Patent claims

1. Solid transdermal therapeutic system with at least one single-layer matrix which comprises a matrix polymer supersaturated with gestodene or a gestodene ester, and/or ethinylestradiol, and a removable protective film directly adjacent to the active-ingredient-containing matrix, characterized in that
no, or on less than 2% of the patch area, fraction of gestodene or gestodene ester not dissolved in the matrix polymer crystallizes out in the form of amorphous or crystalline particles with an average diameter of at most 200 µm at the interface between removable protective film and active-ingredient-containing matrix or in the active-ingredient-containing adhesive matrix, and that the matrix is free from solubility promoters, crystallization inhibitors and dispersants.

2. Solid transdermal therapeutic system with at least one single-layer matrix which comprises a matrix polymer supersaturated with gestodene or a gestodene ester, and/or ethinylestradiol, and a removable protective film directly adjacent to the active-ingredient-containing matrix, characterized in that
the active-ingredient-containing matrix is limited by a siliconized or fluorine-coated polyester removable film (release liner).

3. Solid transdermal therapeutic system with at least one single-layer matrix which comprises a matrix polymer supersaturated with gestodene or a gestodene ester, and/or ethinylestradiol, and a removable protective film directly adjacent to the active-ingredient-containing matrix, characterized in that
FL 2000 75 µm PET 1s (78CC), FL 2000 75 µm PET 1s (RT149), FL 2000 75 µm PET 1s (RT404), Perlasic LF75, Scotchpak 9744, Scotchpak 9741, Silphan S50 M030, Akrosil Release Liner, 490si Release Liner, Primeliner FL PET 2000 Type 78JR, Primeliner FL PET Type 78 GY or Silex PET film my siliconized is used as protective film.

4. Solid transdermal therapeutic system according to Claim 3, characterized in that the release liner is selected from the group Perlasic LF75, Loparex 78CC, Scotchpack 9741, Primeliner FL PET 2000 Type 78JR, Primeliner FL PET Type 78 GY and Silex PET film my siliconized.

5. Solid transdermal therapeutic system according to Claim 1, characterized in that no, or on less than 1% of the patch area, fraction of gestodene or a gestodene ester not dissolved in the matrix polymer crystallizes out in the form of amorphous or crystalline particles with an average diameter of at most 100 µm at the interface between removable protective film and active-ingredient-containing matrix or in the active-ingredient-containing matrix, and that the matrix is free from solubility promoters, crystallization inhibitors and dispersants.

6. Solid transdermal therapeutic system according to one of the preceding claims, characterized in that the layer order starts furthest removed from the skin with a backing layer, an adhesive layer, a release layer, the active-ingredient-containing matrix and the removable protective layer.

7. Solid transdermal therapeutic system according to one of the preceding claims, characterized in that the adhesive layer comprises a UV absorber.

8. Solid transdermal therapeutic system according to Claim 6, characterized in that the UV absorber Tinosorb.

9. Solid transdermal therapeutic system according to one of the preceding claims, wherein gestodene is present in an amount of 2.1 mg and ethinylestradiol is present in an amount of 0.55 mg.

10. Solid transdermal therapeutic system according to Claim 9 with a size of 11 cm^2.

11. Solid transdermal therapeutic system (TTS) according to one of the preceding claims, characterized in that the TTS is a patch.

12. Solid transdermal therapeutic system according to Claim 11 for continuous application over a period of 7 days.

13. Kit comprising 1 to 52, 1 to 26, 1 to 13 patches as defined in Claim 11 for continuous application over a period of 52, 26 or 13 weeks, respectively, in each case plus 7 days without patch.

Claims

1. Solid transdermal therapeutic system with at least one single-layer matrix which comprises a matrix polymer supersaturated with gestodene and/or ethinylestradiol and no or up to a maximum of 5% of crystallization inhibitors based on the total amount of the active ingredient-containing polymer matrix, and whereby the matrix polymer contains polyisobutylene and whereby the matrix polymer contains 1.9 wt% of gestodene and 0.5 wt% of ethinylestradiol calculated based on the weight of the active ingredient-containing matrix and whereby the gestodene is solved in the active ingredient-containing matrix polymer, and a removable protective film directly adjacent to the active-ingredient-containing matrix, characterized in that
the active ingredient-containing matrix is adjacent to a siliconized or fluorine-coated polyester film (release liner) and no, or on less than 2% of the patch area, the amount of gestodene or gestodene ester which is not dissolved in the matrix polymer crystallizes out in the form of amorphous or crystalline particles with an average diameter of at most 200 µm at the interface between removable protective film and active-ingredient-containing matrix or in the active-ingredient-containing adhesive matrix, and that the matrix is free from solubility promoters, crystallization inhibitors and dispersants.

2. Solid transdermal therapeutic system according to Claim 1, characterized in that no, or on less than 1% of the patch area, the amount of gestodene or a gestodene ester which is not dissolved in the matrix polymer crystallizes out in the form of amorphous or crystalline particles with an average diameter of at most 100 µm at the interface between removable protective film and active-ingredient-containing matrix or in the active-ingredient-containing matrix, and that the matrix is free from solubility promoters, crystallization inhibitors and dispersants.

3. Solid transdermal therapeutic system according to Claim 1 or Claim 2, characterized in that the layer sequence that starts with the most distant from the skin with a backing layer, an adhesive layer, a release layer, the active-ingredient-containing matrix and the removable protective layer.

4. Solid transdermal therapeutic system according to Claim 3, characterized in that the adhesive layer comprises a UV absorber.

5. Solid transdermal therapeutic system according to Claim 4, characterized in that the UV absorber is Tinosorb.

6. Solid transdermal therapeutic system according to Claim 5 with a size of 11 cm^2.

7. Solid transdermal therapeutic system (TTS) according to any one of the preceding claims, characterized in that the TTS is a patch.

8. Solid transdermal therapeutic system according to Claim 7 for contraception characterised in that application is continuous over a period of 7 days.

9. Kit comprising 1 to 52, 1 to 26, or 1 to 13 patches as defined in Claim 8, for continuous application over a period of 52, 26 or 13 weeks, respectively, in each case plus 7 days without patch.