CLAIMS

1. An immediate-release pharmaceutical composition containing ketoprofen lysine salt (KLS) having a particle size distribution with a d(0.9) comprised between 150 µm and 250 µm and a d(0.5) greater than 65 µm as the active principle, and mannitol wherein the ratio of ketoprofen lysine salt to mannitol is from 100:100 to 100:250, wherein the immediate-release pharmaceutical composition is in the form of tablet, and wherein the pharmaceutical composition further comprises at least one superdisintegrant,

wherein said at least one superdisintegrant is present in an amount ranging from 25 to 50% by weight of the amount of ketoprofen lysine salt; and

wherein said at least one superdisintegrant is selected from a group comprising crospovidone, croscarmellose, sodium starch glycolate, pregelatinized starch and mixtures thereof.

2. The immediate-release pharmaceutical composition according to claim 1, wherein the mannitol has a particle size distribution with maximum of 35% greater than 150 µm and/or minimum of 70% greater than 75 µm.

3. The immediate-release pharmaceutical composition according to claim 1 or 2, wherein said at least one superdisintegrant is present in an amount ranging from 30 to 45% and more preferably from 35 to 40% by weight of the amount of ketoprofen lysine salt.

4. The immediate-release pharmaceutical composition according to any one of the preceding claims, wherein said at least one superdisintegrant is crospovidone.

5. The immediate-release pharmaceutical composition according to any one of the preceding claims, further comprising at least one lubricant and/or at least one glidant.

6. The immediate-release pharmaceutical composition according to claim 5, wherein said at least one lubricant is present in an amount ranging from 0 to 4.0%, preferably from 1.5 to 2.5% and more preferably from 1.75 to 2.25% by weight of the

composition and/or said at least one glidant is present in an amount ranging from 0 to 2.0%, preferably from 0.5 to 1.5% and more preferably from 0.75 to 1.25% by weight of the composition.

7. The immediate-release pharmaceutical composition according to claim 5 or 6, wherein said at least one lubricant is selected from a group comprising magnesium stearate, stearic acid, talc, sodium laurylsulfate, sodium stearyl fumarate, glyceryl behenate and mixtures thereof, preferably sodium laurylsulfate and sodium stearyl fumarate.

8. The immediate-release pharmaceutical composition according to claim 5 or 6, wherein said at least one glidant is selected from a group comprising colloidal silica, talc, stearic acid and mixture thereof, preferably colloidal silica.

9. An immediate-release pharmaceutical composition according to any one of the preceding claims, obtainable by direct compression with a tableting strength from 7 to 15 kN, preferably from 7 to 10 kN.

10. A process for the preparation of an immediate-release pharmaceutical composition according to any one of the preceding claims, comprising the following steps:

a) providing ketoprofen lysine salt particles having a particle size distribution with a d(0.9) comprised between 150 µm and 250 µm and a d(0.5) greater than 65 µm, and mannitol wherein the ratio of ketoprofen lysine salt to mannitol is from 100:100 to 100:250;

b) mixing the ingredients of step a) in a suitable mixer to achieve a homogeneous mixture;

c) mixing, until a homogeneous powder is obtained, the blend of step b) with:

(i) at least one superdisintegrant, wherein said at least one superdisintegrant is present in an amount ranging from 25 to 50% by weight of the amount of ketoprofen lysine salt and wherein said at least one superdisintegrant is selected from a group comprising crospovidone, croscarmellose, sodium starch glycolate, pregelatinized starch and mixtures thereof; and

(ii) at least one lubricant and/or at least one glidant;

d) compressing the powder mixture of step c) into a tablet;

e) optionally coating the tablet of step d).