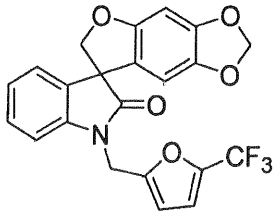
WHAT IS CLAIMED IS

1. A pharmaceutical composition for topical administration to a mammal comprising one or more pharmaceutically acceptable excipients and a therapeutically effective amount of a spiro-oxindole compound having the following formula:



as an enantiomer, a racemate or a non-racemic mixture of enantiomers, or a pharmaceutically acceptable salt thereof.

2. The pharmaceutical composition of Claim 1 comprising two or more pharmaceutically acceptable excipients.

3. The pharmaceutical composition of Claim 2, wherein the pharmaceutically acceptable excipients are selected from one or more solvents, one or more penetration enhancing agents, one or more stiffening agents, or one or more ointment bases.

4. The pharmaceutical composition of Claim 3, further comprising one or more antioxidants.

5. The pharmaceutical composition of Claim 3 or 4, wherein each pharmaceutically acceptable excipient is present in a concentration of from about 0.01% w/w to about 99% w/w.

6. The pharmaceutical composition of Claim 5, wherein an solvent is selected from PEG 400 or PEG 3350, a penetration enhancing agent is selected from Transcutol® P, oleyl alcohol, or isopropyl myristate, a stiffening agent is stearyl alcohol, an ointment base is selected from PEG 400 or PEG 3350, and the antioxidant is butylated hydroxytoluene (BHT).

7. The pharmaceutical composition of Claim 6, wherein PEG 400 is

present in a concentration of from about 30% w/w to about 70% w/w, Transcutol® P is present in a concentration of from about 2% w/w to about 25% w/w, oleyl alcohol is present in a concentration of from about 1% w/w to about 10% w/w, isopropyl myristate is present in a concentration of from about 1% w/w to about 25% w/w, stearyl alcohol is present in a concentration of from about 0.1% w/w to about 10% w/w, BHT is present in a concentration of from about 0.01% w/w to about 2% w/w, and PEG 3350 is present in a concentration of from about 10% w/w to about 50% w/w.

8. The pharmaceutical composition of Claim 7, wherein PEG 400 is present in a concentration of from about 45% w/w to about 55% w/w, Transcutol® P is present in a concentration of from about 5% w/w to about 15% w/w, oleyl alcohol is present in a concentration of from about 2.5% w/w to about 7.5% w/w, isopropyl myristate is present in a concentration of from about 2.5% w/w to about 7.5% w/w, stearyl alcohol is present in a concentration of from about 0.1% w/w to about 7.5% w/w, BHT is present in a concentration of from about 0.05% w/w to about 1% w/w, and PEG 3350 is present in a concentration of from about 15% w/w to about 30% w/w.

9. The pharmaceutical composition of Claim 8, wherein the spiro-oxindole compound is present in a concentration of from about 0.1% w/w to about 10% w/w.

10. The pharmaceutical composition of Claim 9, wherein the spiro-oxindole compound is present in a concentration of from about 2% w/w to about 8% w/w.

11. The pharmaceutical composition of Claim 1 comprising the spiro-oxindole compound at a concentration of 2.0% w/w; PEG 400 at a concentration of 52.9% w/w; Transcutol® P at a concentration of 10% w/w; oleyl alcohol at a concentration of 5% w/w; isopropyl myristate at a concentration of 5% w/w; stearyl alcohol at a concentration of 5% w/w; butylated hydroxytoluene at a concentration of 0.1% w/w; and PEG 3350 at a concentration of 20% w/w of the pharmaceutical composition.

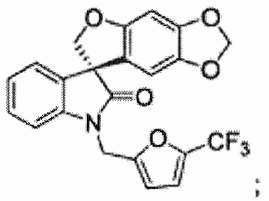
12. The pharmaceutical composition of Claim 1 comprising the spiro-oxindole compound at a concentration of 4% w/w; PEG 400 at a concentration of 50.9% w/w; Transcutol® P at a concentration of 10% w/w; oleyl alcohol at a concentration of 5% w/w; isopropyl myristate at a concentration of 5% w/w; stearyl

alcohol at a concentration of 5% w/w; butylated hydroxytoluene at a concentration of 0.1 % w/w; and PEG 3350 at a concentration of 20% w/w of the pharmaceutical composition.

13. The pharmaceutical composition of Claim 1 comprising the spiro-oxindole compound at a concentration of 4% w/w; PEG 400 at a concentration of 50.9% w/w; Transcutol® P at a concentration of 5% w/w; oleyl alcohol at a concentration of 5% w/w; isopropyl myristate at a concentration of 5% w/w; stearyl alcohol at a concentration of 10% w/w; butylated hydroxytoluene at a concentration of 0.1% w/w; and PEG 3350 at a concentration of 20% w/w of the pharmaceutical composition.

14. The pharmaceutical composition of Claim 1 comprising the spiro-oxindole compound at a concentration of 8% w/w; PEG 400 at a concentration of 46.9% w/w; Transcutol® P at a concentration of 10% w/w; oleyl alcohol at a concentration of 5% w/w; isopropyl myristate at a concentration of 5% w/w; stearyl alcohol at a concentration of 5% w/w; butylated hydroxytoluene at a concentration of 0.1 % w/w; and PEG 3350 at a concentration of 20% w/w of the pharmaceutical composition.

15. The pharmaceutical composition of any one of Claims 1-14 wherein the spiro-oxindole compound is a compound of the following formula:



;

or a pharmaceutically acceptable salt thereof.

16. Use of a pharmaceutical composition of any one of Claims 1 to 15 for the preparation of a medicament for topical administration to a mammal in need thereof, wherein the medicament is for treating, preventing or ameliorating a sodium channel-mediated disease or a condition in the mammal,.

17. The use of Claim 16, wherein said disease or condition is selected from the group consisting of neuropathic pain, inflammatory pain, visceral pain,

postherpetic neuralgia, cancer pain, chemotherapy pain, trauma pain, surgical pain, post-operative pain, pruritis, osteoarthritis, trigeminal neuralgia, familial erythromelalgia, primary erythromelalgia, familial rectal pain, childbirth pain, labor pain, neurogenic bladder, ulcerative colitis, chronic pain, persistent pain, peripherally mediated pain, centrally mediated pain, chronic headache, migraine headache, sinus headache, tension headache, phantom limb pain, peripheral nerve injury, and combinations thereof.

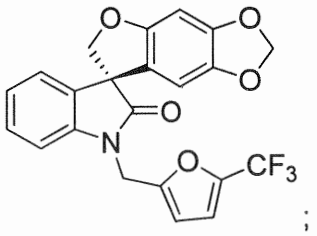
18. The use of Claim 16, wherein the mammal is a human.

19. Use of a pharmaceutical composition of any one of Claims 1 to 15 for the preparation of a medicament for topical administration to a mammal in need thereof, wherein the medicament is for treating pain through inhibition of ion flux through a voltage-dependent sodium channel in the mammal.

20. The use of Claim 19, wherein the mammal is a human.

WHAT IS CLAIMED IS

1. A pharmaceutical composition for topical administration to a mammal comprising two or more pharmaceutically acceptable excipients and a therapeutically effective amount of a spiro-oxindole compound having the following formula:



;

or a pharmaceutically acceptable salt thereof.

2. The pharmaceutical composition of Claim 1, wherein the pharmaceutically acceptable excipients are selected from one or more solvents, one or more penetration enhancing agents, one or more stiffening agents, or one or more ointment bases.

3. The pharmaceutical composition of Claim 2, further comprising one or more antioxidants.

4. The pharmaceutical composition of Claim 2 or 3, wherein each pharmaceutically acceptable excipient is present in a concentration of from about 0.01% w/w to about 99% w/w.

5. The pharmaceutical composition of Claim 4, wherein a solvent is selected from PEG 400 or PEG 3350, a penetration enhancing agent is selected from diethylene glycol mono ether, oleyl alcohol, or isopropyl myristate, a stiffening agent is stearyl alcohol, an ointment base is selected from PEG 400 or PEG 3350, and the antioxidant is butylated hydroxytoluene (BHT).

6. The pharmaceutical composition of Claim 5, wherein PEG 400 is present in a concentration of from about 30% w/w to about 70% w/w, diethylene glycol mono ether is present in a concentration of from about 2% w/w to about 25% w/w, oleyl alcohol is present in a concentration of from about 1% w/w to about 10% w/w, isopropyl myristate is present in a concentration of from about 1% w/w to about 25% w/w, stearyl alcohol is present in a concentration of from about 0.1% w/w to about 10% w/w, BHT is present in a concentration

of from about 0.01% w/w to about 2% w/w, and PEG 3350 is present in a concentration of from about 10% w/w to about 50% w/w.

7. The pharmaceutical composition of Claim 6, wherein PEG 400 is present in a concentration of from about 45% w/w to about 55% w/w, diethylene glycol mono ether is present in a concentration of from about 5% w/w to about 15% w/w, oleyl alcohol is present in a concentration of from about 2.5% w/w to about 7.5% w/w, isopropyl myristate is present in a concentration of from about 2.5% w/w to about 7.5% w/w, stearyl alcohol is present in a concentration of from about 0.1% w/w to about 7.5% w/w, BHT is present in a concentration of from about 0.05% w/w to about 1% w/w, and PEG 3350 is present in a concentration of from about 15% w/w to about 30% w/w.

8. The pharmaceutical composition of Claim 7, wherein the spiro-oxindole compound is present in a concentration of from about 0.1% w/w to about 10% w/w.

9. The pharmaceutical composition of Claim 8, wherein the spiro-oxindole compound is present in a concentration of from about 2% w/w to about 8% w/w.

10. The pharmaceutical composition of Claim 1 comprising the spiro-oxindole compound at a concentration of 2.0% w/w; PEG 400 at a concentration of 52.9% w/w; diethylene glycol mono ether at a concentration of 10% w/w; oleyl alcohol at a concentration of 5% w/w; isopropyl myristate at a concentration of 5% w/w; stearyl alcohol at a concentration of 5% w/w; butylated hydroxytoluene at a concentration of 0.1% w/w; and PEG 3350 at a concentration of 20% w/w.

11. The pharmaceutical composition of Claim 1 comprising the spiro-oxindole compound at a concentration of 4% w/w; PEG 400 at a concentration of 50.9% w/w; diethylene glycol mono ether at a concentration of 10% w/w; oleyl alcohol at a concentration of 5% w/w; isopropyl myristate at a concentration of 5% w/w; stearyl alcohol at a concentration of 5% w/w; butylated hydroxytoluene at a concentration of 0.1% w/w; and PEG 3350 at a concentration of 20% w/w.

12. The pharmaceutical composition of Claim 1 comprising the spiro-oxindole compound at a concentration of 4% w/w; PEG 400 at a concentration of 50.9% w/w; diethylene glycol mono ether P at a concentration of 5% w/w; oleyl alcohol at a concentration of 5% w/w; isopropyl myristate at a concentration of 5% w/w; stearyl alcohol at a

concentration of 10% w/w; butylated hydroxytoluene at a concentration of 0.1% w/w; and PEG 3350 at a concentration of 20% w/w.

13. The pharmaceutical composition of Claim 1 comprising the spiro-oxindole compound at a concentration of 8% w/w; PEG 400 at a concentration of 46.9% w/w; diethylene glycol mono ether P at a concentration of 10% w/w; oleyl alcohol at a concentration of 5% w/w; isopropyl myristate at a concentration of 5% w/w; stearyl alcohol at a concentration of 5% w/w; butylated hydroxytoluene at a concentration of 0.1% w/w; and PEG 3350 at a concentration of 20% w/w.

14. Use of a pharmaceutical composition of any one of Claims 1 to 13 for the preparation of a medicament for topical administration to a mammal in need thereof, wherein the medicament is for treating, preventing or ameliorating a sodium channel-mediated disease or a condition in the mammal.

15. The use of Claim 14, wherein said disease or condition is selected from the group consisting of neuropathic pain, inflammatory pain, visceral pain, postherpetic neuralgia, cancer pain, chemotherapy pain, trauma pain, surgical pain, post-operative pain, pruritis, osteoarthritis, trigeminal neuralgia, familial erythromelalgia, primary erythromelalgia, familial rectal pain, childbirth pain, labor pain, neurogenic bladder, ulcerative colitis, chronic pain, persistent pain, peripherally mediated pain, centrally mediated pain, chronic headache, migraine headache, sinus headache, tension headache, phantom limb pain, peripheral nerve injury, and combinations thereof.

16. The use of Claim 14, wherein the mammal is a human.

17. Use of a pharmaceutical composition of any one of Claims 1 to 13 for the preparation of a medicament for topical administration to a mammal in need thereof, wherein the medicament is for treating pain through inhibition of ion flux through a voltage-dependent sodium channel in the mammal.

18. The use of Claim 17, wherein the mammal is a human.