CLAIMS

1. An applicator for applying a pharmaceutical preparation to a skin surface of a patient in need thereof,

said pharmaceutical preparation having viscosity in a range from 100 to 2000 centipoise at 25°C,

said applicator comprising one or more ~~substantially~~ rigid side walls bounding a cavity which is open at a bottom end and closed at a top end by a top wall ~~substantially~~ perpendicular to said one or more side wall to form a cap which fits over and encloses a top portion of a container and dispenser for the pharmaceutical preparation,

said ~~the~~ side walls being configured to detachably engage with a top portion of the container or dispenser,

said closed top end of the applicator ~~cap~~ having an outer surface comprising:

a central flat and continuous face which is ~~solid and non-porous~~ such that liquid cannot pass through said face, ~~the flat outer face being useful for receiving one or more doses of the pharmaceutical preparation dispensed thereon from the pharmaceutical preparation container,~~ and

a peripheral ridge bounding the flat face and forming a reservoir area for retaining the pharmaceutical preparation within said reservoir area on the flat face when the pharmaceutical preparation is dispensed thereon, and

said reservoir area being formed by a solid, non-porous, non-elastic material, and having a single recess shape for receiving a single dose of the pharmaceutical preparation dispensed thereon from the pharmaceutical preparation container.

2. The applicator of claim 1 wherein the one or more ~~substantially~~ rigid side walls flexibly engage with and detachably affix to the top portion of the container or dispenser.

3. The applicator of claim 1 wherein the ~~substantially~~ rigid side walls comprise a ridge or protrusion formed thereon to matingly engage the top portion of the container or the dispenser.

4. The applicator of claim ~~3~~ 1 wherein ~~the substantially rigid side walls matingly engage the top portion of the container or the dispenser to form a substantially airtight seal.~~the single dose is in a range from 0.1 mL to 1 mL.

5. The applicator of claim ~~3~~ 1 wherein the central flat and continuous face occupies 60% or more of the reservoir area ~~the side wall ridge or protrusion is formed as threads to threadingly engage the top portion of the container or the dispenser~~.

6. The applicator of claim 1 comprising a single side wall forming a cross-sectionally circular or oval shaped applicator.

7. The applicator of claim 6 wherein the outer top surface of the top end of the applicator comprises a circular or oval ridge circumferentially bounding the central flat face of the ~~cap~~applicator.

8. The applicator of claim 1 ~~comprising four side walls forming a cross sectionally rectangular shaped applicator~~wherein a difference in height between an uppermost portion of the reservoir area and a lowermost portion of the reservoir area is in a range from 0.1 mm to 4.0 mm..

9. The applicator of claim 1 wherein the peripheral ridge has a top surface which is rounded.

10. The applicator of claim 1 wherein the one or more side walls of the ~~cap~~ applicator comprise indentations to facilitate gripping and handling or attaching or detaching the ~~cap~~applicator.

11. The applicator of claim 1, wherein the applicator further comprises an overcap which covers at least the central flat surface of the applicator.

12. The applicator of claim 1 wherein the central flat continuous face of the outer surface of the ~~cap~~applicator provides for application of the dispensed dose or doses of pharmaceutical preparation to the skin surface of the patient and the peripheral ridge serves to retain the dispensed pharmaceutical preparation within the reservoir area formed in the central flat face during administration of the pharmaceutical preparation.

13. The applicator of claim 1 wherein the skin surface is on an axilla of the patient.

14. The applicator of claim 1 wherein the preparation comprises an active pharmaceutical ingredient useful to treat or ameliorate excessive sweating or hyperhidrosis.

15. The applicator of claim 14, wherein the active pharmaceutical ingredient is sofpironium bromide.

16. The applicator of claim 1 wherein the pharmaceutical preparation is a gel.

17. A system for applying a pharmaceutically acceptable preparation to a skin surface of a patient in need thereof, said pharmaceutical preparation having viscosity in a range from 100 to 2000 centipoise at 25°C, said system comprising:

- a container for housing and storing a plurality of doses of the pharmaceutical preparation, the container having an opening at a top end for receiving and engaging a dispenser for dispensing a metered dose of the pharmaceutical preparation, and
- an applicator~~cap~~ covering the dispenser and detachably engaging the top portion of the container or a portion of the dispenser,

said applicator~~cap~~ comprising one or more ~~substantially~~ rigid side walls bounding a cavity which is open at a bottom end and closed at a top end by a top wall perpendicular to said one or more side wall to form a cap which fits over and encloses a top portion of a container and dispenser for the pharmaceutical preparation,

said side walls being configured to detachably engage with a top portion of the container or dispenser,

said closed top end of the applicator having an outer surface comprising:

a central flat and continuous face which is such that liquid cannot pass through said face, and

a peripheral ridge bounding the flat face and forming a reservoir area for retaining the pharmaceutical preparation within said reservoir area on the flat face when the pharmaceutical preparation is dispensed thereon, and

said reservoir area being formed by a solid, non-porous, non-elastic material, and having a single recess shape for receiving a single dose of the pharmaceutical preparation dispensed thereon from the pharmaceutical preparation container.

~~, said closed top end of the cap having an outer surface comprising a central flat, continuous face, which is solid and non-porous such that liquid cannot pass through~~

~~said face, and a peripheral ridge bounding the flat face and defining a reservoir area for retaining the pharmaceutical preparation within said reservoir area on the flat face when the pharmaceutical preparation is dispensed thereon,~~

~~wherein the cap further serves as an applicator for receiving and retaining the dispensed pharmaceutical preparation within the reservoir area of said flat face and allowing the pharmaceutical preparation to be administered to the patient from the flat face when applied to the skin surface of said patient.~~

18. The system of claim 17 further comprising an overcap which engages with the ~~cap~~ applicator and covers at least the central flat surface of the applicator.

19. The system of claim 17 wherein the container further comprises a bottom end which is open or in open communication with ambient air outside the container to allow equilibration of pressure within the container following dispensing of the pharmaceutical preparation from the container.

20. The system of claim 17 wherein the container further comprises a piston within the container which reduces storage volume of contents within the container upon each dose dispensation and compresses the contents for ultimately dispensing ~~substantially~~ all the pharmaceutical preparation from the container.

21. The system of claim 17 wherein the container further comprises a collapsible inner liner disposed within the container which reduces storage volume of contents within the container upon each dose dispensation and compresses the contents for ultimately dispensing ~~substantially~~ all the pharmaceutical preparation from the container.

22. The system of claim 17 wherein the container includes a bottom ~~cap~~ applicator forming a base of the container.

23. ~~-~~The system of claim 17 wherein the dispenser is a pump dispenser.

24. The system of claim 23 wherein the pump dispenser is a metered-dose pump dispenser.

~~25. A method for treating or ameliorating excessive sweating or hyperhidrosis in a patient in need thereof, said method comprising the steps of:~~

~~a) providing a container having a contents comprising a pharmaceutical preparation effective for treating or ameliorating excessive sweating or hyperhidrosis, and a dispenser engaged with said container for dispensing the pharmaceutical preparation from said container, said container including a detachable applicator fitting over a top portion of said container and dispenser, said applicator comprising one or more substantially rigid side walls bounding a cavity which is open at a bottom end and closed at a top end substantially perpendicular to said one or more side wall, said closed top end of the applicator having an outer surface comprising a central flat and continuous face which is solid and non-porous, and a peripheral ridge bounding the flat face and forming a reservoir area for retaining the pharmaceutical preparation within said reservoir area on the flat face when the pharmaceutical preparation is dispensed thereon from the container; the applicator optionally comprising an overcap which covers at least the reservoir area on the flat face of the cap;~~

~~b) removing the cap from the container and, if present, removing the overcap from the applicator;~~

c) dispensing one or more doses of the pharmaceutical preparation into the reservoir area on the outer flat face of the applicator; and

d) applying the dispensed dose or doses onto the skin surface of the patient.

26. The method of claim 25 wherein the pharmaceutical preparation is in the form of a solution, suspension, lotion, cream, light ointment, foam or gel.

27. The method of claim 25 wherein the pharmaceutical preparation is dispensed from the container by a metered dose dispenser as a single dose.

28. The method of claim 25 wherein the pharmaceutical preparation comprises an active pharmaceutical ingredient which is effective for treating or ameliorating excessive sweating or hyperhidrosis.

29. The method of claim 25 wherein the active pharmaceutical ingredient is sofpironium bromide.

30. The method of claim 25 wherein the pharmaceutical preparation comprises one or more carriers or excipients selected from the group consisting of a solvent, a co-solvent, a penetration enhancer, a pH modifying agent, and a viscosity modulating agent.

31. The method of claim 30 wherein the pharmaceutical preparation further comprises isopropyl myristate.

32. The method of claim 25 wherein the skin surface is on an axilla of the patient.

~~33. The method of claim 25 wherein the pharmaceutical preparation is dispensed and applied to the skin surface at least one time per day.~~

~~34. The method of claim 25 wherein the pharmaceutical preparation is dispensed and applied to the skin surface one to four times daily.~~

~~35. The method of claim 25 wherein the pharmaceutical preparation is dispensed and applied to the skin surface before the patient's sleep period.~~

~~36. The method of claim 25 wherein the patient is a human.~~

~~37. The method of claim 25 wherein the patient is suffering from hyperhidrosis or excessive sweating.~~

2538. An applicator system used for applying a pharmaceutical preparation for topical or transdermal administration on a body surface, ~~the~~said pharmaceutical preparation having viscosity in a range from 100 to 2000 centipoise at 25°C, ~~the applicator~~said system comprising~~including~~:

- a container configured to accommodate the pharmaceutical preparation; and
- an applicator detachably attached to the container, the applicator including a~~n~~ reservoir area ~~therapeutic surface~~ capable of receiving a single dose of the pharmaceutical preparation to be applied on a body surface,

~~the therapeutic surface~~said reservoir area being formed by a solid, non-porous,~~rigid,~~ non-elastic material, and forming a single recess shape for receiving a

single dose of the pharmaceutical preparation dispensed thereon from the pharmaceutical preparation container.

2639. The applicator system described in Claim 3825, in which the pharmaceutical preparation is selected from the group consisting of a gel, a lotion, a cream and a liquid preparation, each having viscosity in a range from 100 to 1100 centipoise at 25°C.

2740. The applicator system described in Claim 3925, in which the pharmaceutical preparation has viscosity in a range from 100 to 900 centipoise at 25°C.

2841. The applicator system described in any one of Claim 38–25 to 4027, in which the pharmaceutical preparation is a preparation containing 40w/w% or more of one or a plurality of C1-C4 alcohols.

~~42. The applicator system described in any one of Claim 38 to Claim 41, in which the single dose is in a range from 0.1 mL to 1 mL.~~

~~43. The applicator system described in any one of Claim 38 to Claim 42, in which the therapeutic surface includes only an outer peripheral ridge portion merging into a side surface of the applicator and a top outer surface surrounded by the outer peripheral ridge portion.~~

~~44. The applicator system described in Claim 43, in which the top outer surface forms a single flat portion and the single flat portion occupies 5% or more of a surface area of the therapeutic surface.~~

~~45. The applicator system described in Claim 44, in which the single flat portion occupies 60% or more of the surface area of the therapeutic surface.~~

~~46. The applicator system described in any one of Claim 38 to Claim 45, in which a difference in height between an uppermost portion of the therapeutic surface and a lowermost portion of the therapeutic surface is in a range from 0.1 mm to 4.0 mm.~~

~~47. The applicator system described in Claim 46, in which the difference in height between the uppermost portion of the therapeutic surface and the lowermost portion of the therapeutic surface is in a range from 0.1 mm to 1.5 mm.~~

~~48. An applicator system described in any one of Claim 38 to Claim 47, in which the therapeutic surface has a substantially circular shape having a diameter in a range from 20 mm to 45 mm or a substantially oval shape having a long or short diameter in a range from 20 mm to 45 mm as viewed from above.~~

~~49. The applicator system described in any one of Claim 38 to Claim 48, in which the container includes a bottle portion configured to accommodate the pharmaceutical preparation and a pump portion attached to a mouth portion of the bottle portion.~~

~~50. The applicator system described in Claim 49, in which the therapeutic surface is configured to be capable of receiving the single dose of the pharmaceutical preparation dispensed from the pump portion.~~

~~51. The applicator system described in any one of Claim 38 to Claim 50, in which the pharmaceutical preparation includes sofpironium bromide used for treatment of hyperhidrosis.~~

~~52. The applicator system described in any one of Claim 38 to Claim 51 in which the applicator is configured to be applied to an axilla.~~

2953. An applicator used for applying a pharmaceutical preparation for topical or transdermal administration on a body surface,

~~the~~ said pharmaceutical preparation having a viscosity in a range from about 100 to 3000 centipoise at 25°C,

~~the~~ said applicator including a reservoir area~~therapeutic surface~~ capable of receiving a single dose of the pharmaceutical preparation to be applied on a body surface,

~~-~~said reservoir area~~the therapeutic surface~~ being formed by a solid, non-porous, ~~rigid,~~ non-elastic material, and forming a single recess~~ed~~ shape for receiving a single dose of the pharmaceutical preparation dispensed thereon from the pharmaceutical preparation container~~reservoir area~~.

3054. The applicator described in Claim ~~53~~29, in which the pharmaceutical preparation is selected from the group consisting of a gel agent, a lotion agent, a cream agent and a liquid agent, each having viscosity in a range from 100 to 1500 centipoise at 25°C.

3155. The applicator described in Claim 5429, in which the pharmaceutical preparation has viscosity in a range from 100 to 1000 centipoise at 25°C.

3256. The applicator described in any one of Claim 53 29 to Claim 5531, in which the pharmaceutical formulation is a preparation containing 40w/w% or more of one or a plurality of C1-C4 alcohols.

~~57. The applicator described in any one of Claim 53 to Claim 56, in which the single dose is in a range from 0.1 mL to 1 mL.~~

~~58. The applicator described in any one of Claim 53 to Claim 57, in which the therapeutic surface includes only an outer peripheral ridge portion merging into a side wall of the applicator and a top surface, including the therapeutic surface surrounded by the outer peripheral ridge portion.~~

~~59. The applicator described in Claim 58, in which the top outer surface forms a single flat portion and the single flat portion includes a therapeutic surface that occupies 5% or more of a surface area of the applicator top surface.~~

~~60. The applicator described in Claim 59, in which the single flat portion occupies 60% or more of the surface area of the applicator top surface.~~

~~61. The applicator described in any one of Claim 53 to Claim 60, in which a difference in height between an uppermost portion of the outer ridge and the therapeutic surface of the applicator is in a range from 0.1 mm to 4.0 mm.~~

~~62. The applicator described in Claim 61, in which the difference in height between the uppermost portion of outer ridge and the therapeutic surface of the outer ridge is in a range from 0.1 mm to 1.5 mm.~~

~~63. The applicator described in any one of Claim 53 to Claim 62, in which the therapeutic surface has a substantially circular shape having a diameter in a range from 20 mm to 45 mm or a substantially oval shape having a long or short diameter in a range from 20 mm to 45 mm as viewed from above.~~

~~64. The applicator described in any one of Claim 53 to Claim 63, in which the pharmaceutical preparation includes sofpironium bromide used for treatment of hyperhidrosis.~~

~~65. The applicator described in any one of Claim 53 to Claim 64 in which the applicator is configured to be applied to an axilla.~~