CLAIMS

1. An inhalable glucocorticoid composition for use in the therapy of a patient suffering from severe and uncontrolled asthma, wherein said composition is to be administered as a nebulised aerosol generated by an inhalation device, said device being adapted to

(a) emit the nebulised aerosol during the inhalation phase of the patient at a rate of not more than 20 liters per minute;

(b) emit, per inhalation phase, a total volume of 0.4 or more liters of gas phase, said gas phase including nebulised aerosol and optionally aerosol-free air; and

(c) emit, per inhalation phase, not more than 150 milliliters of aerosol-free air before emitting nebulised aerosol,

wherein said therapy further includes the oral administration of a glucocorticoid at a daily dose which is not higher than 40 milligrams of prednisolone or an equipotent dose of another glucocorticoid.

2. The inhalable glucocorticoid composition of claim 1, comprising a glucocorticoid selected from fluticasone propionate, budesonide, beclomethasone dipropionate, ciclesonide, flunisolide, mometasone furoate, and triamcinolone acetonide.

3. The composition of any preceding claim, wherein the orally administered glucocorticoid is selected from hydrocortisone, dexamethasone, prednisone, prednisolone, and methylprednisolone.

4. The composition of any preceding claim, wherein the daily dose of the orally administered glucocorticoid is decreased during the therapy according to claim 1 by 30% or more relative to the initial daily dose.

5. The composition of claim 4, wherein the daily dose of the orally administered glucocorticoid is decreased to zero during the therapy.

6. The composition of claim 1 or 2, wherein said therapy includes no oral administration of a glucocorticoid.

7. The composition of any preceding claim, wherein the inhalation device is adapted to emit, per inhalation phase, a total volume of gas phase in the range from 0.4 to 2 liters, and preferably from 0.4 to 1.4 liters, which total volume is selected on the basis of the patient's inhalation capacity or of the patient's actual and predicted forced expiratory volume in one second.

8. The composition of any preceding claim, wherein the inhalation device is adapted to generate a nebulised aerosol having a mass median aerodynamic diameter (MMAD) from 2 to 6 micrometers, and preferably from 3 to 5 micrometers.

9. The composition of any preceding claim, wherein the inhalation device is adapted to emit the nebulised aerosol during the inhalation phase of the patient at an overpressure of up to 40 mbar.

10. The composition of claim 9, wherein the overpressure is substantially maintained during the inhalation phase at 1 mbar or more.

11. The composition of any preceding claim, wherein the inhalation device is adapted to emit gas phase only after breath actuation by the patient.

12. The composition of any preceding claim, wherein the inhalation device is adapted to emit, per inhalation phase, from 200 to 3,000 milliliters of nebulised aerosol.

13. The composition of any preceding claim, wherein the inhalation device is adapted to emit, per inhalation phase, from 200 to 500 milliliters of aerosol-free air after emitting the nebulised aerosol.

14. The composition of any preceding claim, wherein the inhalation device is adapted to emit the nebulised aerosol at a rate of not more than 300 milliliters per second, and preferably not more than 250 milliliters per second.

15. Use of an inhalable corticosteroid selected from the group consisting of fluticasone, beclomethasone dipropionate, budesonide, mometasone furoate, ciclesonide, flunisolide and triamcinolone acetonide as an aerosol comprising said corticosteroid in amount from 400 to 4000 micrograms in the manufacture of a medicament for treatment of a patient having severe and uncontrollable asthma requiring a concurrent treatment with oral corticosteroids, wherein said medicament is to be administered

using a nebulizer device able to administer an aerosolized corticosteroid into lower lungs with overpressure of 40 mbar or less,

wherein said overpressure results in a larger than 200 micrograms deposition of said corticosteroid into the lower lungs, and

wherein said medicament results in reduction of 30% or more of oral steroids requirement and reduction of oropharyngeal side effects.

16. Use of an inhalable corticosteroid selected from the group consisting of fluticasone, beclomethasone dipropionate, budesonide, mometasone furoate, ciclesonide, flunisolide and triamcinolone acetonide as an aerosol comprising said corticosteroid in amount from 400 to 4000 micrograms in the manufacture of a medicament for treatment of a patient having severe and uncontrollable asthma requiring a concurrent treatment with oral corticosteroids, wherein said medicament is to be administered

during an inspiration time comprising three predefined periods,

wherein in the first period lasting from 1 millisecond to 1

second, an aerosolized particle-free air is to be administered at a preset flow rate and at a preset volume;

wherein in the second period lasting from 0.1 to 5 seconds, an aerosolized corticosteroid is to be administered at a preset flow rate and at a preset volume;

wherein in the third period, lasting from 1 millisecond to 10 seconds, an aerosolized particle-free air is to be administered at a preset flow rate and at a preset volume;

wherein after the third period, the patient is instructed to stop inhaling and exhale;

wherein said protocol is repeated for 6 to 10 minutes or less; and

wherein said medicament results in a larger than 200 micrograms deposition of said corticosteroid into the lower lungs.

17. Use of an inhalable glucocorticoid composition in the manufacture of a medicament for the therapy of a patient suffering from severe and uncontrolled asthma, wherein said composition is to be administered as a nebulised aerosol generated by an inhalation device, said device being adapted to

(a) emit the nebulised aerosol during the inhalation phase of the patient at a rate of not more than 20 liters per minute;

(b) emit, per inhalation phase, a total volume of 0.4 or more liters of gas phase, said gas phase including nebulised aerosol and optionally aerosol-free air; and

(c) emit, per inhalation phase, not more than 150 milliliters of aerosol-free air before emitting nebulised aerosol,

wherein said therapy further includes the oral administration of a glucocorticoid at a daily dose which is not higher than 40 milligrams of prednisolone or an equipotent dose of another glucocorticoid.

18. The use of claim 17, comprising a glucocorticoid selected from fluticasone propionate, budesonide, beclomethasone dipropionate, ciclesonide, flunisolide, mometasone furoate, and triamcinolone acetonide.

19. The use of any one of claims 17 to 18, wherein the orally administered glucocorticoid is selected from hydrocortisone, dexamethasone, prednisone, prednisolone, and methylprednisolone.

20. The use of any one of claims 17 to 19, wherein the daily dose of the orally administered glucocorticoid is decreased during the therapy according to claim 1 by 30% or more relative to the initial daily dose.

21. The use of claim 20, wherein the daily dose of the orally administered glucocorticoid is decreased to zero during the therapy.

22. The use of claims 17 or 18, wherein said therapy includes no oral administration of a glucocorticoid.

23. The use of any one of claims 17 to 22, wherein the inhalation device is adapted to emit, per inhalation phase, a total volume of gas phase in the range from 0.4 to 2 liters, and preferably from 0.4 to 1.4 liters, which total volume is selected on the basis of the patient's inhalation capacity or of the patient's actual and predicted forced expiratory volume in one second.

24. The use of any one of claims 17 to 23, wherein the inhalation device is adapted to generate a nebulised aerosol having a mass median aerodynamic diameter (MMAD) from 2 to 6 micrometers, and preferably from 3 to 5 micrometers.

25. The use of any one of claims 17 to 24, wherein the inhalation device is adapted to emit the nebulised aerosol during the inhalation phase of the patient at an overpressure of up to 40 mbar.

26. The use of claim 25, wherein the overpressure is substantially maintained during the inhalation phase at 1 mbar or more.

27. The use of any one of claims 17 to 26, wherein the inhalation device is adapted to emit gas phase only after breath actuation by the patient.

28. The use of any one of claims 17 to 27, wherein the inhalation device is adapted to emit, per inhalation phase, from 200 to 3,000 milliliters of nebulised aerosol.

29. The use of any one of claims 17 to 28, wherein the inhalation device is adapted to emit, per inhalation phase, from 200 to 500 milliliters of aerosol-free air after emitting the nebulised aerosol.

30. The use of any one of claims 17 to 29, wherein the inhalation device is adapted to emit the nebulised aerosol at a rate of not more than 300 milliliters per second, and preferably not more than 250 milliliters per second.

CLAIMS

1. Use of an inhalable corticosteroid selected from the group consisting of fluticasone, beclomethasone dipropionate, budesonide, mometasone furoate, ciclesonide, flunisolide and triamcinolone acetonide as an aerosol comprising said corticosteroid in amount from 400 to 4000 micrograms in the manufacture of a medicament for treatment of a patient having severe and uncontrollable asthma requiring a concurrent treatment with oral corticosteroids, wherein said medicament is to be administered

using a nebulizer device able to administer an aerosolized corticosteroid into lower lungs with overpressure of 40 mbar or less,

wherein said overpressure results in a larger than 200 micrograms deposition of said corticosteroid into the lower lungs, and

wherein said medicament results in reduction of 30% or more of oral steroids requirement and reduction of oropharyngeal side effects.

2. Use of an inhalable corticosteroid selected from the group consisting of fluticasone, beclomethasone dipropionate, budesonide, mometasone furoate, ciclesonide, flunisolide and triamcinolone acetonide as an aerosol comprising said corticosteroid in amount from 400 to 4000 micrograms in the manufacture of a medicament for treatment of a patient having severe and uncontrollable asthma requiring a concurrent treatment with oral corticosteroids, wherein said medicament is to be administered

during an inspiration time comprising three predefined periods,

wherein in the first period lasting from 1 millisecond to 1

second, an aerosolized particle-free air is to be administered at a preset flow rate and at a preset volume;

wherein in the second period lasting from 0.1 to 5 seconds, an aerosolized corticosteroid is to be administered at a preset flow rate and at a preset volume;

wherein in the third period, lasting from 1 millisecond to 10 seconds, an aerosolized particle-free air is to be administered at a preset flow rate and at a preset volume;

wherein after the third period, the patient is instructed to stop inhaling and exhale;

wherein said protocol is repeated for 6 to 10 minutes or less; and

wherein said medicament results in a larger than 200 micrograms deposition of said corticosteroid into the lower lungs.

3. Use of an inhalable glucocorticoid composition in the manufacture of a medicament for the therapy of a patient suffering from severe and uncontrolled asthma, wherein said composition is to be administered as a nebulised aerosol generated by an inhalation device, said device being adapted to

(a) emit the nebulised aerosol during the inhalation phase of the patient at a rate of not more than 20 liters per minute;

(b) emit, per inhalation phase, a total volume of 0.4 or more liters of gas phase, said gas phase including nebulised aerosol and optionally aerosol-free air; and

(c) emit, per inhalation phase, not more than 150 milliliters of aerosol-free air before emitting nebulised aerosol,

wherein said therapy further includes the oral administration of a glucocorticoid at a daily dose which is not higher than 40 milligrams of prednisolone or an equipotent dose of another glucocorticoid.

4. The use of claim 3, comprising a glucocorticoid selected from fluticasone propionate, budesonide, beclomethasone dipropionate, ciclesonide, flunisolide, mometasone furoate, and triamcinolone acetonide.

5. The use of any one of claims 3 to 4, wherein the orally administered glucocorticoid is selected from hydrocortisone, dexamethasone, prednisone, prednisolone, and methylprednisolone.

6. The use of any one of claims 3 to 5, wherein the daily dose of the orally administered glucocorticoid is decreased during the therapy according to claim 1 by 30% or more relative to the initial daily dose.

7. The use of claim 6, wherein the daily dose of the orally administered glucocorticoid is decreased to zero during the therapy.

8. The use of claims 3 or 4, wherein said therapy includes no oral administration of a glucocorticoid.

9. The use of any one of claims 3 to 8, wherein the inhalation device is adapted to emit, per inhalation phase, a total volume of gas phase in the range from 0.4 to 2 liters, and preferably from 0.4 to 1.4 liters, which total volume is selected on the basis of the patient's inhalation capacity or of the patient's actual and predicted forced expiratory volume in one second.

10. The use of any one of claims 3 to 9, wherein the inhalation device is adapted to generate a nebulised aerosol having a mass median aerodynamic diameter (MMAD) from 2 to 6 micrometers, and preferably from 3 to 5 micrometers.

11. The use of any one of claims 3 to 10, wherein the inhalation device is adapted to emit the nebulised aerosol during the inhalation phase of the patient at an overpressure of up to 40 mbar.

12. The use of claim 11, wherein the overpressure is substantially maintained during the inhalation phase at 1 mbar or more.

13. The use of any one of claims 3 to 12, wherein the inhalation device is adapted to emit gas phase only after breath actuation by the patient.

14. The use of any one of claims 3 to 13, wherein the inhalation device is adapted to emit, per inhalation phase, from 200 to 3,000 milliliters of nebulised aerosol.

15. The use of any one of claims 3 to 14, wherein the inhalation device is adapted to emit, per inhalation phase, from 200 to 500 milliliters of aerosol-free air after emitting the nebulised aerosol.

16. The use of any one of claims 3 to 15, wherein the inhalation device is adapted to emit the nebulised aerosol at a rate of not more than 300 milliliters per second, and preferably not more than 250 milliliters per second.