Claims

1. A transdermal therapeutic system comprising

   a) a backing layer (1),

   b) a matrix layer (2) containing a drug; and

   c) a release liner (4) to be removed before use,

wherein the drug is rotigotine,

wherein the matrix layer (2) contains one or more non-amine-resistant pressure sensitive silicone adhesives in an amount of more than 50% by weight, based on the total weight of the pressure sensitive adhesives of the matrix layer (2), and paraffin in an amount of at least 0.1% by weight, based on the total weight of the matrix layer (2), wherein the rotigotine in the matrix layer (2) is substantially present in a non-crystalline form in the dispersed phase of a solid dispersion comprising a polyvinylpyrrolidone.

2. The transdermal therapeutic system according to claim 1, wherein the matrix layer (2) contains paraffin in an amount of 0.2-20.0% by weight, preferably 0.5-10.0% by weight, more preferably 1.0-4.0% by weight, based on the total weight of the matrix layer (2).

3. The transdermal therapeutic system according to any of the preceding claims, wherein the matrix layer (2) has a weight per unit area of 40-70 g/m^2, preferably 50-60 g/m^2.

4. The transdermal therapeutic system according to any of claims 1-3 in which at least one additional initially active ingredient-free pressure sensitive adhesive layer (3) is between the matrix layer (2) and the release liner (4) to be removed before use, wherein the at least one additional initially active ingredient-free pressure sensitive adhesive layer (3) contains one or more non-amine-resistant pressure sensitive silicone adhesives in an amount of more than 50% by weight, based on the total weight of the pressure sensitive adhesives of the at least one additional initially active ingredient-free pressure sensitive adhesive layer (3), and paraffin in an amount of at least 0.1% by weight, preferably 0.2-20.0% by weight, more preferably 1.0-5.0% by weight, based on the total weight of the at least one additional initially active ingredient-free pressure sensitive adhesive layer (3).

5. The transdermal therapeutic system according to claim 4, wherein the at least one additional initially active ingredient-free pressure sensitive adhesive layer (3) has a weight per unit area of 20-40 g/m^2, preferably 25-35 g/m^2.

6. The transdermal therapeutic system according to any of the preceding claims, wherein the matrix layer (2) has a weight percentage of non-amine-resistant pressure sensitive silicone adhesive of more than 75% by weight, preferably more than 90% by weight, based on the total weight of the pressure sensitive adhesive of the matrix layer (2).

7. The transdermal therapeutic system according to any of claims 4 to 6, wherein the at least one additional initially active ingredient-free pressure sensitive adhesive layer (3) has a weight percentage of non-amine-resistant pressure sensitive silicone adhesive of more than 75% by weight, preferably more than 90% by weight, based on the total weight of the pressure sensitive adhesive of the at least one additional initially active ingredient-free pressure sensitive adhesive layer (3).

8. The transdermal therapeutic system according to any of the preceding claims, wherein the matrix layer (2) and, if present, the at least one additional initially active ingredient-free pressure sensitive adhesive layer (3), exclusively have non-amine-resistant pressure sensitive silicone adhesives as the pressure sensitive adhesives.

9. The transdermal therapeutic system according to any of the preceding claims, wherein the non-amine-resistant pressure sensitive silicone adhesives are silanol-reduced silicone adhesives.

10. The transdermal therapeutic system according to any of the preceding claims, wherein the weight ratio of rotigotine to polyvinylpyrrolidone is at most 9:6.4, preferably at most 9:6.5, more preferably at most 9:7.

11. The transdermal therapeutic system according to claim 10, wherein the weight ratio of rotigotine to polyvinylpyrrolidone is 9:7 to 9:10.

12. The transdermal therapeutic system according to any of claims 1-11, in which the content of active ingredient in the matrix layer (2) is in the range of from 6% by weight to 20% by weight, preferably in the range of from 6.5% by weight to 11.5% by weight, based on the total weight of the matrix layer (2).

13. The transdermal therapeutic system according to any of the preceding claims, wherein the one or more non-amine-resistant pressure sensitive silicone adhesives of the matrix layer (2) and/or the at least one additional initially active ingredient-free pressure sensitive adhesive layer (3), if at least one additional initially active ingredient-free pressure sensitive adhesive layer (3) is present, comprise two or more non-amine-resistant pressure sensitive silicone adhesives, wherein preferably one or more of the non-amine-resistant pressure sensitive silicone adhesives have a medium tack and one or more of the non-amine-resistant pressure sensitive silicone adhesives have a high tack.

14. The transdermal therapeutic system according to any of the preceding claims, wherein the one or more non-amine-resistant pressure sensitive silicone adhesives of the matrix layer (2) and/or the at least one additional initially active ingredient-free pressure sensitive adhesive layer (3), if at least one additional initially active ingredient-free pressure sensitive adhesive layer (3) is present, exclusively consist of a silanol-reduced non-amine-resistant pressure sensitive silicone adhesive.

15. The transdermal therapeutic system according to any of the preceding claims, wherein the matrix layer (2) contains one or more antioxidants and/or sodium metabisulfite.

16. The transdermal therapeutic system according to any of claims 1-15 for use in the treatment of the Parkinson disease.

17. A method for the preparation of a transdermal therapeutic system according to any of claims 1-3, 6, and 8-15, as a monolayer formulation comprising the steps of

a) preparing a homogenized coating mass by adding together all components of the matrix layer (2) in a suitable solvent and mixing to the desired homogeneity;

b) applying the homogenized coating mass onto a backing layer (1) or preferably onto a release liner (4) and removing the solvent by drying; and

c) laminating the remaining layer, i.e. a release liner (4) or preferably a backing layer (1), onto the matrix layer (2), and blanking transdermal therapeutic systems of the suitable size.

18. The method for the preparation of a transdermal therapeutic system according to any of claims 4-15 comprising the steps of

a) preparing a first precursor of the transdermal therapeutic system comprising

a1) preparing a first homogenized coating mass by adding together all the components of the matrix layer (2) in a suitable solvent and mixing to the desired homogeneity;

a2) applying the first homogenized coating mass onto a backing layer (1) or preferably onto a temporary release liner (4) and removing the solvent by drying; and

a3) laminating the remaining layer, i.e., a temporary release liner (4) or preferably a backing layer (1), onto the matrix layer (2);

b) preparing a second precursor of the transdermal therapeutic system comprising

b1) preparing a homogenized coating mass by adding together all the components of the at least one additional initially active ingredient-free pressure sensitive adhesive layer (3) in a suitable solvent and mixing to the desired homogeneity;

b2) applying the further homogenized coating mass onto a release liner (4) and removing the solvent by drying; and

c) removing the temporary release liner (4) from the first precursor of the transdermal therapeutic system of a), laminating the first precursor and the second precursor of the transdermal therapeutic system to an overall laminate comprising in this layering order a backing layer (1), an active ingredient-containing matrix layer (2), at least one additional initially active ingredient-free pressure sensitive adhesive layer (3) and a release liner (4), and blanking transdermal therapeutic systems of the suitable size.