

{8-fluoro-2-[4-(3-methoxyphenyl)piperazine-1-yl]-3-[2-methoxy-5-(trifluoromethyl)phenyl]-3,4-dihydroquinazoline-4-yl}acetic acid and which also remain stable for an adequate period of time, e.g. more than 24 hours.

- 5 In a first aspect, there is provided a pharmaceutical composition, particularly for intravenous administration, 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 ~~the cyclodextrins, lysine and arginine~~, and c) water.
- 10 In a second aspect, there is provided a solid pharmaceutical composition produced by lyophilizing a pharmaceutical preparation as disclosed herein.

In a third aspect, there is provided a method for producing a pharmaceutical composition as disclosed herein using the following steps, namely: A) Dissolving the at least one excipient in the water, B) Adding {8-fluoro-2-[4-(3-methoxyphenyl)piperazine-1-yl]-3-[2-methoxy-5-(tri-fluoromethyl)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, 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.

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In a fourth aspect, there is provided a method for producing a pharmaceutical composition as disclosed herein 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-(tri-fluoromethyl)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 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

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Claims

1. A pharmaceutical composition, particularly for intravenous administration, comprising the following, namely:
 - 5 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 ~~the cyclodextrins, lysine and arginine~~, and
 - c) water.
- 10 2. The pharmaceutical composition according to claim 1, further comprising at least one buffer, preferably selected from the phosphate buffers, the Tris buffers and the citrate buffers.
- 15 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, maltose, trehalose, sorbitol and mannitol.
- 20 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 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.
- 25 5. The pharmaceutical composition according to any one of claims 1 to 4, characterized in that the preparation has a pH in the range of 7.5 to 8.5.
- 30 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.

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,
- b) 2.5 g, preferably 0.5 – 1.5 g of arginine,
- 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 NaH₂PO₄, and
- e) water,

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

8. The pharmaceutical composition according to any one of claims 1 to 5, characterized in that the excipient is selected from ~~the cyclodextrins, preferably the β -cyclodextrins and the modified β -cyclodextrins~~, in particular the hydroxyalkyl β -cyclodextrins, the alkyl-hydroxyalkyl β -cyclodextrins and the sulfoalkyl cyclodextrins.

9. The pharmaceutical composition according to claim 8, 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 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.

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