CLAIMS

1. A pharmaceutical composition for preventing and/or treating mucosal disorder, comprising 10 mg/mL - 50 mg/mL rebamipide having a mean particle size of less than 500 nm as an active ingredient, at least one dispersing agent, and at least one viscosity enhancing agent, wherein the viscosity of the liquid preparation is in a range of 10 mPa·s - 500 mPa·s.

2. The pharmaceutical composition of claim 1 wherein the mean particle size of rebamipide is less than 300 nm, the content of rebamipide is 20 mg/mL - 40 mg/mL, and the viscosity of the liquid preparation is in a range of 20 mPa·s - 300 mPa·s.

3. The pharmaceutical composition of claim 1 or 2 wherein the dispersing agent comprises at least one ingredient selected from the group consisting of polyvinylpyrrolidone, hydroxypropylmethylcellulose, polyoxyethylene polyoxypropylene glycol, and carboxymethylcellulose sodium.

4. The pharmaceutical composition of claim 3 wherein the dispersing agent comprises polyvinylpyrrolidone.

5. The pharmaceutical composition of claim 4 wherein the dispersing agent comprises polyvinylpyrrolidone K25 and/or polyvinylpyrrolidone K30.

6. The pharmaceutical composition of any one of claims 1 - 5 wherein the viscosity enhancing agent comprises polyvinylpyrrolidone K90.

7. The pharmaceutical composition of any one of claims 1 - 5 wherein the viscosity enhancing agent comprises pullulan.

8. The pharmaceutical composition of any one of claims 1 - 5 wherein the viscosity enhancing agent comprises polyvinylpyrrolidone K90 and pullulan.

9. The pharmaceutical composition of claim 8 wherein the viscosity enhancing agent comprises 5 mg/mL - 30 mg/mL polyvinylpyrrolidone K90 and 10 mg/mL - 30 mg/mL pullulan.

10. The pharmaceutical composition of any one of claims 1 - 9 wherein the viscosity enhancing agent has no aggregative action for the rebamipide particles.

~~11. The pharmaceutical composition of any one of claims 1 - 9 which is prepared via the following steps~~

~~mixing at least one dispersing agent, an aqueous acid solution, an aqueous solution comprising a water soluble rebamipide salt, and optional other ingredient(s) or solvent(s) to prepare an aqueous suspension comprising rebamipide having a mean particle size of less than 500 nm, and then~~

~~adding a viscosity enhancing agent thereto.~~

~~12. The pharmaceutical composition of claim 11 which is prepared via the following steps~~

~~mixing at least one dispersing agent, an aqueous acid solution, an aqueous solution comprising a water soluble rebamipide salt, and optional other ingredient(s) or solvent(s) to prepare an aqueous suspension comprising rebamipide having a mean particle size of less than 500 nm,~~

~~adding a base thereto to adjust pH of the aqueous suspension to 3 - 7,~~

~~dispersing and/or dialyzing the aqueous suspension,~~

~~adjusting pH of the aqueous suspension to 5 - 7, and then~~

~~adding a viscosity enhancing agent thereto.~~

11~~13~~. The pharmaceutical composition of any one of claims 1 - 10~~12~~ wherein the mean particle size of rebamipide is less than 200 nm.

12~~14~~. The pharmaceutical composition of any one of claims 1 - 11~~13~~ wherein the shape of rebamipide is a uniform needle crystal having the longest diameter of less than 1000 nm and the shortest diameter of less than 60 nm, provided that the longest diameter/the shortest diameter is more than 3.

13~~15~~. The pharmaceutical composition of any one of claims 1 - 12~~14~~, further comprising a parahydroxybenzoate derivative as a preserving agent (antiseptic agent).

14~~16~~. The pharmaceutical composition of any one of claims 1 - 13~~15~~, further comprising an isotonic agent, a sweetening agent, and/or a flavor.

15~~17~~. The pharmaceutical composition of claim 14~~16~~ comprising stevia as a sweetening agent.

16~~18~~. The pharmaceutical composition of any one of claims 1 - 15~~17~~ which is in the form of aqueous suspension.

17~~19~~. A method for preparing the pharmaceutical composition of any one of claims 1 - 16~~18~~, comprising

mixing at least one dispersing agent, an aqueous acid solution, an aqueous solution comprising a water-soluble rebamipide salt, and optional other ingredient(s) or solvent(s) to prepare an aqueous suspension comprising rebamipide having a mean particle size of less than 500 nm,

adding a base thereto to adjust pH of the aqueous suspension to 3 - 7,

dispersing and/or dialyzing the aqueous suspension,

adjusting pH of the aqueous suspension to 5 - 7, and then

adding a viscosity enhancing agent thereto and optionally adding a preserving agent (antiseptic agent)—, an isotonic agent, a sweetening agent, and/or a flavor thereto.

18~~20~~. The pharmaceutical composition of any one of claims 1 - 16~~A method for preventing and/or treating mucousal disorder in the oral cavity~~, comprising administering the pharmaceutical composition ~~of any one of claims 1 - 18~~ in the oral cavity.

19~~21~~. The pharmaceutical composition of any one of claims 1 - 16~~A method~~ for preventing and/or treating mucosal disorder in the oral cavity and/or mucosal disorder in the pharynx, wherein the pharmaceutical composition is~~comprising~~ administered~~ing~~ in an amount of 3 mL - 20 mL ~~of the pharmaceutical composition of any one of claims 1 - 18~~ in the oral cavity and then optionally getting the patient to swallow the pharmaceutical composition.

20~~22~~. The pharmaceutical composition~~method~~ of claim 18 or 19~~21~~ wherein the mucosal disorder ~~in the oral cavity and/or mucosal disorder in the pharynx~~ is caused by radiation.

21. The pharmaceutical composition of claim 18 or 19 wherein the mucosal disorder is caused by radiotherapy and chemotherapy.

22. The pharmaceutical composition of claim 20 wherein~~,~~ ~~and~~ the amount of the pharmaceutical composition administered in the oral cavity is 5 mL - 10 mL.

23. The pharmaceutical composition of any one of claims 19 to 22~~A method for preventing and/or treating mucosal disorder in the oral cavity~~, wherein~~comprising repeating~~ the operation of the administration and the optional swallow is repeated~~method defined in claim 21 or 22~~ twice to six times a day.

24. The pharmaceutical composition of claim 23~~A method for preventing and/or treating mucosal disorder in the oral cavity and/or mucosal disorder in the pharynx caused by radiation and chemotherapy,~~ wherein~~comprising repeating~~ the operation of the administration and the optional swallow is repeated four times~~method defined in claim 21 or 22 twice~~ to six times a day.

25. The pharmaceutical composition of any one of claims 1 - 16~~A method~~ for preventing and/or treating xerostomia and/or hyposalivation, comprising administering the pharmaceutical composition ~~of any one of claims 1 - 18~~ in the oral cavity.

26. The pharmaceutical composition of claim 20 wherein the pharmaceutical composition is administered in the oral cavity and then optionally swallowed by the patient, and wherein the daily dose of rebamipide is 400 mg to 2400 mg.

27. The pharmaceutical composition of claim 26 wherein the operation of the administration and the optional swallow is repeated four to six times a day, and wherein the radiotherapy is for treating head and neck cancer.