CLAIMS

1. An intranasal pharmaceutical dosage form comprising a dosing unit comprising naloxone or a pharmaceutically acceptable salt thereof in an amount of equivalent to between about 0.65 mg naloxone HCl and about 0.8 mg naloxone HCl or between about 1.3 mg naloxone HCl and about 1.6 mg naloxone HCl dissolved in an application fluid of a volume of ≤ about 250 µl, preferably ≤ about 200 µl.

2. Dosage form according to claim 1, wherein said dosing unit comprises naloxone or a pharmaceutically acceptable salt thereof in an amount of equivalent to between about 0.65 mg naloxone HCl and about 0.8 mg naloxone HCl if a single application step comprises the administration to two nostrils.

3. Dosage form according to claim 1, wherein said dosing unit comprises naloxone or a pharmaceutically acceptable salt thereof in an amount of equivalent to between about 1.3 mg naloxone HCl and about 1.6 mg naloxone HCl if a single application step comprises the administration to one nostril.

4. Dosage form according to any of claims 1 to 3, wherein the volume of the application fluid is within a range of about 200 µl to about 35 µl, preferably of about 200 µl to about 50 µl, more preferably of about 200 µl to about 100 µl.

5. Dosage form according to any of the preceding claims, wherein the application fluid is selected from the group comprising water and an aqueous saline solution, preferably an aqueous NaCl solution, more preferably an aqueous 0.9% (weight/volume) NaCl solution.

6. Dosage form according to any of the preceding claims, wherein the dosage form is selected from the group of dosage forms comprising a nasal spray, a nasal mucoadhesive dosage form and a Mucosal Atomizer Device.

7. An intranasal pharmaceutical dosage form comprising naloxone or a pharmaceutically acceptable salt thereof dissolved in an application fluid for use in the treatment of opioid overdosing and/or at least one symptom thereof, wherein an amount of equivalent to between about 1.3 mg naloxone HCl and about 1.6 mg naloxone HCl is administered intranasally, wherein said amount is provided by administration to one nostril or wherein said amount is provided by administration to two nostrils, and wherein the volume of the application fluid per nostril is ≤ about 250 µl, preferably ≤ about 200 µl.

8. Dosage form for use according to claim 7, wherein an amount of naloxone or a pharmaceutically acceptable salt thereof equivalent to about 1.3 mg naloxone HCl or about 1.4 mg naloxone HCl or about 1.5 mg naloxone HCl or about 1.6 mg naloxone HCl is administered intranasally.

9. Dosage form for use according to claim 7 or 8, wherein the volume of the application fluid per nostril is within a range of about 200 µl to about 35 µl, preferably of about 200 µl to about 50 µl, more preferably of about 200 µl to about 100 µl.

10. Dosage form for use according to any of claims 7 to 9, wherein the volume of the application fluid per nostril is within a range of about 150 µl to about 100 µl.

11. Dosage form for use according to any of claims 7 to 10, wherein said amount is provided by administration to one nostril.

12. Dosage form for use according to any of claims 7 to 11, wherein the application fluid is selected from the group comprising water and an aqueous saline solution, preferably an aqueous NaCl solution, more preferably an aqueous 0.9% (weight/volume) NaCl solution.

13. Dosage form for use according to any of claims 7 to 12, wherein the dosage form comprises said amount or half of said amount dissolved in an application fluid in a dosing unit, the amount being dependent on whether said amount is provided by administration to one nostril or by administration to two nostrils.

14. Dosage form for use according to claim 13, wherein the dosage form comprises a single dosing unit or two dosing units, dependent on whether said amount is provided by administration to one nostril or by administration to two nostrils, and is for single use.

15. Dosage form for use according to claim 13, wherein the dosage form comprises at least two dosing units, preferably at least three dosing units, more preferably at least four dosing units and most preferably at least five dosing units and is for multiple uses.

16. Dosage form for use according to any of claims 7 to 15, wherein the dosage form is selected from the group of dosage forms comprising a nasal spray, a nasal mucoadhesive dosage form and a Mucosal Atomizer Device.

17. Dosage form for use according to any of claims 7 to 16, wherein the dosage form comprises naloxone as the only pharmaceutically active compound.

18. Dosage form for use according to any of claims 7 to 17, wherein the opioid overdosing is caused by the illicit use of opioids or by an accidental misuse of opioids during medical opioid therapy.

19. Dosage form for use according to any of claims 7 to 18, wherein the opioid overdosing symptom is selected from the group comprising respiratory depression, optionally postoperative opioid respiratory depression; altered level

consciousness; miotic pupils; hypoxemia; acute lung injury and aspiration pneumonia.

20. Dosage form for use according to any of claims 7 to 19, wherein said amount is re-administered during an initial titration period in order to provide for an effective amount of naloxone.

21. Dosage form for use according to any of claims 7 to 20, wherein the dosage form is combined with an intramuscular and/or intravenous dosage form comprising naloxone or a pharmaceutically acceptable salt thereof.

Claims:

1. An invention not claimed in any divisional application.