Claims

1. An administration system in film form for transmucosal administration of a steroid hormone, comprising 0.01-50% by weight of a steroid hormone and 50-99.99% by weight of a carrier material, characterized in that the steroid hormone is present dissolved in the carrier material.

2. The administration system as claimed in claim 1, characterized in that the carrier material is selected from the group consisting of cellulose, cellulose derivatives, poly-N-vinylpyrrolidones, vinylpyrrolidone-vinyl acetate copolymers, starch, starch derivatives, gelatin, gelatin derivatives and combinations thereof.

3. The administration system as claimed in claim 1 or 2, characterized in that the carrier material is methylcellulose, ethylcellulose, hydroxypropylcellulose, hydroxyethylcellulose, hydroxypropylmethylcellulose (HPMC) or a combination thereof.

4. The administration system as claimed in any of the preceding claims, characterized in that the carrier material is hydroxypropylmethylcellulose (HPMC).

5. The administration system as claimed in any of the preceding claims, characterized in that it additionally comprises liquid excipients which are able to dissolve

the steroid hormone and to form a second phase in the carrier material.

6. The administration system as claimed in claim 5, characterized in that the steroid hormone is present dissolved in the liquid excipient.

7. The administration system as claimed in any of the preceding claims, characterized in that it comprises between 2 and 15% by weight, preferably between 3 and 8% by weight and particularly preferably 5% by weight of a steroid hormone.

8. The administration system as claimed in any of the preceding claims, characterized in that it has an area of between 1 and 10 cm^2, preferably an area of between 5 and 8 cm^2 and particularly preferably an area of 7 cm^2.

9. The administration system as claimed in any of the preceding claims, characterized in that it has a weight per unit area of between 50 and 250 g/m^2, preferably between 100 and 150 g/m^2.

10. The administration system as claimed in any of the preceding claims, characterized in that it has a thickness of between 40 and 130 μm, preferably between 50 and 100 μm.

11. The administration system as claimed in any of the preceding claims, characterized in that it is mucoadhesive.

12. The administration system as claimed in any of the preceding claims, characterized in that it dissolves completely in a period of less than 30 minutes, preferably in a period of less than 15 minutes, in the mouth.

13. The administration system as claimed in any of the preceding claims, characterized in that the steroid hormone is an estrogen, preferably ethinylestradiol, a progesterone, preferably drospirenone, dienogest, gestodene, levonorgestrel or cyproterone acetate, an androgen, preferably testosterone, dihydrotestosterone, 7α-methyl-19-nortestosterone (MENT), MENT 17-acetate, 7α-methyl-11β-fluoro-19-nortestosterone (eF-MENT), mesterolone, metenolone, nandrolone, oxandrolone or androstenedione, a corticosteroid, preferably hydrocortisone, hydrocortisone 21-acetate, methyl-prednisolone aceponate, prednisolone, deflazacort, deflazacort alcohol, fluocortolone, fluocortolone hydrate or fluocortolone 21-pivalate or a mixture of these steroid hormones.

14. The administration system as claimed in any of the preceding claims, characterized in that the steroid hormone has a log P in the range of 1.0-4.3.

15. The administration system as claimed in any of the preceding claims, characterized in that the steroid hormone is testosterone, 7α-methyl-19-nortestosterone (MENT) or 7α-methyl-11β-fluoro-19-nortestosterone (eF-MENT).

16. The administration system as claimed in any of the preceding claims, characterized in that it additionally comprises at least one excipient from the group of flavorings, colorants, permeation enhancers, sweeteners, fillers, plasticizers, solubilizers, pH stabilizers, disintegrants.

17. The administration system as claimed in any of the preceding claims, characterized in that it releases the steroid hormone contained therein on buccal application with a bioavailability of at least 25%, preferably of at least 50%.

18. The administration system as claimed in any of the preceding claims, characterized in that it releases the steroid hormone contained therein on buccal application with a bioavailability of between 70 and 75%.

19. The use of a steroid hormone for producing a medicament in the form of an administration system in film form for transmucosal administration for the treatment of disorders and/or dysfunctions attributable to a steroid hormone deficiency.

20. The use as claimed in claim 19, characterized in that the steroid hormone is an estrogen, a progesterone, an androgen, a corticosteroid or a mixture of these steroid hormones.

21. The use as claimed in one or more of claims 19 to 20, characterized in that the disorder and/or dysfunction attributable to a steroid hormone deficiency is an androgen deficiency, in particular a testosterone deficiency.

22. The use as claimed in one or more of claims 19 to 21, characterized in that the steroid hormone reaches a maximum blood concentration in a period of less than 60 min after administration of the medicament.

23. The use as claimed in claim 22, characterized in that the steroid hormone reaches a maximum blood concentration in a period of less than 30 min after administration of the medicament.

24. The use as claimed in one or more of claims 19 to 23, characterized in that the steroid hormone is administered with a bioavailability of at least 25%, preferably of at least 50%.

25. A process for producing an administration system in film form for transmucosal administration of a steroid hormone, characterized in that the steroid hormone is mixed in the form of a solution in a pharmaceutically acceptable solvent with a water-containing mixture of a carrier material, the mixture produced thereby is spread out as a thin layer and is dried by removing the solvent and with formation of a film.

26. The process as claimed in claim 25, characterized in that the resulting film is divided into individual administration systems by perforation, cutting transversely and/or cutting longitudinally.

27. A method for the treatment of disorders and/or dysfunctions attributable to a steroid hormone deficiency, characterized in that in a first step an administration system in film form which comprises at least one steroid hormone is applied to the mucosa in the mouth, and in a second step the at least one steroid hormone penetrates transmucosally into the bloodstream.

28. The method as claimed in claim 27, characterized in that the steroid hormone penetrates into the bloodstream in a period of less than 30 min after application of the administration system to the mucosa in the mouth, preferably in less than 15 min.

Claims

1. A steroid hormone administration system in film form, for the transmucosal administration of a steroid hormone, comprising 0.01-50% by weight of a steroid hormone having a log P value in the range of 1.0-4.3, and 50-99.99% by weight of a carrier material selected from the group consisting of cellulose, cellulose derivatives, poly-N-vinylpyrrolidones, vinyl-pyrrolidone-vinyl acetate copolymers, starch, starch derivatives, gelatin, gelatin derivatives and combinations thereof, characterized in that the steroid hormone is present in a dissolved form in the carrier material.

2. The administration system as claimed in claim 1, characterized in that the carrier material is selected from the group consisting of methylcellulose, ethylcellulose, hydroxypropyl-cellulose, hydroxyethylcellulose, hydroxypropylmethyl-cellulose (HPMC) and a combination thereof.

3. The administration system as claimed in any of the preceding claims, characterized in that it further comprises liquid excipients which are able to dissolve the steroid hormone and to form a second phase in the carrier material.

4. The administration system as claimed in claim 3, characterized in that the steroid hormone is present dissolved in the liquid excipient.

5. The administration system as claimed in any one of claims 1 to 4, characterized in that it comprises between 2 and 15% by weight, preferably between 3 and 8% by weight and particularly preferably 5% by weight of a steroid hormone.

6. The administration system as claimed in any one of claims 1 to 5, characterized in that it has an area of between 1 and 10 cm^2, preferably an area of between 5 and 8 cm^2 and particularly preferably an area of 7 cm^2.

7. The administration system as claimed in any one of claims 1 to 6, characterized in that it has a weight per unit area of between 50 and 250 g/m^2, preferably between 100 and 150 g/m^2.

8. The administration system as claimed in any one of claims 1 to 7, characterized in that it has a thickness of between 40 and 130 μm, preferably between 50 and 100 μm.

9. The administration system as claimed in any one of claims 1 to 8, characterized in that it is mucoadhesive.

10. The administration system as claimed in any one of claims 1 to 9, characterized in that it dissolves completely in a period of less than 30 minutes, preferably in a period of less than 15 minutes, in the mouth.

11. The administration system as claimed in any one of claims 1 to 10, characterized in that the steroid hormone is selected from the group consisting of estrogens, preferably ethinylestradiol, a progesterone, preferably drospirenone, dienogest, gestodene, levonorgestrel or cyproterone acetate, androgens, preferably testosterone, dihydrotestosterone, 7α-methyl-19-nortestosterone (MENT), MENT 17-acetate, 7α-methyl-11β-fluoro-19-nor-testosterone (eF-MENT), mesterolone, metenolone, nandrolone, oxandrolone or androstenedione, corticosteroids, preferably hydrocortisone, hydrocortisone 21-acetate, methyl-prednisolone aceponate, prednisolone, deflazacort, deflazacort alcohol, fluocortolone, fluocortolone hydrate or fluocortolone 21-pivalate, and a mixture of these steroid hormones.

12. The administration system as claimed in any one of claims 1 to 11, characterized in that it further comprises at least one excipient selected from the group consisting of flavorings, colorants, permeation enhancers, sweeteners, fillers, plasticizers, solubilizers, pH stabilizers and disintegrants.

13. The administration system as claimed in any one of claims 1 to 12, characterized in that it releases the steroid hormone contained therein on buccal application with a bioavailability of at least 50%.

14. The administration system as claimed in any one of claims 1 to 13, characterized in that it releases the steroid hormone contained therein on buccal application with a bioavailability of between 70 and 75%.

15. The use of a steroid hormone in the production of a medicament, the medicament being in the form of an administration system in film form for the transmucosal administration of a steroid hormone for the treatment of disorders and/or dysfunctions attributable to a steroid hormone.

16. The use as claimed in claim 15, characterized in that the steroid hormone is selected from the group consisting of estrogens, progesterones, androgens, corticosteroids and a mixture of these steroid hormones.

17. The use as claimed in claim 15 or 16, characterized in that the disorder and/or dysfunction attributable to a steroid hormone deficiency is an androgen deficiency, in particular a testosterone deficiency.

18. The use as claimed in any one of claims 15 to 17, characterized in that the steroid hormone reaches a maximum blood concentration in a period of less than 60 min after administration of the medicament.

19. The use as claimed in claim 18, characterized in that the steroid hormone reaches a maximum blood concentration in a period of less than 30 min after administration of the medicament.

20. The use as claimed in any one of claims 15 to 19, characterized in that the steroid hormone is administered with a bioavailability of at least 25%, preferably of at least 50%.

21. A process for producing a steroid hormone administration system in film form for the transmucosal administration of a steroid hormone, characterized in that the steroid hormone is mixed in the form of a solution in a pharmaceutically acceptable solvent with a water-containing mixture of a carrier material, the mixture produced thereby is spread out as a thin layer and is dried by removing the solvent, with the formation of a film.

22. The process as claimed in claim 21, characterized in that the resulting film is divided into individual administration systems by perforation, cutting transversely and/or cutting longitudinally.

23. Use of a steroid hormone in the manufacture of a

medicament, the medicament being in the form of an administration system in film form, for the treatment of disorders and/or dysfunctions attributable to a steroid hormone deficiency, in a subject requiring said treatment, wherein said medicament comprises a therapeutically effective amount of a steroid hormone, and comprises at least one steroid hormone in dissolved form, whereby the medicament is in a first step to be applied to the mucosa of the mouth, and in a second step the at least one steroid hormone penetrates transmucosally into the bloodstream.

24. The use as claimed in claim 23, characterized in that the steroid hormone penetrates into the bloodstream in a period of less than 30 min after application of the administration system to the mucosa in the mouth, preferably in less than 15 min.

25. Use of a steroid hormone in the manufacture of a medicament, the medicament being in the form of an administration system in film form, for the prevention of a condition in a subject, wherein said medicament comprises a therapeutically effective amount of a steroid hormone to prevent said condition, and comprises at least one steroid hormone in dissolved form, whereby the medicament is in a first step to be applied to the mucosa of the mouth, and in a second step the at least one steroid hormone penetrates transmucosally into the bloodstream.

26. Use of at least one steroid hormone in the manufacture of a medicament, the medicament being in the form of an administration system in film form, for delivery of said at least one steroid hormone to a subject in need of the at least one steroid hormone, wherein said medicament comprises an effective amount of the at least one steroid hormone, and comprises at least one steroid hormone in dissolved form, whereby the medicament is in a first step to be applied to the mucosa of the mouth, and in a second step the at least one steroid hormone penetrates transmucosally into the bloodstream.