

PATENT SPECIFICATION

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(54) OPHTHALMIC APPLICATOR

(71) We, MERCK & CO. INC., a corporation duly organized and existing under the laws of the State of New Jersey, United States of America, of Rahway, New Jersey, 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:—

The usual treatment of various eye conditions involves applying doses of appropriate medicaments in aqueous solutions, suspensions or ointments. While such treatments are satisfactory for treating eye conditions where only one or a few applications of the medicinal agents are necessary, certain eye conditions require more frequent doses and the treatment is inconvenient to the patient. Recently, it has been proposed to apply the ophthalmically active medicinal agents in a solid form that will completely dissolve in the lachrymal fluid (see Loucas et al., J of Pharm. Sci., Vol. 61, page 985, June 1972). The shape of the insert is not critical: it may be in the form of a disc, oval, rectangle or rod.

The present invention provides an ophthalmic applicator for mechanically inserting solid medicaments, in the form of inserts, below the eye lid and into the cul-de-sac of the eye, comprising an elongated tip of non-toxic pliable material and terminating in two flexible opposed jaws integral with the tip and separated by a groove enabling the jaws to releasably grip an insert by frictionally engaging the insert between the jaws; and a handle attached to or integral with the tip at the end of the tip opposite the jaws and forming an interior angle of from 30° to 120° with the tip.

The invention is illustrated in the accompanying drawings, which show a preferred applicator in accordance with the invention.

In the drawings,

Figure 1 is a perspective view of an ophthalmic applicator;

Figure 2 is a top view of the applicator of Figure 1; and

Figure 3 is an enlarged top view of the tip of the applicator of Figure 1.

Figure 1 is a perspective view of an ophthalmic applicator comprising an elongated tip 1 of a non-toxic pliable material. The tip 1 is 8 to 12 mm in length and terminates at one end in two flexible opposed jaws 3, which are separated by a groove that enables the jaws 3 to releasably grip an insert 11 by frictionally engaging the insert 11 between the jaws 3. A handle 5 is attached to tip at the end opposite the jaws 3. The angle between the tip and the handle is preferably 45° to 90° and especially about 70°. A reinforcing rib 9 is provided where the handle and tip meet.

Figure 2 is a top view of the ophthalmic applicator device which indicates one form of the handle 5. The shape of the handle 5 is not critical, and in this embodiment is formed of a planar element in the form of a sector of a circle attached to one end of the tip 1 at that portion of the sector corresponding to the centre 7 of the circle. The portion of the handle 5 corresponding to the periphery of a sector of a circle is of sufficient size to allow the person inserting the medicament into the eye to easily grasp the handle. The length of the handle is not critical and is generally from 25 to 75 mm in length, preferably 40 to 60 mm. The angle of the sector of the circle is not critical and generally is from 15° to 45° and preferably 25° to 35°. The thickness of the handle is not critical, and generally would be dependent upon the elastic modulus of the material used in the construction of the ophthalmic applicator. It would generally be from 1.5 to 2.5 mm, preferably about 2.0 mm. The reinforcing rib 9 may be used to immobilize the tip 1 so that the angle between the tip 1 and the handle 5 remains constant. All edges of the device may be rounded to minimize the possibility of accidental injury to the eye while inserting the medicament.

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Figure 3 is an enlarged top view of the tip 1 of the applicator highlighting the position of the jaws 3. The two opposed jaws 3 are separated by a groove running their entire length. The shape of the groove is not critical and generally conforms to the shape of an ophthalmic insert at that portion of the insert intended to be grasped by the jaws. It may be from 0.5 to 2.0 mm in depth and slightly smaller than the shape of the insert, thereby enabling the jaws 3 to releasably grip the insert by frictionally engaging it between the two jaws 3. The shape of the insert is not critical. As an example, the insert may be cylindrical (rod-like) in shape with a diameter of from 0.5 to 1.5 mm and a length of from 2 to 12 mm. Accordingly, the groove would be shaped to accept a cylindrical shape with dimensions slightly smaller than the insert. The jaws 3 are approximately equal in size and are integrally moulded into the pliable tip 1. The jaws 3 may be from 1.0 to 3.0 mm in width, preferably 1.5 to 2.5 mm and especially 2.0 mm; from 0.5 to 2.0 mm in depth, preferably 1.0 to 1.5 mm and especially 1.0 mm; and from 0.2 to 0.8 mm in thickness, preferably 0.3 to 0.6 and especially 0.4 mm. The gripping (inner) surface of the jaws is not critical and may be smooth, wavelike or irregular. The tip is from 8 to 12 mm in length, preferably 9 to 11 mm and especially 9 to 10 mm, so as to enable the user of the insert to insert the medicament into the proper area of the cul-de-sac or fornix of the eye without assistance. The thickness and width of the tip are not critical, and generally, would be sufficient to maintain the shape of the tip in the absence of external forces, but to readily deform upon application of mild forces such as would be encountered upon accidental contact with the eye ball or the surrounding tissues. The tip may be from 3.0 to 6.0 mm in width at the portion attached to the handle, preferably 4.0 to 5.0 mm, tapering to 1.5 to 3.0 mm at the tip containing the jaws, preferably about 2.0 mm, and from 1.5 to 3.0 mm in thickness, and may be tapered so that the thickest portion is at the end of the tip containing the jaws. The end of the tip containing the jaws should be of such dimensions that the integral jaws may be moulded as part of the tip.

The ophthalmic applicator of the invention may be produced in one piece by suitable forming techniques such as compression moulding and especially injection moulding. The tip and handle may be in different planes but are preferably in the same plane to facilitate packaging the device.

The ophthalmic applicator device may be produced from a non-toxic pliable material

that is not readily water-soluble, does not support the growth of microorganisms and is readily sterilized, such as a silicone rubber composition and especially a thermoplastic elastomer composition. Thermoplastic elastomer polymers behave like thermoplastic materials above their softening point and may be processed in ordinary thermoplastic processing equipment. The thermoplastic rubber composition may be a block copolymer terminated at each end with a sequence of styrene units and having a long central block of diene units such as butadiene or isoprene. The block copolymer may be partially hydrogenated as described in U.S. Patent No. 3,595,942. The thermoplastic rubber compositions may be obtained and used as the gum polymer or as a composition comprising the polymer and in addition one or more of the following items: a processing and flow-promoting aid such as a rubber processing oil, a resin such as a polyethylene or a polystyrene, a stabilizer such as one of the hindered phenols or an unsaturated ester and a filler such as a clay, a silica or a carbon black. Such thermoplastic rubbers are commercially produced and sold under various trade marks, e.g. Solprene, Uniroyal TPR and Kraton. One such thermoplastic rubber which may be used is Kraton G-2705 thermoplastic rubber (formerly GX-7050) which is a thermoplastic rubber composition comprising a partially hydrogenated block copolymer as described in U.S. Patent 3,595,942, a processing aid (such as a rubber processing oil) and a stabilizer (such as a hindered phenol or an unsaturated ester). The material used in the construction of the device should be easily sterilized by common methods such as immersion in a 0.01% aqueous benzalkonium chloride solution, 70% isopropanol solution or running hot water (45° to 70°C) for 10 to 30 seconds.

Typically in the use of the ophthalmic applicator device, the hands of the person inserting the device should be thoroughly washed with soap and water. The applicator device is then sterilized by holding it under running hot water for 15 seconds and shaking off the excess water. Placing the handle of the applicator between the thumb and middle finger with the forefinger located near the end of the handle attached to the tip, the tip of the applicator incorporating the groove is gently pressed onto the insert. The ophthalmic insert will adhere to the applicator. Looking into a mirror and using the free hand to gently grasp the surface of the outer one-third of the lower lid between the thumb and index (fore)finger, the eye

70 lid is pulled away from the eye-ball creating
a pocket between the eyeball and the eye
lid. The tip of the applicator containing the
ophthalmic insert is placed into the pocket
5 created between the lid and the eyeball
over the white part of the eye (sclera),
keeping from the colored part of the eye
(cornea). The applicator device is removed
and the ophthalmic insert remains in the
10 cul-de-sac or fornix of the eye. To ensure
proper placement in the eye, the lower lid
should be pulled out and up and over the
ophthalmic insert while looking down by
grasping the skin surface of the outer one-
15 third of the lower lid between the thumb
and index finger. A properly positioned
insert resides in the lower portion of the eye
behind the lower lid.

85 WHAT WE CLAIM IS:—

20 1. An ophthalmic applicator for
mechanically inserting solid medicaments,
in the form of inserts, below the eye lid and
into the cul-de-sac of the eye, comprising
an elongated tip of non-toxic pliable
25 material and terminating in two flexible
opposed jaws integral with the tip and
separated by a groove enabling the jaws to
releasably grip an insert by frictionally
engaging the insert between the jaws; and a
30 handle attached to or integral with the tip at
the end of the tip opposite the jaws and
forming an interior angle of from 30° to
120° with the tip.

100 2. A one-piece applicator as claimed in
Claim 1.

3. An applicator as claimed in Claim 1 or
Claim 2 including a reinforcing rib at the
point where the tip joins the handle.

105 4. An applicator as claimed in any
preceding claim made of a thermoplastic
rubber composition.

5. An applicator as claimed in Claim 4, in
which the thermoplastic rubber
composition is a block copolymer
terminated at each end with a sequence of
45 styrene units and having a long central
block of diene units.

6. An applicator as claimed in Claim 5, in
which the block polymer is partially
50 hydrogenated.

7. An applicator as claimed in any
preceding claim, in which the axes of the tip
and the handle are in the same plane.

8. An applicator as claimed in any
preceding claim, in which the tip is from 8
55 to 12 mm in length, tapering to a diameter
of from 1.5 to 3.0 mm at the end with the
jaws and containing a groove of width from
0.5 to 1.5 mm and depth from 0.5 to 2.0 mm,
the groove running perpendicular to the tip
60 and parallel to the jaws, the jaws are equal
in size and are from 1.0 to 3.0 mm in width,
0.5 to 2.0 mm in depth and 0.2 to 0.8 mm in
thickness, and the handle is from 25.0 to
75.0 mm in length.

9. An applicator as claimed in Claim 11,
in which the tip is from 9 to 11 mm in
length, the groove is in the shape of a
cylinder of diameter from 0.5 to 1.5 mm,
the jaws are from 1.5 to 2.5 mm in width,
70 from 1.0 to 1.5 mm in depth and from 0.3 to
0.6 mm in thickness, and the handle is from
40 to 60 mm in length and is attached to the
tip at an angle of from 45° to 90°.

10. An applicator as claimed in Claim 1
75 substantially as hereinbefore described with
reference to the accompanying drawings.

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lid is pulled away from the eye-ball creating a pocket between the eyeball and the eye lid. The tip of the applicator containing the ophthalmic insert is placed into the pocket created between the lid and the eyeball over the white part of the eye (sclera), keeping from the colored part of the eye (cornea). The applicator device is removed and the ophthalmic insert remains in the cul-de-sac or fornix of the eye. To ensure proper placement in the eye, the lower lid should be pulled out and up and over the ophthalmic insert while looking down by grasping the skin surface of the outer one-third of the lower lid between the thumb and index finger. A properly positioned insert resides in the lower portion of the eye behind the lower lid.

WHAT WE CLAIM IS:—

- 20 1. An ophthalmic applicator for mechanically inserting solid medicaments, in the form of inserts, below the eye lid and into the cul-de-sac of the eye, comprising an elongated tip of non-toxic pliable material and terminating in two flexible opposed jaws integral with the tip and separated by a groove enabling the jaws to releasably grip an insert by frictionally engaging the insert between the jaws; and a handle attached to or integral with the tip at the end of the tip opposite the jaws and forming an interior angle of from 30° to 120° with the tip.
- 35 2. A one-piece applicator as claimed in Claim 1.
- 3. An applicator as claimed in Claim 1 or Claim 2 including a reinforcing rib at the point where the tip joins the handle.
- 40 4. An applicator as claimed in any preceding claim made of a thermoplastic rubber composition.

5. An applicator as claimed in Claim 4, in which the thermoplastic rubber composition is a block copolymer terminated at each end with a sequence of styrene units and having a long central block of diene units.

6. An applicator as claimed in Claim 5, in which the block polymer is partially hydrogenated.

7. An applicator as claimed in any preceding claim, in which the axes of the tip and the handle are in the same plane.

8. An applicator as claimed in any preceding claim, in which the tip is from 8 to 12 mm in length, tapering to a diameter of from 1.5 to 3.0 mm at the end with the jaws and containing a groove of width from 0.5 to 1.5 mm and depth from 0.5 to 2.0 mm, the groove running perpendicular to the tip and parallel to the jaws, the jaws are equal in size and are from 1.0 to 3.0 mm in width, 0.5 to 2.0 mm in depth and 0.2 to 0.8 mm in thickness, and the handle is from 25.0 to 75.0 mm in length.

9. An applicator as claimed in Claim 11, in which the tip is from 9 to 11 mm in length, the groove is in the shape of a cylinder of diameter from 0.5 to 1.5 mm, the jaws are from 1.5 to 2.5 mm in width, from 1.0 to 1.5 mm in depth and from 0.3 to 0.6 mm in thickness, and the handle is from 40 to 60 mm in length and is attached to the tip at an angle of from 45° to 90°.

10. An applicator as claimed in Claim 1 substantially as hereinbefore described with reference to the accompanying drawings.

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