Claims

1. A pharmaceutical dosage form that is suitable for peroral administration to the gastrointestinal tract, which dosage form comprises a pharmaceutical composition comprising N-butyloxycarbonyl-3-(4-imidazol-1-ylmethylphenyl)-5-iso-butylthiophene-2-sulfonamide, or a pharmaceutically-acceptable salt thereof, in which composition the N-butyloxycarbonyl-3-(4-imidazol-1-ylmethylphenyl)-5-iso-butylthiophene-2-sulfonamide or salt thereof is protected by the presence of a coating comprising an enteric substance.

2. A dosage form as claimed in Claim 1, wherein the enteric substance is polyvinyl acetate phthalate or a methacrylic acid copolymer.

3. A dosage form as claimed in Claim 1 or Claim 2, wherein the final dosage form comprises an enterically-coated pill, tablet, capsule or film.

4. A dosage form as claimed in Claim 3, wherein the final dosage form is an enterically-coated capsule.

5. A dosage form as claimed in any one of the preceding claims, wherein N-butyloxycarbonyl-3-(4-imidazol-1-ylmethylphenyl)-5-iso-butylthiophene-2-sulfonamide or the salt thereof is provided in the form of a powder, a simple mixture, granules, pellets, beads, a solution or a suspension.

6. A dosage form as claimed in Claim 5, wherein the form is a simple powder mixture.

7. A dosage form as claimed in Claim 6 as dependent on Claim 4, wherein the capsule is a hard-shell, two-piece capsule.

8. A dosage form as claimed in Claim 7, wherein the capsule comprises hydroxypropyl methylcellulose.

9. A dosage form as claimed in Claim 5, wherein the form is a suspension of particles of N-butyloxycarbonyl-3-(4-imidazol-1-ylmethylphenyl)-5-iso-butylthiophene-2-sulfonamide or the salt thereof in a lipid carrier in which it is insoluble.

10. A dosage form as claimed in Claim 9 as dependent on Claim 4, wherein the capsule is a soft-shell, single-piece capsule.

11. A dosage form as claimed in Claim 10, wherein the capsule comprises gelatin.

12. A dosage form as claimed in any one of the preceding claims wherein N-butyloxycarbonyl-3-(4-imidazol-1-ylmethylphenyl)-5-iso-butyl-thiophene-2-sulfonamide or pharmaceutically-acceptable salt thereof is provided in the form of the particles having a weight- and/or a volume-based mean diameter that is no more than about 50 μm.

13. A dosage form as claimed in any one of the preceding claims that is essentially water-free.

14. A dosage form as claimed in any one of the preceding claims wherein the pharmaceutically-acceptable salt of N-butyloxycarbonyl-3-(4-imidazol-1-ylmethyl-phenyl)-5-iso-butylthiophene-2-sulfonamide is a sodium salt.

15. A process for the production of a dosage form as defined in any one of the preceding claims, which process comprises coating a composition comprising N-butyloxycarbonyl-3-(4-imidazol-1-ylmethyl-phenyl)-5-iso-butylthiophene-2-sulfonamide or a pharmaceutically-acceptable salt thereof with an enteric substance.

16. A process for the production of a dosage form as defined in any one of Claims 4 to 14, which comprises loading N-butyloxycarbonyl-3-(4-imidazol-1-ylmethyl-phenyl)-5-iso-butylthiophene-2-sulfonamide or a pharmaceutically-acceptable salt thereof into a capsule, which capsule is coated with an enteric substance.

17. A dosage form obtainable by a process as defined in Claims 15 or Claim 16.

18. A dosage form as defined in any one of the Claims 1 to 14 or 17 for use in the treatment of an interstitial lung disease.

19. The use of a dosage form as defined in any one of the Claims 1 to 14 or 17 for the manufacture of a medicament for the treatment of an interstitial lung disease.

20. A method of treatment of an interstitial lung disease, which method comprises the administration of a dosage form as defined in any one of the Claims 1 to 14 or 17 to a patient in need of such treatment.

21. A dosage form for use as defined in Claim 18, a use as defined in Claim 19, or a method of treatment as defined in Claim 20, wherein the interstitial lung disease is idiopathic pulmonary fibrosis.

22. A dosage form for use as defined in Claim 18, a use as defined in Claim 19, or a method of treatment as defined in Claim 20, wherein the interstitial lung disease is sarcoidosis.

23. A dosage form as defined in any one of the Claims 1 to 14 or 17 for use in the treatment of respiratory virus-induced tissue damage.

24. The use of a dosage form as defined in any one of the Claims 1 to 14 or 17 for the manufacture of a medicament for the treatment of respiratory virus-induced tissue damage.

25. A method of treatment of respiratory virus-induced tissue damage, which method comprises the administration of a dosage form as defined in any one of the Claims 1 to 14 or 17 to a patient in need of such treatment.

26. A dosage form for use as defined in Claim 23, a use as defined in Claim 24, or a method of treatment as defined in Claim 25, wherein the damage comprises injury and/or dysfunction of the mucosal tissue of the respiratory tract that is caused by a respiratory virus.

27. A dosage form for use, a use or a method of treatment as claimed in Claim 26, wherein the respiratory virus is a coronavirus or is an influenza virus.

28. A dosage form for use, a use or a method of treatment as claimed in Claim 27, wherein the respiratory virus is severe acute respiratory syndrome coronavirus 2.

29. A dosage form for use, a use or a method of treatment as claimed in any one of Claims 23 to 28 (as appropriate), wherein the treatment includes treatment of the symptoms of the disease that is being, or has been, caused by the virus.

30. A dosage form for use, a use or a method of treatment as claimed in Claim 29, wherein the symptoms of the damage or the disease include one or more of cough, dyspnea, respiratory distress, respiratory failure, pneumonia, fibrosis in one or more internal organs selected from the lungs, the heart and/or the kidneys.

31. A dosage form for use, a use, or a method of treatment as defined in any lone of Claims 18 to 30 (as appropriate), wherein the treatment includes prevention of morbidity and/or mortality in the relevant condition.

32. A dosage form for use, a use, or a method of treatment as defined in any lone of Claims 18 to 31 (as appropriate), wherein the composition is administered by the peroral route.

CLAIMS

1. A pharmaceutical dosage form that is suitable for peroral administration to the gastrointestinal tract, which dosage form comprises a pharmaceutical composition comprising N-butyloxycarbonyl-3-(4-imidazol-1-ylmethylphenyl)-5-iso-butylthiophene-2-sulfonamide, or a pharmaceutically-acceptable salt thereof, in which composition the N-butyloxycarbonyl-3-(4-imidazol-1-ylmethylphenyl)-5-iso-butylthiophene-2-sulfonamide or salt thereof is protected by the presence of a coating comprising an enteric substance.

2. A dosage form according to Claim 1, in which the enteric substance is polyvinyl acetate phthalate or a methacrylic acid copolymer.

3. A dosage form according to Claim 1 or 2, in which the final dosage form comprises an enterically-coated pill, tablet, capsule or film.

4. A dosage form according to Claim 3, in which the final dosage form is an enterically-coated capsule.

5. A dosage form according to any preceding claim, in which N-butyloxycarbonyl-3-(4-imidazol-1-ylmethylphenyl)-5-iso-butylthiophene-2-sulfonamide or the salt thereof is provided in the form of a powder, a simple mixture, granules, pellets, beads, a solution or a suspension.

6. A dosage form according to Claim 5, in which the form is a simple powder mixture.

7. A dosage form according to Claim 6 as dependent on Claim 4, in which the capsule is a hard-shell, two-piece capsule.

8. A dosage form according to Claim 7, in which the capsule comprises hydroxypropyl methylcellulose.

9. A dosage form according to Claim 5, in which the form is a suspension of particles of N-butyloxycarbonyl-3-(4-imidazol-1-ylmethylphenyl)-5-iso-butylthiophene-2-sulfonamide or the salt thereof in a lipid carrier in which it is insoluble.

10. A dosage form according to Claim 9 as dependent on Claim 4, in which the capsule is a soft-shell, single-piece capsule.

11. A dosage form according to Claim 10, in which the capsule comprises gelatin.

12. A dosage form according to any preceding claim, in which N-butyloxycarbonyl-3-(4-imidazol-1-ylmethylphenyl)-5-iso-butyl-thiophene-2-sulfonamide or pharmaceutically-acceptable salt thereof is provided in the form of the particles having a weight- and/or a volume-based mean diameter that is no more than about 50 μm.

13. A dosage form according to any preceding claim that is essentially water-free.

14. A dosage form according to any preceding claim, in which the pharmaceutically-acceptable salt of N-butyloxycarbonyl-3-(4-imidazol-1-ylmethyl-phenyl)-5-iso-butylthiophene-2-sulfonamide is a sodium salt.

15. A process for the production of a dosage form as defined in any preceding claim, which process comprises coating a composition comprising N-butyloxycarbonyl-3-(4-imidazol-1-ylmethyl-phenyl)-5-iso-butylthiophene-2-sulfonamide or a pharmaceutically-acceptable salt thereof with an enteric substance.

16. A process for the production of a dosage form as defined in any of Claims 4 to 14, which comprises loading N-butyloxycarbonyl-3-(4-imidazol-1-ylmethyl-phenyl)-5-iso-butylthiophene-2-sulfonamide or a pharmaceutically-acceptable salt thereof into a capsule, which capsule is coated with an enteric substance.

17. A dosage form obtainable by a process as defined in Claims 15 or 16.

18. A dosage form as defined in any of Claims 1 to 14 or 17 for use in the treatment of an interstitial lung disease.

19. Use of a dosage form as defined in any of Claims 1 to 14 or 17 for the manufacture of a medicament for the treatment of an interstitial lung disease.

20. A dosage form for use as defined in Claim 18 or a use as defined in Claim 19, in which the interstitial lung disease is idiopathic pulmonary fibrosis.

21. A dosage form for use as defined in Claim 18 or a use as defined in Claim 19, in which the interstitial lung disease is sarcoidosis.

22. A dosage form as defined in any of Claims 1 to 14 or 17 for use in the treatment of respiratory virus-induced tissue damage.

23. Use of a dosage form as defined in any of Claims 1 to 14 or 17 for the manufacture of a medicament for the treatment of respiratory virus-induced tissue damage.

24. A dosage form for use as defined in Claim 22 or a use as defined in Claim 23, in which the damage comprises injury and/or dysfunction of the mucosal tissue of the respiratory tract that is caused by a respiratory virus.

25. A dosage form for use or a use according to Claim 24, in which the respiratory virus is a coronavirus or is an influenza virus.

26. A dosage form for use or a use according to Claim 25, in which the respiratory virus is severe acute respiratory syndrome coronavirus 2.

27. A dosage form for use or a use according to any of Claims 22 to 26 (as appropriate), in which the treatment includes treatment of the symptoms of the disease that is being, or has been, caused by the virus.

28. A dosage form for use or a use according to Claim 27, in which the symptoms of the damage or the disease include one or more of cough, dyspnea, respiratory distress, respiratory failure, pneumonia, fibrosis in one or more internal organs selected from the lungs, the heart and/or the kidneys.

29. A dosage form for use or a use as defined in any lone of Claims 18 to 28 (as appropriate), in which the treatment includes prevention of morbidity and/or mortality in the relevant condition.

30. A dosage form for use or a use as defined in any lone of Claims 18 to 29 (as appropriate), in which the composition is to be administered by the peroral route.