Claims

1. Electrospun fibers comprising

i) a hydrophilic polymer that is soluble in a first solvent, wherein the hydrophilic polymer has a solubility in said first solvent of 3 g/100 ml or more at 25 °C or 10 g/100 ml or more at 25 °C,

ii) a bioadhesive substance that has a solubility in said first solvent of 0.5 g/100 ml or less at 25°C or 0.1g/100 ml or less at 25°C,

iii) one or more corticosteroids.

2. Electrospun fibres according to claim 1, wherein the hydrophilic polymer is selected from polyvinylpyrrolidone (PVP), ethylcellulose, hydroxypropylcellulose, acrylates, polymers of acrylic/methacrylic esters, and mixtures thereof.

3. Electrospun fibres according to claim 1 or 2, wherein the bioadhesive substance is selected from dextrans, polyethylene oxides (PEOs), alginate, tragacanth, carrageenan, pectin, gelatin, guar, xanthan, gellan, methylcellulose, hydroxypropylmethylcellulose (HPMC), polyvinylalcohol (PVA), polymers of acrylic acids (PAA derivatives), chitosan, lectins, thiolated polymers, non-ionic water-soluble polyethylene oxide resions (polyoxo WSRA),and PAA-co-PEG (PEG is polyethylene glycol), and mixtures thereof.

4. Electrospun fibers according to any of the preceding claims, wherein the corticosteroid is selected from betamethasone, budenoside, clobetasol, clobetasone, desoximethasone, diflucortolon, diflorasone, fluocinonide, fluocinolon, halcinonide, halobetasol, hydrocortisone, mometasone and triamcinolone, or a pharmaceutically acceptable ester thereof.

5. Electrospun fibers according to any of the preceding claims, wherein the corticosteroid is a corticosteroid ester selected from betamethasone acetate, betamethasone dipropionate, betamethasone valerate, clobetasol propionate, dexamethasone acetate, flumethasone pivalate, fluticasone propionate, hydrocortisone acetate, hydrocortisone butyrate and mometasone furoate.

6. Electrospun fibres according to any of the preceding claims, wherein the bioadhesive substance is at the most very slightly soluble in said first solvent.

~~7. Electrospun fibres according to any of the preceding claims, wherein at least 90% w/w of the bioadhesive substance is present in undissolved form.~~

~~8. Electrospun fibres according to any of the preceding claims, wherein at least 95% w/w or 99% w/w of the bioadhesive substance is present in undissolved form.~~

~~9. Electrospun fibres according to any of the preceding claims, wherein said first solvent is ethanol or ethanol-water mixtures.~~

~~10. Electrospun fibres according to claim 9, wherein said ethanol-water mixtures contain 20% v/v water or less or 10% v/v water or less.~~

~~11. Electrospun fibres according to claim 9 or 10, wherein said ethanol-water mixtures contain 5% v/v water or less such as 3% v/v water of less.~~

~~12. Electrospun fibers according to any of the preceding claims, wherein the hydrophilic polymer is PVP or polymers of acrylic/methacrylic esters (Eudragit®), or mixtures thereof.~~

~~13. Electrospun fibres according to any of the preceding claims, wherein the bioadhesive substance is dextran having an average molecular weight of from 400,000 Da to 2,000,000 Da.~~

~~14. Electrospun fibres according to any of the preceding claims, wherein the bioadhesive substance is dextran having an average molecular weight of about 2,000,000 Da.~~

~~15. Electrospun fibres according to any of claims 1-14, wherein the bioadhesive substance is polyethylene oxide having an average molecular weight of from 100,000 Da to 4,000,000 Da.~~

~~16. Electrospun fibres according to any of claims 1-14, wherein the bioadhesive substance is polyethylene oxide having an average molecular weight of 2,000,000 Da.~~

~~17. Electrospun fibres according to any of the preceding claims, wherein the weight ratio between the bioadhesive substance and the fibre-forming polymer in the fibres is in a range of from 0.1 to 10.~~

~~18. Electrospun fibres according to any of the preceding claims, wherein the drug substance is selected from drug substances, which are indicated for treatment of a disease of the skin or mucosa.~~

~~19. Electrospun fibres according to any of the preceding claims, wherein the drug substance is selected from drug substances, which are indicated for treatment of a disease in the oral cavity.~~

~~20. Electrospun fibres according to claim 19, wherein the drug substance is selected from drug substances, which are indicated for local treatment of a disease in the oral cavity.~~

~~21. Electrospun fibres according to any of the preceding claims, wherein the water content is at the most about 5% w/w.~~

~~22. Electrospun fibres according to any of the preceding claims for use in medicine.~~

~~23. Electrospun fibres according to any of the preceding claims for use in the treatment of diseases of the oral cavity.~~

~~24. A composition comprising electrospun fibres as defined in any of claims 1-23.~~

~~25. A composition according to claim 24, wherein the concentration of the electrospun fibres in the composition is from 70 to 100% w/w.~~

~~26. A composition according to claim 24 or 25 in the form of a layered composition.~~

~~27. Electrospun fibres according to any one of claims 1-23 or a composition according to any one of claims 24-26, wherein an outer surface of said electrspun fibres or composition is provided with a coating.~~

28. Electrospun fibres or a composition according to claim 27, wherein the coating is water-impermeable.

29. Electrospun fibres or a composition according to claim 27 or 28, wherein the coating comprises carbothane, polycapronlactone or polyethylene-co-vinyl acetate, or mixtures thereof.

30. Electrospun fibres as defined in any of claims 1-23 or a composition as defined in any of claims 24-28 for use in medicine.

31. Electrospun fibres or a composition as defined in any of claims 24-30 for use in the treatment of diseases of the oral cavity.

32. A kit comprising
i) electrospun fibres or a composition as defined in any of the preceding claims, and
ii) an applicator for applying the composition in the oral cavity.

33. A method for preparing electrospun fibres as defined in any of claims 1-23, the method comprising
i) dissolving the hydrophilic polymer in a first solvent,
ii) suspending the bioadhesive substance in the resulting solution from step i)
iii) adding the drug substance to the resulting dispersion from step ii)
iv) electrospinning the resulting mixture from step iii),
wherein said hydrophilic polymer is soluble in said first solvent, and said bioadhesive substance is slightly soluble or less in said first solvent,
to obtain electrospun fibres, wherein at least 90% w/w of the bioadhesive substance is present in undissolved form.

34. A method for preparing electrospun fibres according to any of claims 1-23, the method comprising
i) dissolving the hydrophilic polymer in a first solvent to obtain a first solution,
ii) dissolving or suspending the drug substance in said first solution to obtain a first mixture,
iii) suspending the bioadhesive substance in the first solvent to obtain a second dispersion,
iv) dual-electrospinning the first mixture and the second dispersion,

~~wherein said hydrophilic polymer is soluble in said first solvent, and said bioadhesive substance is slightly soluble in said first solvent,~~
~~to obtain electrospun fibres, wherein at least 90% w/w of the bioadhesive substance is present in undissolved form.~~

~~35. A method according to claim 33 or 34 further comprising a step of coating an outer surface of the fibres with a hydrophobic polymer.~~

~~36. A method according to claim 35, wherein the coated fibres are subject to heating to melt or soften the hydrophobic polymer.~~

1. A mucosal patch comprising:
a drug-delivery layer comprising electrospun fibers, wherein the electrospun fibers comprise:
polyvinylpyrrolidone, an ammonio methacrylate copolymer type B; and polyethylene oxide
and
a backing layer comprising poly(caprolactone).

2. The mucosal patch of claim 1, wherein the electrospun fibers further comprise clobetasol propionate.

3. The mucosal patch of claim 1 or 2, wherein the amount of polyethylene oxide in the drug-delivery layer is 8% to 50% by weight.

4. The mucosal patch of claim 1 or 2, wherein the amount of polyethylene oxide in the drug-delivery layer is 50% by weight.

5. The mucosal patch of any one of claims 1 to 4, wherein the weight ratio of polyethylene oxide to polyvinylpyrrolidone and ammonio methacrylate copolymer type B is 0.1 to 2.

6. The mucosal patch of claim 1 or 2, wherein the amount of polyvinylpyrrolidone and ammonio methacrylate copolymer type B in the drug-delivery layer is 50% to 85% by weight.

7. The mucosal patch of claim 1 or 2, wherein the amount of polyvinylpyrrolidone and ammonio methacrylate copolymer type B in the drug-delivery layer is 50% by weight.

8. The mucosal patch of any one of claims 1 to 7, wherein the average molecular weight of the polyethylene oxide is 100,000 Da to 4,000,000 Da.

9. The mucosal patch of any one of claims 1 to 8, wherein the weight average molecular weight of the polyvinylpyrrolidone is 900,000 Da to about 3,000,000 Da.

10. The mucosal patch of any one of claims 1 to 8, wherein the weight average molecular weight of the polyvinylpyrrolidone is 1,500,000 Da.

11. The mucosal patch of any one of claims 1 to 10, wherein the poly(caprolactone) comprises melted electrospun poly(caprolactone) fibers.

12. The mucosal patch of any one of claims 1 to 11, wherein the backing layer further comprises a pigment.

13. The mucosal patch for use in the treatment of oral lichen planus, comprising:

a drug-delivery layer comprising electrospun fibers, wherein the electrospun fibers comprise:

clobetasol propionate;

a fibre-forming hydrophilic polymer; and

a bioadhesive substance;

and

a hydrophobic backing layer.

14. The mucosal patch of claim 13, wherein the a fibre-forming hydrophilic polymer is selected from polyvinylpyrrolidone (PVP), ethylcellulose, hydroxypropylcellulose, acrylates and acrylic copolymers (Eudragit®), and mixtures thereof.

15. The mucosal patch of claim 14, wherein the fibre-forming hydrophilic polymer comprises polyvinylpyrrolidone and ammonio methacrylate copolymer type B.

16. The mucosal patch of any one of claims 13-15, wherein the bioadhesive substance is selected from dextrans, polyethylene oxides (PEOs), alginate, tragacanth, carrageenan, pectin, guar, xanthan, gellan, methylcellulose, hydroxypropylmethylcellulose (HPMC), polyvinylalcohol (PVA), polymers of acrylic acids (PAA derivatives), chitosan, lectins, thiolated polymers, PAA-co-PEG (PEG is polyethylene glycol), and mixtures thereof.

17. The mucosal patch of any one of claims 13-16, wherein the bioadhesive substance comprises polyethylene oxide.

18. The mucosal patch of any one of claims 13-17, wherein the fibre-forming hydrophilic polymer comprises polyvinylpyrrolidone and ammonio methacrylate copolymer type B and the bioadhesive substance comprises polyethylene oxide.

19. The mucosal patch of any one of claims 13-18, wherein the hydrophobic layer comprises polycapronelactone or polyethylene-co-vinyl acetate, or mixtures thereof.

20. The mucosal patch of any one of claims 13-19, wherein the hydrophobic layer comprises polycapronelactone.

21. The mucosal patch of any one of claims 16-20, wherein the amount of polyethylene oxide in the drug-delivery layer is 8% to 50% by weight.

22. The mucosal patch of any one of claims 16-20, wherein the amount of polyethylene oxide in the drug-delivery layer is 50% by weight.

23. The mucosal patch of any one of claims 14-22, wherein the weight ratio of polyethylene oxide to polyvinylpyrrolidone and ammonio methacrylate copolymer type B is 0.1 to 2.

24. The mucosal patch of any one of claims 14-22, wherein the amount of polyvinylpyrrolidone and ammonio methacrylate copolymer type B in the drug-delivery layer is 50% to 85% by weight.

25. The mucosal patch of any one of claims 14-22, wherein the amount of polyvinylpyrrolidone and ammonio methacrylate copolymer type B in the drug-delivery layer is 50% by weight.

26. The mucosal patch of any one of claims 16-25, wherein the average molecular weight of the polyethylene oxide is 100,000 Da to 4,000,000 Da.

27. The mucosal patch of any one of claims 14-26, wherein the weight average molecular weight of the polyvinylpyrrolidone is 900,000 Da to 3,000,000 Da.

28. The mucosal patch of any one of claims 14-26, wherein the weight average molecular weight of the polyvinylpyrrolidone is 150,000 Da.

29. The mucosal patch of claim 20, wherein the poly(caprolactone) comprises melted electrospun poly(caprolactone) fibers.

30. The mucosal patch of any one of claims 14-29, wherein the patch is to be applied to the buccal mucosa of the patient.