

EXHIBIT 41

Proposed Claim Amendment
(Korean Patent Application No. 2004-7020819)

1. (Currently amended) A pharmaceutical formulation for nasal or ocular administration, which comprises azelastine hydrochloride or a pharmaceutically acceptable salt thereof, ~~azelastine, or a pharmaceutically acceptable salt, solvate or physiologically functional derivative thereof,~~ and fluticasone a steroid, or a pharmaceutically acceptable salt, ~~solvate~~ esters or physiologically functional derivative thereof, preferably the formulation being in a form suitable for nasal or ocular administration.
2. (Cancelled) A pharmaceutical formulation according to claim 1, wherein said azelastine is present as azelastine hydrochloride.
3. (Cancelled) A ~~formulation according to claim 1 or 2, wherein the steroid is beclomethasone or a pharmaceutically acceptable ester thereof, mometasone or a pharmaceutically acceptable ester thereof, fluticasone or a pharmaceutically acceptable ester thereof, budesonide or cyclofenide, in any chiral form or mixture.~~
4. (Cancelled) A ~~formulation according to claim 3, wherein the steroid is beclomethasone propionate, mometasone furoate, mometasone furoate monohydrate, fluticasone propionate or fluticasone valerate.~~
5. (Currently amended) A formulation according to ~~any of claims 1 to 4,~~ which contains the fluticasone steroid in an amount from about 50 micrograms/ml to about 5 mg/ml of the formulation.
6. (Currently amended) A formulation according to ~~any of claims 1 to 5,~~ wherein the formulation has a particle size of less than about 10 μm , preferably less than 5 μm .
7. (Currently amended) A formulation according to ~~any of claims 1 to 6,~~ which is a suspension containing 0.0005 to 2% (weight/weight of the formulation) of azelastine or a pharmaceutically acceptable salt thereof ~~hydrochloride~~ azelastine or a pharmaceutically acceptable salt of azelastine, and from 0.5 to 1.5% (weight/weight of the formulation) of fluticasone or a pharmaceutically acceptable ester thereof ~~said steroid.~~
8. (Currently amended) A formulation according to claim 7, which contains from 0.001 to 1% (weight/weight of the formulation) of azelastine or a pharmaceutically acceptable salt thereof ~~hydrochloride~~ azelastine, or a pharmaceutically acceptable salt thereof, and from 0.5% to 1.5% (weight/weight of the formulation) steroid of fluticasone or a

pharmaceutically acceptable ester thereof.

9. (Currently amended) A formulation according to ~~any of claims 1 to 8~~, which also contains a surfactant.

10. A formulation according to claim 9, wherein the surfactant comprises a polysorbate or poloxamer surfactant.

11. (Currently amended) A formulation according to claim 9 or 10, which contains from ~~about 50 micrograms to about 1 milligram~~ of surfactant per ml of the formulation.

12. (Currently amended) A formulation according to ~~any of claims 1 to 11~~, which also contains an isotonic agent.

13. A formulation according to claim 12, wherein the isotonic agent comprises sodium chloride, saccharose, glucose, glycerine, sorbitol or 1,2-propylene glycol.

14. (Currently amended) A formulation according to ~~any of claims 1 to 13~~, which also contains at least one of a buffer, a preservative and a suspending or thickening agent.

15. A formulation according to claim 14, wherein said preservative is selected from edetic acid and its alkali salts, lower alkyl p-hydroxybenzoates, chlorhexidine, phenyl mercury borate, or benzoic acid or a salt, a quaternary ammonium compound, or sorbic acid or a salt thereof.

16. A formulation according to claim 14 or 15, wherein the suspending agent or thickening agent is selected from cellulose derivatives, gelatin, polyvinylpyrrolidone, tragacanth, ethoxose (water soluble binding and thickening agents on the basis of ethyl cellulose), alginic acid, polyvinyl alcohol, polyacrylic acid, or pectin.

17. (Currently amended) A formulation according to ~~any of claims 14, 15 or 16~~, wherein the buffer comprises a citric acid-citrate buffer.

18. (Currently amended) A formulation according to ~~any of claims 14, 15, 16 or 17~~, wherein the buffer maintains the pH of the aqueous phase at from 3 to 7, preferably 4.5 to ~~about 6.5~~.

19. (Currently amended) A formulation according to ~~any of claims 1 to 18~~, which is an aqueous suspension or solution.

20. A formulation according to claim 19, which is in the form of an aerosol, an ointment, eye drops, nasal drops, a nasal spray or an inhalation solution.

21. A formulation according to claim 20, which is in the form of nasal drops or nasal spray.

22. A formulation according to claim 20, which is in the form of an aerosol.
23. A pressure packing having a dosage or metering valve, which contains a formulation according to claim 22.
24. (Currently amended) A MDI metered dose inhaler (MDI) which includes a pressure packing according to claim 23.
25. (Cancelled) ~~A formulation according to any of claims 1 to 19, which is in the form of an insufflation powder.~~
26. (Currently amended) A pharmaceutical product comprising (i) azelastine or a pharmaceutically acceptable salt thereof~~hydrochloride~~azelastine, or a pharmaceutically acceptable salt, solvate or physiologically functional derivative thereof, provided in an aerosol formulation preferably together with a propellant typically suitable for metered dose inhaler (MDI) delivery, and (ii) fluticasone~~at least one steroid~~, or a pharmaceutically acceptable salt, solvate or esters ~~physiologically functional derivative thereof~~, provided in an aerosol formulation preferably together with a propellant typically suitable for MDI delivery, as a combined preparation for simultaneous, separate or sequential use in the treatment of conditions for which administration of one or more anti-histamine and/or one or more steroid is indicated.
27. (Currently amended) An aerosol formulation preferably suitable for metered dose inhaler (MDI) delivery comprising (i) azelastine or a pharmaceutically acceptable salt thereof ~~hydrochloride~~azelastine, or a pharmaceutically acceptable salt, solvate or physiologically functional derivative thereof, and (ii) fluticasone~~at least one steroid~~, or a pharmaceutically acceptable salt, solvate esters or physiologically functional derivative thereof, together with a propellant.
28. (Cancelled) ~~A pharmaceutical product comprising (i) azelastine, or a pharmaceutically acceptable salt, solvate or physiologically functional derivative thereof, provided as an insufflation powder, and (ii) at least one steroid, or a pharmaceutically acceptable salt, solvate or physiologically functional derivative thereof, provided as an insufflation powder, as a combined preparation for simultaneous, separate or sequential use in the treatment of conditions for which administration of one or more anti-histamine and/or one or more steroid is indicated.~~
29. (Cancelled) ~~An insufflation powder formulation comprising (i) azelastine, or a pharmaceutically acceptable salt, solvate or physiologically functional derivative thereof,~~

~~and (ii) at least one steroid, or a pharmaceutically acceptable salt, solvate or physiologically functional derivative thereof, together with a pharmaceutically acceptable carrier or excipient therefor.~~

30. (Cancelled) A pharmaceutical product comprising (i) azelastine, or a pharmaceutically acceptable salt thereof, and (ii) at least one steroid selected from the group consisting of beclomethasone, fluticasone, mometasone and pharmaceutically acceptable esters thereof, as a combined preparation for simultaneous, separate or sequential use in the treatment of conditions for which administration of one or more anti-histamine and/or one or more steroid is indicated.

31. (Currently amended) A pharmaceutical formulation comprising (i) azelastine or a pharmaceutically acceptable salt thereof hydrochloride azelastine, or a pharmaceutically acceptable salt thereof, and (ii) at least one steroid selected from the group consisting of beclomethasone, fluticasone or a pharmaceutically acceptable ester thereof, mometasone and pharmaceutically acceptable esters thereof, together with a pharmaceutically acceptable carrier or excipient therefor.

32. (Cancelled) A nasal spray comprising azelastine, or a pharmaceutically acceptable salt thereof, together with mometasone either as mometasone free base or as mometasone furoate, and a pharmaceutically acceptable carrier or excipient therefor.

33. (Cancelled) A pharmaceutical product comprising azelastine hydrochloride and beclomethasone dipropionate, as a combined preparation for simultaneous, separate or sequential use in the treatment of conditions for which administration of one or more anti-histamine and/or one or more steroid is indicated.

34. (Cancelled) A pharmaceutical formulation comprising azelastine hydrochloride and beclomethasone dipropionate, together with a pharmaceutically acceptable carrier or excipient therefor.

35. A pharmaceutical product comprising azelastine hydrochloride and fluticasone propionate, as a combined preparation for simultaneous, separate or sequential use in the treatment of conditions for which administration of one or more anti-histamine and/or one or more steroid is indicated.

36. A pharmaceutical formulation comprising azelastine hydrochloride and fluticasone propionate, together with a pharmaceutically acceptable carrier or excipient therefor.

37. A pharmaceutical product comprising azelastine hydrochloride and fluticasone

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