CLAIMS

The invention claimed is:

1. A composition prepared for topical administration to deliver donepezil intradermally, comprising (i) donepezil or a pharmaceutically acceptable salt thereof, (ii) 2- (2ethoxyethoxy)ethan-1-ol, (iii) a fatty acid ester, and (iv) a monohydric alcohol.

2. The composition of claim 1, comprising:
(i) donepezil or donepezil HCl,
(ii) about 5% to about 30% by weight of 2-(2-ethoxyethoxy)ethan-1-ol,
(iii) about 5% to about 13% by weight of a fatty acid ester selected from the group consisting of isopropyl palmitate, caprylic triglyceride, capric (C10) triglyceride, isopropyl myristate, and any combination thereof, and
iv) about 3% to about 50% by weight of a monohydric alcohol selected from the group consisting of ethanol, cetyl alcohol, and combinations thereof.

3. The composition of claim 1 or claim 2, further comprising (v) at least one low molecular weight polyethylene glycol.

4. The composition of claim 3, wherein the polyethylene glycol comprises PEG 400, PEG600, or a combination thereof.

5. The composition of any one of claims 1-4, comprising at least two monohydric alcohols.

6. The composition of any one of claims 1-5, comprising at least two glycols from the group consisting of: di-, oligo- or poly-ethylene glycols that have at least one terminal alkoxy group in place of a terminal hydroxyl group.

7. The composition of any one of claims 1-6, wherein the composition delivers an intradermal concentration of donepezil relative to the amount of donepezil provided transdermally that is at least twice that provided by a composition of donepezil in a solvent.

8. The composition of any one of claims 1-7, wherein the composition is in a form of a gel, a cream, or an ointment.

9. The composition of any one of claims 1-8, wherein the composition comprises about 5% to about 30% by weight of 2-(2-ethoxyethoxy)ethan-1-ol.

10. The composition of any one of claims 1-9, comprising about 2% to about 10% by weight of isopropyl palmitate.

11. The composition of any one of claims 1-10, wherein the composition comprises about 2% to about 13% by weight of the fatty acid ester.

12. The composition of claim 11, wherein the fatty acid ester is selected from the group consisting of isopropyl palmitate, caprylic triglyceride, capric (C10) triglyceride, isopropyl myristate, and any combination thereof.

13. The composition of any one of claims 1-12, wherein the composition comprises donepezil, ethanol, at least two PEG selected from the group consisting of: PEG 400, PEG1450, and PEG600, 2-(2-ethoxyethoxy)ethan-1-ol, and isopropyl palmitate.

14. The composition of any one of claims 1-13, further comprising hydroxypropl cellulose in amount of 3%.

15. The composition of any one of claims 1-14, further comprising propylene glycol in an amount of 7%.

16. A composition for topical administration comprising:
(i) donepezil or a pharmaceutically acceptable salt thereof,
(ii) 2-(2-ethoxyethoxy)ethan-1-ol,
(iii) a fatty acid ester, and
(iv) ethanol,
wherein the composition is formulated to deliver donepezil intradermally.

17. The composition of any one of claims 1-16, wherein the composition is in a form of a gel.

18. The composition of any one of claims 1-17, wherein the composition comprises donepezil, ethanol, 2-(2-ethoxyethoxy)ethan-1-ol, and isopropyl palmitate.

19. The composition of any one of claims 1-18, wherein the composition comprises up to about 90% by weight of ethanol.

20. The composition of any one of claims 1-19, wherein the composition comprises about 30% to about 90% by weight of ethanol.

21. A composition prepared for topical administration comprising:
(i) donepezil or donepezil HCl,
(ii) about 5% to about 30% by weight of 2-(2-ethoxyethoxy)ethan-1-ol,
(iii) about 5% to about 13% by weight of a fatty acid ester selected from the group consisting of isopropyl palmitate, caprylic triglyceride, capric (C10) triglyceride, isopropyl myristate, and any combination thereof, and
(iv) about 30% to about 90% by weight of ethanol,
wherein the composition is formulated to deliver donepezil intradermally.

22. A composition prepared for topical administration comprising:
(i) donepezil or donepezil HCl,
(ii) about 5% to about 30% by weight of 2-(2-ethoxyethoxy)ethan-1-ol,
(iii) about 5% to about 13% by weight of a fatty acid ester selected from the group consisting of isopropyl palmitate, caprylic triglyceride, capric (C10) triglyceride, isopropyl myristate, and any combination thereof, and
(iv) about 30% to about 90% by weight of ethanol,
wherein the composition is formulated to deliver donepezil intradermally and wherein the composition is in a form of a gel.

23. The composition of claim 22, comprising:

(i) donepezil,

(ii) about 10% to about 30% by weight of 2-(2-ethoxyethoxy)ethan-1-ol,

(iii) about 5% to about 10% by weight of isopropyl palmitate, and

(iv) about 30% to about 50% by weight of ethanol.

24. The composition of claim 13, wherein donepezil present in an amount between 0.5%-1.5% (wt/wt), ethanol in an amount between 30%-40%, PEG 400 in an amount between 16%- 26%, one of either PEG1450 or PEG 600 in an amount of 5%, 2-(2-ethoxyethoxy)ethan-1-ol in an amount between 20%-30%, and isopropyl palmitate in an amount of 5%.

25. The composition of claim 13, wherein donepezil is present in an amount of 1% (wt/wt), ethanol in an amount of 40%, PEG 400 in an amount of 16%, PEG 600 in an amount of 5%, 2(2-ethoxyethoxy)ethan-1-ol in an amount of 30%, and isopropyl palmitate in an amount of 5%.

26. The composition of claim 13, wherein donepezil is present in an amount of 1% (wt/wt), ethanol in an amount of 40%, PEG 400 in an amount of 26%, PEG 600 in an amount of 5%, 2(2-ethoxyethoxy)ethan-1-ol in an amount of 20%, and isopropyl palmitate in an amount of 5%.

27. The composition of claim 18, wherein donepezil is present in an amount of 1% (wt./wt), ethanol in an amount of 40%, 2(2-ethoxyethoxy)ethan-1-ol in an amount of 30%, and isopropyl palmitate in an amount of 5%.

28. A composition prepared for topical administration comprising

(i) donepezil or a pharmaceutically acceptable salt thereof,
(ii) 2-(2-ethoxyethoxy)ethan-1-ol,
(iii) a fatty acid ester, and
(iv) cetyl alcohol,
wherein the composition is formulated to deliver donepezil intradermally.

29. The composition of claim 28, wherein the composition comprises about 3% to about 11% by weight of cetyl alcohol.

30. The composition of claim 28 or claim 29, wherein the composition is in a form of a cream.

31. The composition of any one of claims 28-30, wherein the composition comprises donepezil HCl, water, cetyl alcohol, 2-(2-ethoxyethoxy)ethan-1-ol, a mixture of caprylic and capric (C10) triglyceride, and isopropyl palmitate.

32. The composition of any one of claims 28-31, wherein the composition further comprises water in an amount between about 10% (wt/wt) and about 65% (wt/wt) and the composition comprises 2-(2-ethoxyethoxy)ethan-1-ol in an amount between about 5% (wt/wt) and about 30% (wt/wt).

33. The composition of any one of claims 28-32, wherein the composition comprises donepezil HCl, water, cetyl alcohol, at least two PEG selected from the group consisting of: PEG 400, PEG1450, and PEG600, 2-(2-ethoxyethoxy)ethan-1-ol, a mixture of caprylic and capric (C10) triglyceride, isopropyl myristate, and isopropyl palmitate.

34. The composition of claim 31, wherein the donepezil HCl is present in an amount of 1% (wt/wt), water in amount of 40.3%, cetyl alcohol in an amount of 10%, isopropyl myristate in an amount of 10%, a mixture of caprylic and capric (C10) triglyceride in an amount of 10%, and isopropyl palmitate in an amount of 7%.

35. The composition of claim 31, wherein the donepezil HCl is present in an amount 1% (wt/wt), water in an amount of 56.9%, cetyl alcohol in an amount of 3%, a mixed caprylic and capric (C10) triglyceride in amount of 5%, and isopropyl palmitate in amount of 7%.

36. The composition of claim 31, wherein the donepezil HCl is present in an amount of 1% (wt/wt), water in amount of 48.9%, cetyl alcohol in an amount of 11%, a mixture of caprylic and capric (C10) triglyceride in an amount of 5%, and isopropyl palmitate in an amount of 7%.

37. The composition of claim 31 wherein the donepezil HCl is present in an amount of 1% (wt/wt), water in amount of 51% cetyl alcohol in an amount of 9%, a mixture of caprylic and capric (C10) triglyceride in an amount of 5%, and isopropyl palmitate in an amount of 7%.

38. The composition of claim 31, wherein the donepezil HCl is present in an amount of 1% (wt/wt), water in amount of 49%, cetyl alcohol in an amount of 11%, a mixture of caprylic and capric (C10) triglyceride in an amount of 5%, and isopropyl palmitate in an amount of 7%.

39. Use of the composition of any one of claims 1-38 in the manufacture of a medicament for the treatment of plaque psoriasis (psoriasis vulgaris), wherein the composition is to be topically administered to a psoriasis plaque.

40. The use of claim 39, wherein the composition is to be topically administered to the psoriasis plaque twice daily for a duration of two to six weeks.

41. Use of the composition of any one of any claims 1-38 in the manufacture of a medicament from the treatment of atopic dermatitis, wherein the composition is to be topically administered to a skin.

42. Use of the composition of any one of claims 1-38 in the manufacture of a medicament for the treatment of acne, wherein the composition is to be topically administered to a skin.