

Claims

1. A formulation comprising a halogenated salicylanilide, or a pharmaceutically acceptable salt thereof, and a cyclodextrin.
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2. The formulation according to claim 1, wherein the halogenated salicylanilide is selected from the group consisting of niclosamide, closantel, oxyclozanide and rafoxanide, or a pharmaceutically acceptable salt thereof.
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3. The formulation according to claim 1 or claim 2, wherein the halogenated salicylanilide is niclosamide, or a pharmaceutically acceptable salt thereof.
4. The formulation according to claim 3, wherein the pharmaceutically acceptable salt is niclosamide ethanolamine.
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5. The formulation according to any one of claims 1 to 4, wherein the formulation is in the form of a solid, or wherein the formulation is in the form of a solution, suspension or dispersion of the halogenated salicylanilide, or a pharmaceutically acceptable salt thereof, and the cyclodextrin in a pharmaceutically acceptable solvent; preferably wherein the solvent comprises water.
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6. The formulation according to any preceding claim, wherein the cyclodextrin comprises β -cyclodextrin or a derivative thereof, optionally wherein the cyclodextrin is hydroxypropyl- β -cyclodextrin (HP- β -CD).
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7. The formulation according to any preceding claim, wherein the halogenated salicylanilide, or the pharmaceutically acceptable salt thereof, is present in the formulation in an amount of from 0.05 to 10 % by weight, optionally from 0.5 to 1 % by weight, based on the weight of the formulation.
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8. The formulation according to any preceding claim, wherein the formulation is a liquid formulation and the cyclodextrin is present in the formulation in an amount of from 1 to 25 % by weight, e.g. from 10 to 15 % by weight, based on the weight of the liquid formulation.
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9. The formulation according to any preceding claim, further comprising at least one polymer, optionally wherein the polymer is selected from the group consisting of polyvinylpyrrolidone (PVP), polyvinylalcohol (PVA), polyvinylpyrrolidone/vinyl acetate copolymer (PVP/VA),

hydroxypropylcellulose (HPC), hydroxypropylmethylcellulose acetate succinate (HPMC-AS), poloxamers, hydroxypropylmethylcellulose (HPMC), and any combination thereof, optionally wherein the polymer comprises PVP.

5 10. A formulation comprising a halogenated salicylanilide, or a pharmaceutically acceptable salt thereof, and a cyclodextrin, for use as a medicament, wherein the formulation is as defined by any one of claims 1 to 9.

10 11. A formulation comprising a halogenated salicylanilide, or a pharmaceutically acceptable salt thereof, and a cyclodextrin, for use in the treatment or prevention of an infectious disease or an inflammatory disease in a subject in need thereof, wherein the formulation is as defined by any one of claims 1 to 9.

15 12. The formulation for use according to claim 11, wherein the infectious disease is a viral infection, optionally wherein the viral infection is caused by or associated with a virus selected from respiratory syncytial virus, influenza virus, parainfluenza virus, human metapneumovirus, severe acute respiratory syndrome coronavirus (SARS-CoV), severe acute respiratory syndrome coronavirus (SARS-CoV-2), Middle East respiratory syndrome coronavirus (MERS-CoV), a human rhinovirus (HRVs) and human adenovirus (HAdV).

20 13. The formulation for use according to claim 11, wherein the inflammatory disease is a pulmonary inflammatory disease selected from the group consisting of: asthma, chronic obstructive pulmonary disease (COPD), pulmonary fibrosis, pneumonia, interstitial lung disease, sarcoidosis, bronchiolitis obliterans, pneumonitis, acute respiratory distress
25 syndrome (ARDS), bronchiectasis, cystic fibrosis, idiopathic pulmonary fibrosis, radiation induced fibrosis, silicosis, asbestos induced pulmonary or pleural fibrosis, acute lung injury, usual interstitial pneumonia (UIP), Chronic lymphocytic leukemia (CLL)-associated fibrosis, Hamman-Rich syndrome, Caplan syndrome, coal worker's pneumoconiosis, cryptogenic fibrosing alveolitis, obliterative bronchiolitis, chronic bronchitis, emphysema, Wegner's
30 granulomatosis, lung scleroderma, silicosis, asbestos induced pulmonary and/or pleural fibrosis.

14. The formulation for use according to any one of claims 11 to 13, wherein said use comprises administering the formulation by inhalation intraorally and/or intranasally, optionally
35 wherein the formulation is administered by inhalation intraorally.

15. A formulation comprising a halogenated salicylanilide, or a pharmaceutically acceptable salt thereof, and a cyclodextrin, for use in the treatment or prevention of an infectious ocular disease or an inflammatory ocular disease in a subject, wherein the formulation is as defined by any one of claims 1 to 9.

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16. The formulation for use according to claim 15, wherein the infectious ocular disease is selected from the group consisting of conjunctivitis (including bacterial, fungal and viral conjunctivitis), keratitis (including viral, bacterial, fungal and amoebic keratitis), endophthalmitis, blepharitis, sty, uveitis, cellulitis (e.g. bacterial cellulitis), ocular gonorrhoea and ocular herpes.

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17. The formulation for use according to claim 15, wherein the inflammatory ocular disease is elected from dry eye disorder (DED), ocular rosacea, uveitis (e.g. Birdshot retinochoroidopathy), severe conjunctivitis, diabetic retinopathy, multifocal choroiditis with panuveitis, serpiginous choroidopathy, scleritis, an eye inflammation associated with allergy (such as allergic conjunctivitis), and an eye inflammation associated with an autoimmune disorder (e.g. mucous membrane pemphigoid, eye inflammation associated with infection, retinitis pigmentosa, ankylosing spondylitis, Behcet's syndrome, dermatomyositis, Graves' disease, juvenile rheumatoid arthritis, multiple sclerosis, psoriatic arthritis, blepharitis, Reiter's syndrome, rheumatoid arthritis, Sjogren's syndrome, systemic lupus erythematosus, and Wegener's granulomatosis).

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18. An aerosol of a solution comprising a halogenated salicylanilide, or a pharmaceutically acceptable salt thereof, and cyclodextrin.

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19. An aerosol according to claim 18, wherein the solution comprises niclosamide ethanolamine.

20. The aerosol according to claims 18 or claim 19, wherein the cyclodextrin is β -cyclodextrin or a derivative thereof, optionally wherein the cyclodextrin comprises hydroxypropyl- β -cyclodextrin (HP- β -CD).

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21. The aerosol according to any one of claims 18 to 20, wherein the solution further comprises at least one polymer, optionally wherein the polymer is selected from the group consisting of polyvinylpyrrolidone (PVP), polyvinylalcohol (PVA), polyvinylpyrrolidone/vinyl acetate copolymer (PVP/VA), hydroxypropylcellulose (HPC), poloxamers,

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hydroxypropylmethylcellulose (HPMC), and any combination thereof, optionally wherein the polymer comprises PVP.

22. The aerosol according to any one of claims 18 to 21, for use in the treatment or prevention
5 of an infectious disease or an inflammatory disease in a subject, optionally a pulmonary infectious or inflammatory disease, wherein said use comprises administration of the aerosol to the subject by inhalation.

23. The aerosol for use according to claim 22, wherein the infectious disease is a viral infection.
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24. A system comprising:

- a formulation as defined by any one of claims 1 to 9; and
- an inhaler device and/or an intranasal delivery device.

15 25. A method of preparing a formulation, the method comprising:

- adding cyclodextrin and/or a halogenated salicylanilide, or a pharmaceutically acceptable salt thereof, to a solvent to form a suspension;
- heating the suspension for a period of time sufficient for the cyclodextrin and/or a halogenated salicylanilide, or a pharmaceutically acceptable salt thereof, to dissolve in the
20 solvent, thereby forming a solution;
- optionally, adding one or more polymers to the suspension or the solution, optionally wherein the polymer comprises PVP;
- optionally, raising the pH of the suspension or solution, optionally wherein the pH is raised to a pH of 8-13; and
- 25 - cooling the solution.