Claims

1. A combination of hydromorphone or a pharmaceutically acceptable salt thereof and naloxone or a pharmaceutically acceptable salt thereof in a weight ratio corresponding to about 1:2 of hydromorphone HCl:naloxone HCl for use in the treatment of pain in a patient, wherein hydromorphone or a pharmaceutically acceptable salt thereof is to be orally administered in a daily amount corresponding to from and including about 2 mg up to and including about 64 mg of hydromorphone hydrochloride, and naloxone or a pharmaceutically acceptable salt thereof in a daily amount corresponding to from and including about 4 mg up to and including about 128 mg of naloxone hydrochloride.

2. A combination of hydromorphone or a pharmaceutically acceptable salt thereof and naloxone or a pharmaceutically acceptable salt thereof in a weight ratio corresponding to about 1:2 of hydromorphone HCl:naloxone HCl for use in the treatment of pain and preventing and/or reducing opioid-induced constipation in a patient, wherein hydromorphone or a pharmaceutically acceptable salt thereof is to be orally administered in a daily amount corresponding to from and including about 2 mg up to and including about 64 mg of hydromorphone hydrochloride, and naloxone or a pharmaceutically acceptable salt thereof in a daily amount corresponding to from and including about 4 mg up to and including about 128 mg of naloxone hydrochloride.

3. A combination of hydromorphone or a pharmaceutically acceptable salt thereof and naloxone or a pharmaceutically acceptable salt thereof in a weight ratio corresponding to about 1:2 of hydromorphone HCl:naloxone HCl for use in the treatment of pain in a patient, wherein hydromorphone or a pharmaceutically acceptable salt thereof is to be orally administered in a daily amount corresponding to from and including about 2 mg up to and including about 64 mg of hydromorphone hydrochloride, and naloxone or a pharmaceutically acceptable salt thereof in a daily amount corresponding to from and including about 4 mg up to and including about 128 mg of naloxone hydrochloride, and wherein the patient experiences opioid induced constipation as a consequence of treatment with an opioid in the absence of an opioid antagonist.

4. A combination of hydromorphone or a pharmaceutically acceptable salt thereof and naloxone or a pharmaceutically acceptable salt thereof in a weight ratio corresponding to about 1:2 of hydromorphone HCl:naloxone HCl for use of any one of claims 1, 2, or 3, wherein hydromorphone or a pharmaceutically acceptable salt thereof is to be administered in a daily amount corresponding to from and including about 8 mg up to and including about 48 mg of hydromorphone hydrochloride, and naloxone or a pharmaceutically acceptable salt thereof is to be administered in a daily amount corresponding to from and including about 16 mg up to and including about 96 mg of naloxone hydrochloride.

5. A combination of hydromorphone or a pharmaceutically acceptable salt thereof and naloxone or a pharmaceutically acceptable salt thereof in a weight ratio corresponding to about 1:2 of hydromorphone HCl:naloxone HCl for use of any one of claims 1, 2, 3, or 4, wherein the combination is provided in the form of a solid, oral prolonged release pharmaceutical composition, which is suitable for administration every 12 or 24 hours.

6. A combination of hydromorphone or a pharmaceutically acceptable salt thereof and naloxone or a pharmaceutically acceptable salt thereof in a weight ratio corresponding to about 1:2 of hydromorphone HCl:naloxone HCl for use of any one of claims 1, 2, 3, or 4, wherein hydromorphone or a pharmaceutically acceptable salt thereof is to be administered every 12 hours in an amount corresponding to from and including about 4 mg up to and including about 24 mg of hydromorphone hydrochloride, and naloxone or a pharmaceutically acceptable salt thereof is to be administered concomitantly every 12 hours in an amount corresponding to from and including about 8 mg up to and including about 48 mg of naloxone hydrochloride.

7. A combination of hydromorphone or a pharmaceutically acceptable salt thereof and naloxone or a pharmaceutically acceptable salt thereof in a weight ratio corresponding to about 1:2 of hydromorphone HCl:naloxone HCl for use in the treatment of pain in a patient, wherein hydromorphone or a pharmaceutically acceptable salt thereof is to be orally administered in a daily amount corresponding to about 48 mg of hydromorphone hydrochloride, and naloxone or a pharmaceutically acceptable salt thereof in a daily amount corresponding to about 96 mg of naloxone hydrochloride.

8. A combination of hydromorphone or a pharmaceutically acceptable salt thereof and naloxone or a pharmaceutically acceptable salt thereof in a weight ratio corresponding to about 1:2 of hydromorphone HCl:naloxone HCl for use in the treatment of pain and/or reducing opioid-induced constipation in a patient, wherein hydromorphone or a pharmaceutically acceptable salt thereof is to be orally administered in a daily amount corresponding to about 48 mg of hydromorphone hydrochloride, and naloxone or a pharmaceutically acceptable salt thereof in a daily amount corresponding to about 96 mg of naloxone hydrochloride.

9. A combination of hydromorphone or a pharmaceutically acceptable salt thereof and naloxone or a pharmaceutically acceptable salt thereof in a weight ratio corresponding to about 1:2 of hydromorphone HCl:naloxone HCl for use in the treatment of pain in a patient, wherein hydromorphone or a pharmaceutically acceptable salt thereof is to be orally administered in a daily amount corresponding to about 48 mg of hydromorphone hydrochloride, and naloxone or a pharmaceutically acceptable salt thereof in a daily amount corresponding to about 96 mg of naloxone hydrochloride, wherein the patient experiences opioid induced constipation as a consequence of treatment with an opioid in the absence of an opioid antagonist.

10. A combination of hydromorphone or a pharmaceutically acceptable salt thereof and naloxone or a pharmaceutically acceptable salt thereof in a weight ratio corresponding to about 1:2 of hydromorphone HCl:naloxone HCl for use of any one of claims 7, 8, or 9, wherein the combination is provided in the form of a solid, oral prolonged release pharmaceutical composition, which is suitable for administration every 24 hours.

11. A combination of hydromorphone or a pharmaceutically acceptable salt thereof and naloxone or a pharmaceutically acceptable salt thereof in a weight ratio corresponding to about 1:2 of hydromorphone HCl:naloxone HCl for use of any one of claims 7, 8, or 9, wherein the combination is provided in the form of a solid, oral prolonged release pharmaceutical composition, which is suitable for administration every 12 hours and which comprises 24 mg hydromorphone HCl and 48 mg naloxone HCl.

12. Use of a combination of hydromorphone or a pharmaceutically acceptable salt thereof and naloxone or a pharmaceutically acceptable salt thereof in a weight ratio corresponding to about 1:2 of hydromorphone HCl:naloxone HCl, in the manufacture of a medicament for the treatment of pain in a patient, wherein hydromorphone or a pharmaceutically acceptable salt thereof is to be orally administered in a daily amount corresponding to from and including about 2 mg up to and including about 64 mg of hydromorphone hydrochloride, and naloxone or a pharmaceutically acceptable salt thereof in a daily amount corresponding to from and including about 4 mg up to and including about 128 mg of naloxone hydrochloride.

13. Use of a combination of hydromorphone or a pharmaceutically acceptable salt thereof and naloxone or a pharmaceutically acceptable salt thereof in a weight ratio corresponding to about 1:2 of hydromorphone HCl:naloxone HCl, in the manufacture of a medicament for the treatment of pain and preventing and/or reducing opioid-induced constipation in a patient, wherein hydromorphone or a pharmaceutically acceptable salt thereof is to be orally administered in a daily amount corresponding to from and including about 2 mg up to and including about 64 mg of hydromorphone hydrochloride, and naloxone or a pharmaceutically acceptable salt thereof in a daily amount corresponding to from and including about 4 mg up to and including about 128 mg of naloxone hydrochloride.

14. Use of a combination of hydromorphone or a pharmaceutically acceptable salt thereof and naloxone or a pharmaceutically acceptable salt thereof in a weight ratio corresponding to about 1:2 of hydromorphone HCl:naloxone HCl in the manufacture of a medicament for the treatment of pain in a patient, wherein hydromorphone or a pharmaceutically acceptable salt thereof is to be orally administered in a daily amount corresponding to from and including about 2 mg up to and including about 64 mg of hydromorphone hydrochloride, and naloxone or a pharmaceutically acceptable salt thereof in a daily amount corresponding to from and including about 4 mg up to and including about 128 mg of naloxone hydrochloride, and wherein the patient experiences opioid induced constipation as a consequence of treatment with an opioid in the absence of an opioid antagonist.

15. The use of any one of claims 12-14, wherein hydromorphone or a pharmaceutically

acceptable salt thereof is to be administered in a daily amount corresponding to from and including about 8 mg up to and including about 48 mg of hydromorphone hydrochloride, and naloxone or a pharmaceutically acceptable salt thereof is to be administered in a daily amount corresponding to from and including about 16 mg up to and including about 96 mg of naloxone hydrochloride.

16. The use of any one of claims 12-15, wherein the combination is provided in the form of a solid, oral prolonged release pharmaceutical composition, which is suitable for administration every 12 or 24 hours.

17. The use of any one of claims 12-15, wherein hydromorphone or a pharmaceutically acceptable salt thereof is to be administered every 12 hours in an amount corresponding to from and including about 4 mg up to and including about 24 mg of hydromorphone hydrochloride, and naloxone or a pharmaceutically acceptable salt thereof is to be administered concomitantly every 12 hours in an amount corresponding to from and including about 8 mg up to and including about 48 mg of naloxone hydrochloride.

18. Use of a combination of hydromorphone or a pharmaceutically acceptable salt thereof and naloxone or a pharmaceutically acceptable salt thereof in a weight ratio corresponding to about 1:2 of hydromorphone HCl:naloxone HCl, in the manufacture of a medicament for the treatment of pain in a patient, wherein hydromorphone or a pharmaceutically acceptable salt thereof is to be orally administered in a daily amount corresponding to about 48 mg of hydromorphone hydrochloride, and naloxone or a pharmaceutically acceptable salt thereof in a daily amount corresponding to about 96 mg of naloxone hydrochloride.

19. Use of a combination of hydromorphone or a pharmaceutically acceptable salt thereof and naloxone or a pharmaceutically acceptable salt thereof in a weight ratio corresponding to about 1:2 of hydromorphone HCl:naloxone HCl, in the manufacture of a medicament for the treatment of pain and/or reducing opioid-induced constipation in a patient, wherein hydromorphone or a pharmaceutically acceptable salt thereof is to be orally administered in a daily amount corresponding to about 48 mg of hydromorphone hydrochloride, and naloxone or a

pharmaceutically acceptable salt thereof in a daily amount corresponding to about 96 mg of naloxone hydrochloride.

20. Use of a combination of hydromorphone or a pharmaceutically acceptable salt thereof and naloxone or a pharmaceutically acceptable salt thereof in a weight ratio corresponding to about 1:2 of hydromorphone HCl:naloxone HCl, in the manufacture of a medicament for the treatment of pain in a patient, wherein hydromorphone or a pharmaceutically acceptable salt thereof is to be orally administered to the patient in a daily amount corresponding to about 48 mg of hydromorphone hydrochloride, and naloxone or a pharmaceutically acceptable salt thereof in a daily amount corresponding to about 96 mg of naloxone hydrochloride, wherein the patient experiences opioid induced constipation as a consequence of treatment with an opioid in the absence of an opioid antagonist.

21. The use of any one of claims 18-20, wherein the combination is provided in the form of a solid, oral prolonged release pharmaceutical composition, which is suitable for administration every 24 hours.

22. The use of any one of claims 18-20, wherein the combination is provided in the form of a solid, oral prolonged release pharmaceutical composition, which is suitable for administration every 12 hours and which comprises 24 mg hydromorphone HCl and 48 mg naloxone HCl.