CLAIMS

1. A microneedle patch composition comprising one or more microneedles each comprising
(a) a tapered tip portion containing a therapeutically active ingredient dispersed in a matrix of a biodegradable polymer capable of providing sustained release of the therapeutically active ingredient over a period of at least two days after insertion of the microneedle or microneedles into the skin, and
(b) a fast dissolving microneedle backing layer portion containing a water-soluble polymer overlayering the tip portion,
said microneedle or microneedles being attached to and extending from an adhesive surface of a removable substrate,
wherein the therapeutically active ingredient is released from the microneedles over a period of 2-21 days after insertion of the microneedle or microneedles into the skin.

2. A patch composition according to claim 1 comprising 2-100 microneedles per cm^2, e.g. 5-75 microneedles, 10-50 microneedles, 15-30 microneedles or 20-25 microneedles per cm^2.

3. A patch composition according to claim 1 or 2, wherein the biodegradable polymer is polylactic acid or a derivative thereof such as an ester-terminated polylactide, polyglycolic acid or a derivative thereof such as an ester-terminated polyglycolide, or polylactic co-glycolic acid or a derivative thereof such as an ester-terminated polylactide co-glycolide.

4. A patch composition according to any one of claims 1-3, wherein the biodegradable polymer has a molecular weight of >5000, such as a molecular weight of 7000-17000, 24000-38000, 38000-54000, 54000-69000 or 76000-116000.

5. A patch composition according to claim 3 or 4, wherein the ratio of lactide to glycolide is between 85:15 and 50:50, such as 85:15, 82:18, 75:25, 65:35 or 50:50.

6. A patch composition according to any one of claims 1-5, wherein the biodegradable polymer matrix further comprises an antioxidant, e.g. butylhydroxytoluene, butylhydroxyanisole or α-tocopherol, or a mixture thereof.

7. A patch composition according to claim 6, wherein the concentration of the antioxidant is in the range of 0.01-3% w/w, preferably 0.03-2% w/w such as 0.05-1% w/w of the dry tip portion.

8. A patch composition according to any one of claims 1-7, wherein the water-soluble polymer is selected from the group consisting of polyvinylpyrrolidone, a sugar such as sucrose or trehalose, dextran, carboxymethylcellulose and sodium alginate.

9. A patch composition according to claim 8, wherein the water-soluble polymer is polyvinylpyrrolidone.

10. A patch composition according to any one of claims 1-9, wherein the backing layer portion comprises a plasticizer, e.g. glycerol, polyethylene glycol, dibutyl sebacate, diethyl phthalate, triethyl glycerin or triethyl citrate.

11. A patch composition according to claim 10, wherein the concentration of the plasticizer is in the range of 0.5-6% by weight of the dry backing layer.

12. A patch composition according to any one of claims 1-11, wherein the backing layer comprises a therapeutically active ingredient dispersed in the matrix of the water-soluble polymer.

13. A patch composition according to any one of claims 1-12, wherein the microneedles have a length of 50-1000 µm, e.g. 100-800 µm, 300-700 µm, 400-600 µm or about 500 µm.

14. A patch composition according to any one of claims 1-13, wherein the tip portion constitutes 5-95% of the total volume of the microneedle.

15. A patch composition according to any one of claims 1-14, wherein the substrate is composed of adhesive medical tape.

16. A patch composition according to any one of claims 1-15, wherein the backing layer portion overlayers the base of the tip portion in such a manner that each microneedle is separated from the other microneedles on the patch and forms a discrete entity when the substrate is removed upon application of the patch on the skin.

17. A patch composition according to any one of claims 1-16, wherein the microneedles are either conical or pyramidal thus comprising a number of longitudinally extending ridges to facilitate the insertion of the microneedles into the skin.

18. A patch composition according to claim 17, wherein the microneedles comprise 4-8 longitudinally extending edges.

19. A patch composition according to any one of claims 1-18, wherein the therapeutically active ingredient is selected from the group consisting of a vitamin D analogue, a glucocorticoid receptor modulator, ingenol or an ingenol derivative, a calcineurin inhibitor, a JAK inhibitor, a PDE4 inhibitor, a non-steroidal anti-inflammatory agent, an antibiotic, an antifungal agent or a local anesthetic, or mixtures thereof.

20. A patch composition according to any one of claims 1-19 comprising one or more microneedles each comprising
(a) a tapered tip portion containing one or more therapeutically active ingredients selected from the group consisting of calcipotriol and a betamethasone ester dispersed in a matrix of a biodegradable polymer selected from the group consisting of an ester-terminated polylactide, an ester-terminated polyglycolide and an ester-terminated polylactide co-glycolide, and
(b) a fast dissolving microneedle backing layer portion containing a water-soluble polymer overlayering the tip portion,
said microneedle or microneedles being attached to and extending from an adhesive surface of a removable substrate.

21. A patch composition according to claim 20, wherein the betamethasone ester is betamethasone dipropionate or betamethasone valerate, in particular betamethasone dipropionate.

22. A patch composition according to claim 20 or 21 comprising 0.08-30 µg of calcipotriol per cm^2.

23. A patch composition according to any one of claims 20-22 comprising 1-60 µg of betamethasone dipropionate per cm^2.

24. A patch composition according to any one of claims 20-23, wherein the biodegradable polymer is an ester-terminated polylactide co-glycolide.

25. A patch composition according to any one of claims 20-24, wherein the biodegradable polymer has a molecular weight of >5000, such as a molecular weight of 7000-17000, 24000-38000, 38000-54000, 54000-69000 or 76000-116000.

26. A patch composition according to claim 24 or 25, wherein the ratio of lactide to glycolide is between 85:15 and 50:50, such as 85:15, 82:18, 75:25, 65:35 or 50:50.

27. A patch composition according to any one of claims 20-27, wherein the backing layer comprises calcipotriol and/or a betamethasone ester dispersed in the matrix of the water-soluble polymer.

28. A patch composition according to any one of claims 20-27, wherein the water-soluble polymer is polyvinylpyrrolidone.

29. A microneedle patch composition for use in treating a skin condition, the composition comprising one or more microneedles each comprising
(a) a tapered tip portion containing a therapeutically active ingredient dispersed in a matrix of a biodegradable polymer capable of providing sustained release of the therapeutically active ingredient over a period of at least two days after insertion of the microneedle or microneedles into the skin, and
(b) a fast dissolving microneedle backing layer portion containing a water-soluble polymer overlayering the tip portion,
said microneedle or microneedles being attached to and extending from an adhesive surface of a removable substrate
wherein the therapeutically active ingredient is released from the microneedles over a period of 2-21 days after insertion of the microneedle or microneedles into the skin.

30. A patch composition according to claim 29 comprising 2-100 microneedles per cm^2, e.g. 5-75 microneedles, 10-50 microneedles, 15-30 microneedles or 20-25 microneedles per cm^2.

31. A patch composition according to claim 29 or 30, wherein the biodegradable polymer is polylactic acid or a derivative thereof such as an ester-terminated polylactide, polyglycolic acid or a derivative thereof such as an ester-terminated polyglycolide, or polylactic co-glycolic acid or a derivative thereof such as an ester-terminated polylactide co-glycolide.

32. A patch composition according to any one of claims 29-31, wherein the biodegradable polymer has a molecular weight of >5000, such as a molecular weight of 7000-17000, 24000-38000, 38000-54000, 54000-69000 or 76000-116000.

33. A patch composition according to claim 31 or 32, wherein the ratio of lactide to glycolide is between 85:15 and 50:50, such as 85:15, 82:18, 75:25, 65:35 or 50:50.

34. A patch composition according to any one of claims 29-33, wherein the biodegradable polymer matrix further comprises an antioxidant, e.g. butylhydroxytoluene, butylhydroxyanisole or α-tocopherol, or a mixture thereof.

35. A patch composition according to claim 34, wherein the concentration of the antioxidant is in the range of 0.01-3% w/w, preferably 0.03-2% w/w such as 0.05-1% w/w of the dry tip portion.

36. A patch composition according to any one of claims 29-35, wherein the water-soluble polymer is selected from the group consisting of polyvinylpyrrolidone, a sugar such as sucrose or trehalose, dextran, carboxymethylcellulose and sodium alginate.

37. A patch composition according to claim 36, wherein the water-soluble polymer is polyvinylpyrrolidone.

38. A patch composition according to any one of claims 29-37, wherein the backing layer portion comprises a plasticizer, e.g. glycerol, polyethylene glycol, dibutyl sebacate, diethyl phthalate, triethyl glycerin or triethyl citrate.

39. A patch composition according to claim 38, wherein the concentration of the plasticizer is in the range of 0.5-6% by weight of the dry backing layer.

40. A patch composition according to any one of claims 29-39, wherein the backing layer comprises a therapeutically active ingredient dispersed in the matrix of the water-soluble polymer.

41. A patch composition according to any one of claims 29-40, wherein the microneedles have a length of 50-1000 μm, e.g. 100-800 μm, 300-700 μm, 400-600 μm or about 500 μm.

42. A patch composition according to any one of claims 29-41, wherein the tip portion constitutes 5-95% of the total volume of the microneedle.

43. A patch composition according to any one of claims 29-42, wherein the substrate is composed of adhesive medical tape.

44. A patch composition according to any one of claims 29-43, wherein the backing layer portion overlayers the base of the tip portion in such a manner that each microneedle is separated from the other microneedles on the patch and forms a discrete entity when the substrate is removed upon application of the patch on the skin.

45. A patch composition according to any one of claims 29-44, wherein the microneedles are either conical or pyramidal thus comprising a number of longitudinally extending ridges to facilitate the insertion of the microneedles into the skin.

46. A patch composition according to claim 45, wherein the microneedles comprise 4-8 longitudinally extending edges.

47. A patch composition according to any one of claims 29-46, wherein the therapeutically active ingredient is selected from the group consisting of a vitamin D analogue, a glucocorticoid receptor modulator, ingenol or an ingenol derivative, a calcineurin inhibitor, a JAK inhibitor, a PDE4 inhibitor, a non-steroidal anti-inflammatory agent, an antibiotic, an antifungal agent or a local anesthetic, or mixtures thereof.

48. The method according to any one of claims 29-47, wherein the skin condition is psoriasis, actinic keratosis, squamous cell carcinoma, basal cell carcinoma, contact dermatitis, atopic dermatitis, eczema, hand eczema, warts, genital warts, alopecia, acne, rosacea or skin infections.