

Claims

1. A transdermal therapeutic system for administering an active substance through the skin comprising:

- a) a cover layer,
- b) a reservoir present on the cover layer, comprising a polymer matrix containing the active substance,
- c) an adhesive layer present on the reservoir comprising a contact adhesive, and
- d) a removable layer present on the adhesive layer,

wherein the active substance is rivastigmine or a physiologically tolerable salt, hydrate or solvate thereof,

characterized in that the polymer matrix of the reservoir includes neither hydroxyl groups nor carboxyl groups, and the reservoir does not contain tocopherol, butylhydroxydianisol and butylhydroxytoluol.

2. The transdermal therapeutic system of claim 1, characterized in that it does not contain any antioxidants selected from the group consisting of tocopherols and their esters, sesamol, the coniferyl benzoate of benzoin, nordihydroguaiaretic resin and -guaiaretic acid, gallates, butylhydroxydianisole, ascorbic acid and salts thereof, ascorbylpalmitate, erythorbic acid and salts thereof, monothioglycerol, sodium formaldehyde sulfoxylate, sodium metabisulphite, sodium bisulphite, sodium sulphite, potassium metabisulphite, butylated hydroxyanisole, butylated hydroxytoluene and propionic acid.

3. The transdermal therapeutic system of claim 1 or 2, wherein the reservoir contains 20-30 wt% active substance and 70-80 wt% polymer matrix in relation to the total weight of the reservoir.

4. The transdermal therapeutic system of any one of claims 1 to 3, wherein the adhesive layer additionally contains a gelling agent selected from the group consisting of highly dispersed silicon dioxide and pyrogenic silica, and an emollient selected from the group consisting of mineral oil, neutral oil, paraffin, polybutene, linseed oil, octyl palmitate, squalene, squalane, silicone oil, isobutyl myristate, isostearyl alcohol and oleyl alcohol.
5. The transdermal therapeutic system of claim 4, wherein the adhesive layer contains 60.0 to 74.9 wt% contact adhesive, 0.1 to 2.0 wt% gelling agent and 25 to 39.9 wt% emollient in relation to the total weight of the adhesive layer.
6. The transdermal therapeutic system of any one of claims 1 to 5, wherein the polymer matrix comprises at least one polymer and/or copolymer selected from the group consisting of polyacrylates, acrylate-vinyl acetate copolymers, polyisobutylene, styrene-butadiene copolymers and mixtures thereof.
7. The transdermal therapeutic system of any one of claims 1 to 6, characterized in that the contact adhesive is polyisobutylene.
8. The transdermal therapeutic system of any one of claims 1 to 7, characterized in that the polyisobutylene is a mixture of two polyisobutylene polymers of different molecular weights.
9. The transdermal therapeutic system of claim 8, characterized in that the first polyisobutylene polymer has a mean molecular weight M_v of 40,000 g/mol, and the second polyisobutylene polymer has a mean molecular weight M_v of 400,000 g/mol.
10. The transdermal therapeutic system of claim 8 or 9, characterized in that the weight ratio of the first polyisobutylene polymer in relation to the second polyisobutylene polymer is 4:6.
11. The transdermal therapeutic system of any one of claims 4 to 10, characterized in that the emollient is paraffin, neutral oil, mineral oil or a mixture thereof.
12. The transdermal therapeutic system of claim 1 comprising
 - a) a cover layer,

- b) a reservoir present on the cover layer containing 20-30 wt% active substance and 70-80 wt% polymer matrix in relation to the total weight of the reservoir, wherein the polymer matrix essentially consists of an acrylate-vinyl acetate copolymer without hydroxyl groups and without carboxyl groups;
- c) an adhesive layer present on the reservoir comprising 0.1-1 wt% silicon dioxide, 25-39.9 wt% paraffinum perliquidum (Ph. Eur.) and 60-79.9 wt% of a mixture of polyisobutylene having a mean molecular weight M_v of 40,000 g/mol, and polyisobutylene having a mean molecular weight M_v of 400,000 g/mol; and
- d) a removable layer present on the adhesive layer.

13. A method for preparing the transdermal therapeutic system of anyone of claims 1 to 12 comprising

- i) preparing a component containing the reservoir, comprising the cover layer and the reservoir, which is located on the side of the cover layer that is intended as the side to be directed toward the skin,
- ii) preparing a compound containing the adhesive layer made up of the removable layer and the adhesive layer located on the removable layer and
- iii) laminating to combine the components from i) and ii) so that in the end, in the cross-section of the completed TTS, the cover and removable layers constitute the outermost, opposite layers.

14. The method of claim 13 comprising

- i) applying, and optionally subsequently drying, a film of a composition forming the reservoir, optionally in form of a solution or dispersion in a suitable medium, onto the side of the cover layer that is to be directed toward the skin,

- ii) applying, and optionally subsequently drying, a film of a composition forming the adhesive layer, optionally in the form of a solution or dispersion in a suitable medium, to the removable layer, and
- iii) laminating together the components from i) and ii) in order for the cover layer and the removable layer to constitute in the cross-section of the completed TTS the outermost, opposite layers.

15. Use of a polymer or copolymer having neither hydroxyl groups nor carboxyl groups, wherein these polymers or copolymers constitute the polymer matrix of the reservoir, in which the active substance rivastigmine is embedded, for stabilizing the active substance rivastigmine and/or reducing the degradation of the active substance rivastigmine in the transdermal therapeutic system of claim 1.

16. The use of claim 15, characterized in that the polymer or copolymer containing no hydroxyl groups and no carboxyl groups is selected from the group consisting of polyacrylates, acrylate-vinyl acetate copolymers, polyisobutylene and styrene-butadiene copolymers.

17. The transdermal therapeutic system of anyone of claims 1 to 12 for use in a method for the treatment of Alzheimer's disease and Parkinson's dementia.