

PATENT SPECIFICATION (11)

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(54) IMPROVEMENTS IN AND RELATING TO FLUID ADMINISTRATION DEVICES

(71) We, IMS LIMITED, a corporation organised according to the laws of the state of Delaware, United States of America, of 1886 Santa Anita Avenue, South El Monte, California, 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 devices for the administration of fluids, and especially to devices suitable for the administration of viscous fluids to the human urethral tract.

Various medicaments are administered to the urethral tract. One of the most common is a topical anaesthetic such as lidocaine hydrochloride which is used in the form of a viscous fluid having a carboxymethyl cellulose carrier. Presently, this viscous fluid is supplied in a malleable metal, roll-up tube which resembles a toothpaste tube. In use, a urethral tip is attached to the open end of the tube, and a key is attached to the closed end of the tube. By rotation of the key, the tube is rolled up, discharging the contents of the tube through the tip. This device is very awkward in use. In the case of administration of males, it is virtually impossible for one person to administer the medication since one hand is needed to hold the tube, a second is required to turn the key to roll-up the tube, and a third being necessary to maintain the urethral tip within the end of the penis.

There has been a long-standing need for a device capable of use by a single physician or nurse to administer medicaments to the urethral tract.

The present invention provides a device for the administration of viscous fluids comprising a barrel, one end of which has an end wall and the other end of which is open, an elongate thrust portion within said barrel and terminating in proximity to the open end of said barrel, a fluid passage member extending lengthwise within and terminating

within said thrust portion, said fluid passage member having a central bore of sufficient diameter to readily allow the passage of viscous fluid therethrough, puncturing means associated with the end of said fluid passage member that is nearer to the open end of the barrel, and an elongate urethral tip extending from said barrel at the end remote from the open end and communicating with said central bore, said tip including a cylindrical portion and a smooth rounded end immediately adjacent the cylindrical portion, there being a hole in the rounded end which serves as an outlet and the cylindrical portion and rounded end being adapted to be received within the urethral tract, and the thrust portion is provided with interlocking means, the arrangement being such that, in use of the device with a vial having an open end and a closed end and a resilient reciprocable stopper in the vial provided with interlocking means adapted to be interlocked with the interlocking means of the thrust portion, the stopper of the vial can be punctured by the puncturing means and the stopper and thrust portion interlocked so that the contents of the vial can be expelled by relative movement of the vial towards the barrel.

The device of the invention enables one person to administer medication to the urethral tract. The device can be operated with one hand, freeing the other for maintaining the urethral tip in the proper position. Viscous medication can thus be administered with a minimum of time and manual effort, and the device eliminates the need for malleable tubes and other metal parts.

The urethral tip may be made separately from the barrel and the thrust portion, which may be formed integrally with each other. Similarly, the fluid passage member may be made separately from the thrust portion and barrel.

A tip may be carried on said fluid passage member at the end that is nearer to the open end of the barrel, said tip comprising a solid puncturing point at one end of the tip and

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a zone of generally larger diameter than said point, the interior of said zone communicating with said central bore, and said zone having one or more orifices therein to provide fluid communication between the central bore and the exterior of said zone. The tip may be made separately from the fluid passage member. A flange may be provided on said tip on the side of said zone remote from the puncturing point, said flange being adapted to limit the lateral movement of said fluid passage member and tip with relation to said thrust portion to maintain an essentially concentric relationship therebetween.

A flange adapted to limit the lateral movement of the fluid passage member with relation to the thrust portion to maintain an essentially concentric relationship therebetween may be provided on the fluid passage member.

The urethral tip may have, adjacent to the cylindrical portion, an externally tapered portion extending to the barrel and having its largest diameter at the barrel. The urethral tip may have a hollow internal central bore which communicates with the said central bore of the fluid passage member, the bore of the urethral tip being at least equal in inside diameter to the inside diameter of the fluid passage member.

The invention also provides a combination of a device for the administration of viscous fluids as defined above and a vial having an open end and a closed end and a resilient reciprocable stopper sealing on the walls of said vial, the stopper being provided with interlocking means adapted to be interlocked with the interlocking means of the thrust portion, the arrangement being such that, after the stopper has been punctured by the puncturing means and the stopper and thrust portion interlocked, the stopper can be reciprocated in the vial by pushing or pulling the vial relative to the barrel.

The stopper may have a centre hole therein bridged by an imperforate diaphragm.

Devices for the administration of viscous fluids and vials for use therewith will now be described, by way of example, with reference to the accompanying drawings, in which:

Figure 1 is a sectional view of a first, preferred, device, and of a vial, in the disassembled state;

Figures 2 to 5 are perspective views of various parts of the device and vial of Figure 1;

Figure 6 is a sectional view of the device and vial of Figure 1 in the assembled or operating position;

Figure 7 is an enlarged view of a part of the assembly of Figure 6;

Figure 8 shows the use of the device of

Figure 1 in the administration of a drug to the penis;

Figure 9 illustrates a second device and a vial for use therewith; and

Figure 10 is a perspective view of a part of the device of Figure 9.

Turning to the drawings in detail, the first device includes a barrel 10, flanges 12, and a thrust portion 14. The thrust portion 14 is provided with interlocking means in the form of internal or female threads 16 at its open end.

The vial 18 normally has straight walls and a resilient reciprocable stopper 20 within its open end. The stopper 20 has a plurality of rings 22 which seal on the inside wall of the vial 18. The stopper 20 also has a projection 24 which has interlocking means in the form of threads. The male threads 26 on projection 24 are adapted to be made up with threads 16. The stopper 20 has a central bore 32 which is bridged prior to use by diaphragm 34 to form a flat smooth end.

Caps 36 and 38 which form an aseptic seal on the vial 18 and barrel 10, respectively, prior to use are held in place by an interference or snap-fit. At the time of use, these caps are removed and discarded. A fluid passage member 40, which extends lengthwise in the thrust portion 14, has a centre bore 42 which allows for the ready passage of viscous or thixotropic materials therethrough. A flange 44 on the fluid passage member 40 is received and held in recess 46 in the bottom of barrel 10. The fluid passage member 40 may be held in recess 46 by fusion, such as is produced by spin welding, or by glue or cement. The fluid passage member 40 carries at its free end a tip 48. The tip 48 comprises a solid puncturing point 50 at one end having a generally circular cross-section, and a zone 52 of generally larger diameter than said point, the interior 54 of said zone 52 communicating with the central bore 42, and said zone 52 having one or more orifices or openings 56 therein to provide fluid communication between central bore 42 and the exterior of zone 52. The external diameter of zone 52 in proximity to the orifices 56 is less than the inside diameter of the central bore 32 of stopper 20. The interior 54 of the zone 52 is preferably adapted to receive the end of fluid passage member 40 with a snug or interference fit. The zone 52 above the end of fluid passage member 40 preferably has the same inside diameter as the central bore 42 to provide a fluid passage of substantially uniform cross-sectional area.

A flange 58 on the tip 48 acts as a centralizer, and prevents any substantial lateral movement of the tip 48 and fluid passage member 40 within thrust portion 14. Flange 58 thus ensures that the tip 48 and its

orifices 56 are within central bore 32, to provide proper fluid communication.

An elongate urethral tip 59 extends from an end wall which is provided at the lower end (as seen in the drawings) of barrel 10. The central or axial opening in tip 59 is in alignment with centre bore 42. The end portion of tip 59 is generally cylindrical, as shown at 60, and has a smooth external surface. An opening 62 in the end of tip 59 meets the cylindrical portion 60 in a rounded-off portion 64 and serves as an outlet.

A cover 66 is received with a snap fit on the exterior of tip 59 to form an aseptic seal. The cover 66 is, of course, removed just prior to use.

The tip 59 can be spun welded, glued, or otherwise formed or joined with the barrel 10.

In operation, the stopper 20 is interlocked with the thrust portion 14 by the making up of threads 16 and 26, thereby causing the puncturing point 50 to pierce the diaphragm 34. Fluid communication between the vial 18 and fluid passage member 40 is thereby established. (Figures 6 and 7). The tip 59 is then inserted in the urethral tract as shown in Figure 8. The device may be held in place with one hand by grasping, for example, the lower end of barrel 10 and the end of the penis. Injection of the contents of vial 18 is then carried out with the other hand by applying a squeezing force between the end of vial 18 and flanges 12 until the stopper 20 reaches the bottom of the vial 18.

The invention is particularly adapted to the administration of thick viscous materials such as lidocaine hydrochloride in a carb-oxy-methyl cellulose carrier. The inside diameter of central bore 42 is considerably larger than that of a conventional large gauge cannula. The size of central bore 42 permits the discharge therethrough of viscous materials with a minimum of time and manual effort on the part of the physician or nurse. The invention is, however, not limited to use in the urethral tract.

Turning to Figures 9 and 10, the second device comprises a barrel 100, flanges 102, thrust portion 104 and threads 106, which are identical to the barrel 10, flanges 12, thrust portion 14 and threads 16, respectively, of the first device. Likewise, vial 108, stopper 110, sealing rings 112, projection 114, threads 116, central bore 118, diaphragm 120 and urethral tip 122 of the second device are identical to vial 18, stopper 20, sealing rings 22, projection 24, threads 26, central bore 32, diaphragm 34 and urethral tip 59, respectively, of the first device. The fluid passage member 124 of the second device is, as with the fluid passage member 40 of the first device, considerably larger in inside diameter than a con-

ventional large gauge cannula. The central bore 126 allows the ready passage of viscous material therethrough. The fluid passage member has a flange 128 which is received in recess 130 in the bottom of barrel 100 as in the first device. The external diameter of the free end 132 of fluid passage member 124 may be smaller, equal to, or even slightly larger than the inside diameter of central bore 118. A centralizing disk or flange 134 on the fluid passage member 124 functions as previous described in relation to the flange 58 of the first device, that is, it limits the lateral movement of the fluid passage member 124 with relation to the thrust portion 104 to maintain an essentially concentric relationship therebetween.

The materials of construction of the second device are normally plastics except for the glass vial 18 and the rubber stopper 20.

WHAT WE CLAIM IS:—

1. A device for the administration of viscous fluids comprising a barrel, one end of which has an end wall and the other end of which is open, an elongate thrust portion within said barrel and terminating in proximity to the open end of said barrel, a fluid passage member extending lengthwise within and terminating within said thrust portion, said fluid passage member having a central bore of sufficient diameter to readily allow the passage of viscous fluid therethrough, puncturing means associated with the end of said fluid passage member that is nearer to the open end of the barrel, and an elongate urethral tip extending from said barrel at the end remote from the open end and communicating with said central bore, said tip including a cylindrical portion and a smooth rounded end immediately adjacent the cylindrical portion, there being a hole in the rounded end which serves as an outlet and the cylindrical portion and rounded end being adapted to be received within the urethral tract, and the thrust portion is provided with interlocking means, the arrangement being such that, in use of the device with a vial having an open end and a closed end and a resilient reciprocable stopper in the vial provided with interlocking means adapted to be interlocked with the interlocking means of the thrust portion, the stopper of the vial can be punctured by the puncturing means and the stopper and thrust portion interlocked so that the contents of the vial can be expelled by relative movement of the vial towards the barrel.

2. A device as claimed in claim 1, in which a tip is carried on said fluid passage member at the end that is nearer to the open end of the barrel, said tip comprising a solid puncturing point at one end of the tip and a

orifices 56 are within central bore 32, to provide proper fluid communication.

5 An elongate urethral tip 59 extends from an end wall which is provided at the lower end (as seen in the drawings) of barrel 10. The central or axial opening in tip 59 is in alignment with centre bore 42. The end portion of tip 59 is generally cylindrical, as shown at 60, and has a smooth external surface. An opening 62 in the end of tip 59 meets the cylindrical portion 60 in a rounded-off portion 64 and serves as an outlet.

15 A cover 66 is received with a snap fit on the exterior of tip 59 to form an aseptic seal. The cover 66 is, of course, removed just prior to use.

20 The tip 59 can be spun welded, glued, or otherwise formed or joined with the barrel 10.

25 In operation, the stopper 20 is interlocked with the thrust portion 14 by the making up of threads 16 and 26, thereby causing the puncturing point 50 to pierce the diaphragm 34. Fluid communication between the vial 18 and fluid passage member 40 is thereby established. (Figures 6 and 7). The tip 59 is then inserted in the urethral tract as shown in Figure 8. The device may be held in place with one hand by grasping, for example, the lower end of barrel 10 and the end of the penis. Injection of the contents of vial 18 is then carried out with the other hand by applying a squeezing force between the end of vial 18 and flanges 12 until the stopper 20 reaches the bottom of the vial 18.

35 The invention is particularly adapted to the administration of thick viscous materials such as lidocaine hydrochloride in a carb-oxy-methyl cellulose carrier. The inside diameter of central bore 42 is considerably larger than that of a conventional large gauge cannula. The size of central bore 42 permits the discharge therethrough of viscous materials with a minimum of time and manual effort on the part of the physician or nurse. The invention is, however, not limited to use in the urethral tract.

40 Turning to Figures 9 and 10, the second device comprises a barrel 100, flanges 102, thrust portion 104 and threads 106, which are identical to the barrel 10, flanges 12, thrust portion 14 and threads 16, respectively, of the first device. Likewise, vial 108, stopper 110, sealing rings 112, projection 114, threads 116, central bore 118, diaphragm 120 and urethral tip 122 of the second device are identical to vial 18, stopper 20, sealing rings 22, projection 24, threads 26, central bore 32, diaphragm 34 and urethral tip 59, respectively, of the first device. The fluid passage member 124 of the second device is, as with the fluid passage member 40 of the first device, considerably larger in inside diameter than a con-

ventional large gauge cannula. The central bore 126 allows the ready passage of viscous material therethrough. The fluid passage member has a flange 128 which is received in recess 130 in the bottom of barrel 100 as in the first device. The external diameter of the free end 132 of fluid passage member 124 may be smaller, equal to, or even slightly larger than the inside diameter of central bore 118. A centralizing disk or flange 134 on the fluid passage member 124 functions as previous described in relation to the flange 58 of the first device, that is, it limits the lateral movement of the fluid passage member 124 with relation to the thrust portion 104 to maintain an essentially concentric relationship therebetween.

80 The materials of construction of the second device are normally plastics except for the glass vial 18 and the rubber stopper 20.

WHAT WE CLAIM IS:—

1. A device for the administration of viscous fluids comprising a barrel, one end of which has an end wall and the other end of which is open, an elongate thrust portion within said barrel and terminating in proximity to the open end of said barrel, a fluid passage member extending lengthwise within and terminating within said thrust portion, said fluid passage member having a central bore of sufficient diameter to readily allow the passage of viscous fluid therethrough, puncturing means associated with the end of said fluid passage member that is nearer to the open end of the barrel, and an elongate urethral tip extending from said barrel at the end remote from the open end and communicating with said central bore, said tip including a cylindrical portion and a smooth rounded end immediately adjacent the cylindrical portion, there being a hole in the rounded end which serves as an outlet and the cylindrical portion and rounded end being adapted to be received within the urethral tract, and the thrust portion is provided with interlocking means, the arrangement being such that, in use of the device with a vial having an open end and a closed end and a resilient reciprocable stopper in the vial provided with interlocking means adapted to be interlocked with the interlocking means of the thrust portion, the stopper of the vial can be punctured by the puncturing means and the stopper and thrust portion interlocked so that the contents of the vial can be expelled by relative movement of the vial towards the barrel.

2. A device as claimed in claim 1, in which a tip is carried on said fluid passage member at the end that is nearer to the open end of the barrel, said tip comprising a solid puncturing point at one end of the tip and a



zone of generally larger diameter than said point, the interior of said zone communicating with said central bore, and said zone having one or more orifices therein to provide fluid communication between the central bore and the exterior of said zone.

3. A device as claimed in claim 2, in which there is provided a flange on said tip on the side of said zone remote from the puncturing point, said flange being adapted to limit the lateral movement of said fluid passage member and tip with relation to said thrust portion to maintain an essentially concentric relationship therebetween.

4. A device as claimed in claim 1 or claim 2, in which there is provided a flange on said fluid passage member adapted to limit the lateral movement of said fluid passage member with relation to said thrust portion to maintain an essentially concentric relationship therebetween.

5. A device as claimed in any one of claims 1 to 4, in which the interlocking means comprises internal threads formed on the end portion of the thrust portion that is nearer to the open end of the barrel for engagement with an externally threaded stopper.

6. A device as claimed in any one of claims 1 to 5, in which the urethral tip has, adjacent to the cylindrical portion, an externally tapered portion extending to the barrel and having its largest diameter at the barrel.

7. A device as claimed in any one of claims 1 to 6, in which the urethral tip has a hollow internal central bore which communicates with the said central bore of the fluid passage member, the bore of the urethral tip being at least equal in inside diameter to the inside diameter of the fluid passage member.

8. A device for the administration of fluids and suitable for use with a vial having a resilient reciprocable stopper therein substantially as hereinbefore described with reference to, and as shown in Figures 1 to 8, or Figures 9 and 10, of the accompanying drawings.

9. A device for the administration of fluids as claimed in any one of claims 1 to 7, in combination with a vial having an open end and a closed end and a resilient reciprocable stopper sealing on the walls of said vial, the stopper being provided with inter-

locking means adapted to be interlocked with the interlocking means of the thrust portion, the arrangement being such that, after the stopper has been punctured by the puncturing means and the stopper and thrust portion interlocked, the stopper can be reciprocated in vial by pushing or pulling the vial relative to the barrel.

10. A combination as claimed in claim 9, in which the stopper has a centre hole therein bridged by an imperforate diaphragm.

11. A combination as claimed in claim 10, in which the imperforate diaphragm is at the outer end of said stopper.

12. A combination as claimed in claim 10 or claim 11, in which a tip is carried on said fluid passage member at the end that is nearer to the open end of the barrel, said tip comprising a solid puncturing point at one end of the tip and a zone of generally larger diameter than said point, the interior of said zone communicating with said central bore, and said zone having one or more orifices therein to provide fluid communication between the central bore and the exterior of said zone, and in which the centre hole of the stopper is larger in internal diameter than the exterior of the zone of the tip in proximity to the orifices.

13. A combination as claimed in any one of claims 9 to 12, in which there is a viscous material within said vial.

14. A combination as claimed in any one of claims 9 to 13, in which the vial is a cylindrical shell vial.

15. A combination as claimed in any one of claims 9 to 14, in which the interlocking means comprises internal threads formed on the end portion of the thrust portion that is nearer to the open end of the barrel and external threads formed on a projection on the stopper.

16. A combination of a device for the administration of viscous fluids and a vial having an open end and a closed end and a stopper therein substantially as hereinbefore described with reference to, and as shown in, Figures 1 to 8, or Figures 9 and 10 of the accompanying drawings.

ABEL & IMRAY,
Chartered Patent Agents,
Northumberland House,
303-306 High Holborn,
London, WC1V 7LH.

