CLAIMS

1. A method of treating a disease or condition mediated by modulation of Nav1.7 and other voltage-gated sodium channels in a patient in need thereof which comprises administering a therapeutically effective amount of a compound which is (5*R*)-5-(4-{[(2-fluorophenyl)methyl]oxy}phenyl)-L-prolinamide, or a pharmaceutically acceptable salt thereof, characterised in that said compound, or a pharmaceutically acceptable salt thereof, is administered to a subject in need thereof at a dosage of either 200 mg two times per day (BID) or 150 mg or 250 mg three times per day (TID), such that said 150 mg dosage is administered only to a patient identified as a responder to treatment with said compound.

2. A method of treating a disease or condition mediated by modulation of Nav1.7 and other voltage-gated sodium channels in a patient in need thereof which comprises administering a therapeutically effective amount of a compound which is (5*R*)-5-(4-{[(2-fluorophenyl)methyl]oxy}phenyl)-L-prolinamide, or a pharmaceutically acceptable salt thereof, characterised in that said compound, or a pharmaceutically acceptable salt thereof, is administered to a subject in need thereof at a dosage of either 150 mg or 250 mg three times per day (TID), such that said 150 mg dosage is administered only to a patient identified as a responder to treatment with said compound.

3. The method as defined in claim 1 or 2, wherein said compound, or a pharmaceutically acceptable salt thereof, is administered at a dosage of 200 mg two times per day (BID).

4. The method as defined in claim 1 or 2, wherein said compound, or a pharmaceutically acceptable salt thereof, is administered at a dosage of 150 mg three times per day (TID).

5. The method as defined in claim 1 or 2, wherein said compound, or a pharmaceutically acceptable salt thereof, is administered at a dosage of 250 mg three times per day (TID).

6. The method as defined in any one of claims 1, 2, or 5, wherein said 250 mg dosage is administered to a patient not previously treated with said compound, or a pharmaceutically acceptable salt thereof.

7. The method as defined in any one of claims 1, 2, or 5, wherein said 250 mg dosage is administered to a patient previously administered with a 150 mg dosage of said compound and wherein said patient has been identified as a non-responder to treatment with the 150 mg dosage of said compound, or a pharmaceutically acceptable salt thereof.

8. A method of treating a disease or condition mediated by modulation of Nav1.7 and other voltage-gated sodium channels in a patient in need thereof which comprises administering a therapeutically effective amount of a compound which is (5*R*)-5-(4-{[(2-fluorophenyl)methyl]oxy}phenyl)-L-prolinamide, or a pharmaceutically acceptable salt thereof, characterised in that said compound, or a pharmaceutically acceptable salt thereof, is administered to a subject in need thereof at a dosage of either 300 mg or 400 mg two times per day (BID).

9. The method as defined in claim 8, wherein said 300mg BID dosage is administered to a female patient.

10. The method as defined in claim 8 or claim 9, wherein said 300 mg BID dosage is administered following a dosage of 400 mg BID for an initial period of time.

11. The method as defined in claim 10, wherein said initial period of time comprises approximately 1 week.

12. The method as defined in claim 8, wherein said 400 mg BID dosage is administered to a male patient.

13. The method as defined in any of claims 1 to 12, wherein said compound, or a pharmaceutically acceptable salt thereof, is administered orally.

14. The method as defined in any of claims 1 to 13, wherein said compound, or a pharmaceutically acceptable salt thereof, is administered in combination with one or more therapeutically effective medicaments.

15. The method as defined in any of claims 1 to 14, wherein said disease or condition is selected from pain.

16. The method as defined in claim 15, wherein said pain is selected from neuropathic pain.

17. The method as defined in claim 16, wherein said neuropathic pain is selected from: diabetic neuropathy; sciatica; non-specific lower back pain; painful lumbosacral radiculopathy; multiple sclerosis pain; fibromyalgia; HIV-related neuropathy; post-herpetic neuralgia; trigeminal neuralgia; and pain resulting from physical trauma, amputation, cancer, toxins or chronic inflammatory conditions.

18. The method as defined in claim 17, wherein said neuropathic pain is selected from trigeminal neuralgia, painful lumbosacral radiculopathy, erythromelalgia and small fibre neuropathy.

19. The method as defined in claim 17 or claim 18, wherein said neuropathic pain is selected from trigeminal neuralgia or painful lumbosacral radiculopathy.

20. The method as defined in claim 19, wherein said neuropathic pain is trigeminal neuralgia (TN) and said compound, or a pharmaceutically acceptable salt thereof, is administered to a subject in need thereof at a dosage of 250 mg three times per day (TID).

21. The method as defined in claim 19, wherein said neuropathic pain is painful lumbosacral radiculopathy (PLSR) and said compound, or a pharmaceutically acceptable salt thereof, is administered to a subject in need thereof at a dosage of 200 mg two times per day (BID).

22. The method as defined in any one of claims 1 to 21, wherein said compound, or a pharmaceutically acceptable salt thereof is administered as a pharmaceutical

composition comprising one or more pharmaceutically acceptable one or more pharmaceutically acceptable carrier(s), diluent(s) and/or excipient(s).

23. The method as defined in any one of claims 1 to 22, wherein the compound is administered in the form of a hydrochloride salt.

24. A method of treating a disease or condition mediated by modulation of Nav1.7 which comprises administering a therapeutically effective amount of (5*R*)-5-(4-{[(2-fluorophenyl)methyl]oxy}phenyl)-L-prolinamide, or a pharmaceutically acceptable salt thereof, to a subject in need thereof and avoiding the use or administration of a UGT inducer.

25. The method of claim 24, wherein the UGT inducer is selected from rifampin, ritonavir, ethinyl estradiol, methsuximide, phenytoin, phenobarbital, rifabutin, carbamazepine and oxcarbazepine.

26. The method of claim 24, wherein the UGT inducer is carbamazepine.

27. The method of claim 26, wherein the subject is instructed to stop using carbamazepine before beginning administration of (5*R*)-5-(4-{[(2-fluorophenyl)methyl]oxy}phenyl)-L-prolinamide, or a pharmaceutically acceptable salt thereof.

28. The method of claim 26, wherein the subject is instructed to stop using carbamazepine at least three weeks before beginning administration of (5*R*)-5-(4-{[(2-fluorophenyl)methyl]oxy}phenyl)-L-prolinamide, or a pharmaceutically acceptable salt thereof.

29. A method of treating a disease or condition mediated by modulation of Nav1.7 which comprises administering a therapeutically effective amount of a (5*R*)-5-(4-{[(2-fluorophenyl)methyl]oxy}phenyl)-L-prolinamide, or a pharmaceutically acceptable salt thereof, to a subject in need thereof, wherein the subject is using a UGT inducer.

30. The method claim 29, wherein the UGT inducer is selected from rifampin, ritonavir, ethinyl estradiol, methsuximide, phenytoin, phenobarbital, rifabutin, carbamazepine and oxcarbazepine.

31. The method claim 29, wherein the UGT inducer is carbamazepine.

32. The method of claim 31, wherein the subject's dosage of (5*R*)-5-(4-{[(2-fluorophenyl)methyl]oxy}phenyl)-L-prolinamide, or a pharmaceutically acceptable salt thereof, is increased at least 30% relative to what it would have been had the subject not been using carbemazepine.

33. The method of claim 31, wherein the subject's dosage of (5*R*)-5-(4-{[(2-fluorophenyl)methyl]oxy}phenyl)-L-prolinamide, or a pharmaceutically acceptable salt thereof, is increased at least 50% relative to what it would have been had the subject not been using carbemazepine.

34. The method of claim 33, wherein the subject's dosage of (5*R*)-5-(4-{[(2-fluorophenyl)methyl]oxy}phenyl)-L-prolinamide, or a pharmaceutically acceptable salt thereof, is increased to a dosage of 250 mg TID.