

Claims

1. A pharmaceutical composition, particularly for intravenous administration,
 5 comprising the following, namely:
 - a) {8-fluoro-2-[4-(3-methoxyphenyl)piperazine-1-yl]-3-[2-methoxy-5-(trifluoromethyl)phenyl]-3,4-dihydroquinazoline-4-yl} acetic acid or a salt, a solvate or a solvate of a salt thereof,
 - b) at least one excipient selected from modified β -cyclodextrins, in particular the
 10 hydroxyalkyl β -cyclodextrins, the alkylhydroxyalkyl β -cyclodextrins and the sulfoalkyl cyclodextrins, and
 - c) water.
2. The pharmaceutical composition according to claim 1, further comprising at least
 15 one buffer, preferably selected from the phosphate buffers, the Tris buffers and the citrate buffers.
3. The pharmaceutical composition according to claim 1 or 2, further comprising at least one sugar, preferably selected from the group consisting of glucose, sucrose, lactose,
 20 maltose, trehalose, sorbitol and mannitol.
4. The pharmaceutical composition according to any one of claims 1 to 3 characterized in that {8-fluoro-2-[4-(3-methoxyphenyl)piperazine-1-yl]-3-[2-methoxy-5-(trifluoromethyl)phenyl]-3,4-dihydroquinazoline-4-yl}acetic acid or a salt, a solvate or a
 25 solvate of a salt thereof is present in an amount corresponding to 1 to 100 mg, preferably 2 to 50 mg, more preferably 2 to 25 mg, and in particular to 5 to 20 mg of pure active compound per ml of preparation.
5. The pharmaceutical composition according to any one of claims 1 to 4,
 30 characterized in that the preparation has a pH in the range of 7.5 to 8.5.
6. The pharmaceutical composition according to any one of claims 1 to 5, characterized in that the at least one excipient is present in an amount of 1 to 5 equivalents, preferably of 2 to 5 equivalents and more preferably of 2.5 to 4.5 equivalents in relation to

the content of {8-fluoro-2-[4-(3-methoxyphenyl)piperazine-1-yl]-3-[2-methoxy-5-(trifluoromethyl)phenyl]-3,4-dihydroquinazoline-4-yl} acetic acid.

- 5 7. The pharmaceutical composition according to any one of claims 1 to 6, characterized in that 100 ml of said composition comprises the following:
- a) 0.2 - 2.0 g, preferably 0.5 - 1.25 g of {8-fluoro-2-[4-(3-methoxyphenyl)piperazine-1-yl]-3-[2-methoxy-5-(trifluoromethyl)phenyl]-3,4-dihydroquinazoline-4-yl} acetic acid or a salt, a solvate or a solvate of a salt thereof,
 - 10 b) 2.5 g, preferably 0.5 - 1.5 g of cyclodextrin,
 - c) 1.5 - 9.5 g, preferably 2.0 - 4.75 g of glucose,
 - d) 0.6 - 4.0 g, preferably 0.75 - 2.0 g of NaH_2PO_4 , and
 - e) water,

wherein said composition has a pH in the range of 7.5 to 8.5, preferably 7.7 to 8.0.

15

8. The pharmaceutical composition according to claim 1, characterized in that said preparation, in relation to the content of {8-fluoro-2-[4-(3-methoxyphenyl)piperazine-1-yl]-3-[2-methoxy-5-(trifluoromethyl)phenyl]-3,4-dihydroquinazoline-4-yl} acetic acid, contains 1 to 10 equivalents, preferably 2 to 7 equivalents, and in particular 2.5 to 5
- 20 equivalents of cyclodextrin as well as 0 to 2.0 equivalents, preferably 0.5 to 1.5 equivalents, and in particular 0.75 to 0.9 equivalents of NaOH.

- 9 The pharmaceutical composition according to any one of claims 1 to 5 or according to claim 8, characterized in that 100 ml of said composition comprises the following:

25

30

- a) 0.5 - 2.5 g, preferably 1.0 - 2.0 g {8-fluoro-2-[4-(3-methoxyphenyl)piperazine-1-yl]-3-[2-methoxy-5-(trifluoromethyl)phenyl]-3,4-dihydroquinazoline-4-yl}acetic acid or a salt, a solvate or a solvate of a salt thereof,
 - b) 10.0 - 30.0 g, preferably 12.5g - 22.5 g of HP- β -cyclodextrin,
 - 5 c) 0.0 - 350 mg, preferably 75 - 225 mg, in particular 100 - 125 mg of NaOH, and
 - d) water,
- wherein said preparation has a pH in the range of 7.5 to 8.5.

10. A solid pharmaceutical composition produced by lyophilizing a pharmaceutical
10 preparation according to any one of claims 1 to 9.

11. A method for producing a pharmaceutical composition according to any one of claims 1 to 7 using the following steps, namely:
- A) Dissolving the at least one excipient in the water,
 - 15 B) Adding {8-fluoro-2-[4-(3-methoxyphenyl)piperazine-1-yl]-3-[2-methoxy-5-(trifluoromethyl)phenyl]-3,4-dihydroquinazoline-4-yl}acetic acid or a salt, a solvate or a solvate of a salt thereof to the solution obtained in step A),
 - C) If necessary, add at least one sugar and/or at least one buffer,
 - D) Adjust the pH to the desired value in order to obtain a pharmaceutical composition,
 - 20 and
 - E) Sterile-filter the solution obtained in step D) and fill into suitable containers.
 - F) If necessary, perform a final sterilization, of the solution obtained in step E) under heat.

- 25 12. A method for producing a pharmaceutical composition according to any one of claims 1 to 7 using the following steps, namely:
- I.) Dissolving the at least one excipient in a part of the water,
 - II.) Adding {8-fluoro-2-[4-(3-methoxyphenyl)piperazine-1-yl]-3-[2-methoxy-5-(trifluoromethyl)phenyl]-3,4-dihydroquinazoline-4-yl}acetic acid or a salt, a solvate or a
 - 30 solvate of a salt thereof to the solution obtained in step I.),

- III.) If necessary, adjusting the pH of the solution obtained in step II.) to the desired value to obtain a first solution,
- IV.) Dissolving at least one sugar and/or a buffer in a part of the water,
- V.) If necessary, adjust the pH of the solution obtained in step IV.) to the desired value to obtain a second solution,
- VI.) Mixing the first and second solution to obtain a pharmaceutical composition, and
- VII.) Sterile filtration of the solution obtained in step VI.) and filling into suitable containers.
- VIII.) If necessary, perform a final sterilization of the solution obtained in step VII.) under heat.
13. A method for producing a pharmaceutical composition according to any one of claims 1 to 5 or according to claim 8 or 9 using the following steps, namely:
- a.) Adding {8-fluoro-2-[4-(3-methoxyphenyl)piperazine-1-yl]-3-[2-methoxy-5-(trifluoromethyl)phenyl]-3,4-dihydroquinazoline-4-yl}acetic acid or a salt, a solvate or a solvate of a salt to an aqueous NaOH solution, preferably an aqueous 0.1M NaOH solution to produce a solution or suspension,
- b.) Adding water to the solution or suspension obtained in step a.),
- c.) Adding cyclodextrin and NaCl to the solution or suspension obtained in step b.),
- d.) Sterile filtration of the solution obtained in step c.) and fill into suitable containers.
- e.) If necessary, perform a final sterilization of the solution obtained in step d.) under heat.
14. A method for producing a solid pharmaceutical composition according to claim 10 comprising the production of a pharmaceutical composition corresponding to a method according to any one of claims 11 to 13 followed by lyophilization of the pharmaceutical composition obtained in order to obtain a solid pharmaceutical composition.

15. The pharmaceutical composition according to any one of claims 1 to 10 for use in a method of treatment and/or prophylaxis of diseases, in particular of virus infections, preferably human cytomegalovirus (HCMV) infections or infections with another member of the herpes viridae group.

5

16. The use of a pharmaceutical composition according to any one of claims 1 to 10 for producing a medicament for the treatment and/or prophylaxis of diseases, in particular of virus infections, preferably human cytomegalovirus (HCMV) infections or infections with another member of the herpes viridae group.