids, substantially as hereinbefore described with reference to, and as shown in, the accompanying drawings.

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said rounded end, the end of said thrust portion adjacent the other end of said passage having a sharp terminal portion having one or more holes therein communicating with the said other end of said passage, said thrust portion also having in proximity to the end adjacent the said other end of said passage stopping means for the vial stopper, the arrangement being such that, when in use said stopper is forced over said sharp terminal portion and said central diaphragm portion is punctured by said sharp terminal portion, said stopper is held by said stopping means and functions as a piston to expel the contents of the vial through said passage as said vial is moved into said tubular member.

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7. A device as claimed in any one of claims 1 to 6, wherein the exterior of the tubular member tapers in the vicinity of the rounded end with the degree of taper gradually increasing in the direction of the rounded end.

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