Claims

1. 5-amino-2,3-dihydro-1,4-phthalazinedione or one of its pharmaceutically acceptable salts for use in the prophylaxis or treatment of inflammatory pulmonary diseases by inhalatory administration,
wherein a vibrating mesh nebulizer releases for the inhalatory administration an aerosol containing liquid droplets of 5-amino-2,3-dihydro-1,4-phthalazinedione or one of its pharmaceutically acceptable salts,
and the median mass aerodynamic diameter of the liquid droplets of the aerosol is between 3.0 µm and 3.3 µm,
and said aerosol is characterized in that the fine particle mass is at least 50% of the liquid droplets of the aerosol, wherein the fine particle mass indicates the percentage of the liquid droplets with a diameter in the range of 1.0 to 5.0 µm.

2. 5-amino-2,3-dihydro-1,4-phthalazinedione or one of its pharmaceutically acceptable salts for use according to claim 1, wherein said mesh nebulizer is a vibrating mesh nebulizer.

3. 5-amino-2,3-dihydro-1,4-phthalazinedione or one of its pharmaceutically acceptable salts for use according to any one of claims 1 or 2, wherein at least 50% of the liquid droplets of the aerosol have a mass aerodynamic diameter between 1.0 µm and 3.2 µm.

4. 5-amino-2,3-dihydro-1,4-phthalazinedione or one of its pharmaceutically acceptable salts for use according to any one of claims 1 to 3, wherein the pharmaceutically acceptable salt of 5-amino-2,3-dihydro-1,4-phthalazinedione is 5-amino-2,3-dihydro-1,4-phthalazinedione sodium salt.

5. 5-amino-2,3-dihydro-1,4-phthalazinedione or one of its pharmaceutically acceptable salts for use according to claim 4, wherein 5-amino-2,3-dihydro-1,4-phthalazinedione sodium salt is provided as one of crystalline anhydrate polymorph forms I, II or III characterized by crystallography values determined by means of x-ray powder diagrams:
d values: 13.5; 6.9; 5.2; 4.6; 3.9; 3.5; 3.4; 3.3; 3.1; 3.0 and/or
2-theta values: 6.5; 12.7; 16.9; 19.3; 22.8; 25.8; 26.6; 27.2; 28.7; 30.3 for form I,
d values: 12.9; 7.9; 7.1; 6.5; 5.3; 4.0; 3.7; 3.6; 3.3; 3.2 and/or
2-theta values: 6.8; 11.2; 12.5; 13.7; 16.7; 22.4; 24.3; 24.9; 27.2; 27.8 for form II,

and
d values: 13.131; 7.987; 7.186; 6.566; 6.512; 5.372; 3.994; 3.662; 3.406; 3.288; 3.283; 3.222; 3.215; 3.127; 2.889 and/or
2-theta values: 6.73; 11.07; 12.31; 13.48; 13.59; 16.49; 22.24; 24.29; 26.14; 27.10; 27.14; 27.67; 27.72; 28.52; 30.93 for form III.

6. 5-amino-2,3-dihydro-1,4-phthalazinedione or one of its pharmaceutically acceptable salts for use according to any one of claims 1 to 5, wherein the inflammatory pulmonary disease is selected from a group comprising inflammations of the lower airways due to a bacterial, viral, fungal or parasitic infection, chronic lower respiratory diseases, lung diseases due to an external agent, respiratory diseases principally affecting the interstitium, suppurative and/or necrotic conditions of lower respiratory tract, pleura diseases, postprocedural or related lower respiratory diseases, pulmonary diseases specific to the perinatal period, trauma and injuries of the lower respiratory tract and/or the thorax, and malignant neoplasms of the lower respiratory tract.

7. 5-amino-2,3-dihydro-1,4-phthalazinedione or one of its pharmaceutically acceptable salts for use according to any one of claims 1 to 6, wherein the inflammatory pulmonary disease is selected from a group comprising chronic obstructive pulmonary disease, asthma, sarcoidosis of the lung, cystic fibrosis, bronchiectasis, adult respiratory distress syndrome, pulmonary fibrosis, berylliosis, chronic lung allograft dysfunction, pulmonary edema, lung ischemia reperfusion injury and primary graft dysfunction after lung transplantation.

8. 5-amino-2,3-dihydro-1,4-phthalazinedione or one of its pharmaceutically acceptable salts for use in an aerosol for inhalatory administration for the prophylaxis or treatment of inflammatory pulmonary diseases,
wherein the median mass aerodynamic diameter of the liquid droplets of the aerosol is between 3.0 µm and 3.3 µm,
and said aerosol is characterized in that the fine particle mass is at least 50% of the liquid droplets of the aerosol, wherein the fine particle mass indicates the percentage of the liquid droplets with a diameter in the range of 1.0 to 5.0 µm.

9. An aerosol produced by a vibrating mesh nebulizer, containing
5-amino-2,3-dihydro-1,4-phthalazinedione or one of its pharmaceutically acceptable salts in the range of 0.01% per weight to 10 % per weight,
an aqueous solution in the range of 70 % per weight to 99.99 % per weight, and

optionally at least one pharmaceutically acceptable excipient in the range of 0 % per weight to 20 % per weight,
wherein said percentages add up to 100 %,
the median mass aerodynamic diameter of the liquid droplets of the aerosol is between 3.0 µm and 3.3 µm
and said aerosol is characterized in that the fine particle mass is at least 50% of the liquid droplets of the aerosol, wherein the fine particle mass indicates the percentage of the liquid droplets with a diameter in the range of 1.0 to 5.0 µm.

10. A method for producing an aerosol as defined in claim 9, comprising the following steps:
    a) filling 0.1 ml to 5 ml of an aqueous solution containing 5-amino-2,3-dihydro-1,4-phthalazinedione or one of its pharmaceutically acceptable salts and optionally at least one pharmaceutically acceptable excipient into the nebulization chamber of a mesh nebulizer,
    b) starting vibration of the mesh of the mesh nebulizer at a frequency of 80 kHz to 200 kHz, and
    c) discharging the generated aerosol at the side of the mesh of the mesh nebulizer opposite to the nebulization chamber.

11) The method according to claim 10,
characterized in that at least 90 % in weight of 5-amino-2,3-dihydro-1,4-phthalazinedione or one of its pharmaceutically acceptable salts contained in said aqueous solution are nebulized in the generated aerosol.

12) The method according to any one of claims 10 or 11,
characterized in that at least 80 % of the generated aerosol are produced during three minutes after starting nebulization in the mesh nebulizer.

13) A kit, comprising a vibrating mesh nebulizer and a pharmaceutically acceptable container with an aqueous solution containing 5-amino-2,3-dihydro-1,4-phthalazinedione or one of its pharmaceutically acceptable salts and optionally at least one pharmaceutically acceptable excipient,
wherein said vibrating mesh nebulizer is able to produce an aerosol from said aqueous solution that is characterized in that the median mass aerodynamic diameter of the liquid droplets of the aerosol is between 3.0 µm and 3.3 µm, and

in that the fine particle mass is at least 50% of the liquid droplets of the aerosol, wherein the fine particle mass indicates the percentage of the liquid droplets with a diameter in the range of 1.0 to 5.0 µm.

14) A kit, comprising a vibrating mesh nebulizer, a first pharmaceutically acceptable container with water for injection or physiological saline solution and a second pharmaceutically acceptable container with a solid form of 5-amino-2,3-dihydro-1,4-phthalazinedione or one of its pharmaceutically acceptable salts,
wherein optionally at least one pharmaceutically acceptable excipient is contained in the first pharmaceutically acceptable container and/or the second pharmaceutically acceptable container, and
said vibrating mesh nebulizer is able to produce an aerosol from a solution resulting from the mixing of the content of the first container and the second container, and said aerosol is characterized in that the median mass aerodynamic diameter of the liquid droplets of the aerosol is between 3.0 µm and 3.3 µm, and
in that the fine particle mass is at least 50% of the liquid droplets of the aerosol, wherein the fine particle mass indicates the percentage of the liquid droplets with a diameter in the range of 1.0 to 5.0 µm.

15) A kit as defined in any one of claims 13 or 14, additionally comprising a mouthpiece for inhalation fitting to said mesh nebulizer.

16) Use of 5-amino-2,3-dihydro-1,4-phthalazinedione as defined in any of claims 1 to 8 in the production of a medication for the treatment of inflammatory pulmonary diseases, wherein said treatment comprises the steps of

a) providing an aerosol as defined in claim 9 by nebulization with a mesh nebulizer, and
b) administering a therapeutically effective amount of said aerosol to a patient in need thereof via a mouthpiece for inhalation fitting to said mesh nebulizer via self-inhalation by the patient.