Tablet containing steroid hormones

SUMMARY

In a first aspect, there is provided 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.

In a second aspect, there is provided 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.

In a third aspect, there is provided the 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.

In a fourth aspect, there is provided the 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.

In a fifth aspect, there is provided the 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.

In a sixth aspect, there is provided 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.

DETAILED DESCRIPTION

The invention relates to a pharmaceutical composition in the form of a system in film form for transmucosal administration of steroid hormones.

Various administration forms of steroid hormones have been described. Besides conventional oral administration, also available are implants, patches and gels. These administration forms aim at continuous delivery of the steroid hormones which is as uniform as possible over a lengthy period. However, for various applications, an administration leading a rapid rise in the concentration of the steroid hormone in the blood would be desirable. In order for example in a case of male testosterone deficiency to restore the physiological state, it would be necessary to achieve a concentration peak in the morning. The prerequisite for this would be a rapid uptake of the hormone and a high bioavailability in order to achieve a high blood concentration in a short time.

Rapid release of active ingredients can be achieved by a transmucosal administration. Dosage forms which disintegrate in an aqueous environment, e.g. in the mouth, are known for this purpose. Buccal administration systems such as patches, suckable tablets, chewing gum, films and melting tablets are known.

Particular mention should be made in this connection of systems in film form, called wafer (US 5,948,430). After application of a wafer in the mouth, the active ingredient is released into the surroundings. To achieve a rapid rise in the concentration of the active ingredient in the blood, it is particularly important that absorption of the active ingredient through the oral mucosa is rapid. Poor solubility or absorption