CLAIMS

1. A film-coated tablet comprising:

(a) an inner core comprising:

- a triazine derivative selected from the group consisting of 2-amino-3,6-dihydro-4-dimethylamino-6-methyl-1,3,5-triazine and pharmaceutically acceptable salts thereof, in an amount of at least 80 wt.%, relative to the total weight of the tablet,
- hydroxypropylcellulose as a binder,
- at least one glidant,
- at least one disintegrant, and
- at least one lubricant; and

(b) an external coating comprising at least one water-soluble film-forming agent.

2. The film-coated tablet according to claim 1, characterized in that the triazine derivative is selected from the group consisting of (+)-2-amino-3,6-dihydro-4-dimethylamino-6-methyl-1,3,5-triazine and pharmaceutically acceptable salts thereof; (-)-2-amino-3,6-dihydro-4-dimethylamino-6-methyl-1,3,5-triazine and pharmaceutically acceptable salts thereof; and their mixtures.

3. The film-coated tablet according to claim 2, characterized in that the triazine derivative is selected from the group consisting of (+)-2-amino-3,6-dihydro-4-dimethylamino-6-methyl-1,3,5-triazine and pharmaceutically acceptable salts, optionally mixed with (-)-2-amino-3,6-dihydro-4-dimethylamino-6-methyl-1,3,5-triazine and pharmaceutically acceptable salts thereof in a (+):(-) weight ratio of at least 95:5.

4. The film-coated tablet according to any one of claims 1 to 3, characterized in that the salt is hydrochloride salt.

5. The film-coated tablet according to any one of claims 1 to 4, characterized in that the water-soluble film-forming agent is an acrylic polymer or a cellulosic polymer, preferably hydroxypropylmethylcellulose, and the coating optionally further includes at least one

compound selected from opacifying and/or coloring agent, plasticizing agents, fillers, sweeteners, lubricants, surfactants, and mixtures thereof.

6. The film-coated tablet according to any one of claims 1 to 5, characterized in that the tablet comprises from 250 to 1000 mg, preferably 500 or 750 mg, of said triazine derivative.

7. The film-coated tablet according to any one of claims 1 to 6, characterized in that the glidant is selected from the group consisting of: anhydrous colloidal silica, magnesium stearate, starch, talc and mixtures thereof, preferably the glidant is anhydrous colloidal silica.

8. The film-coated tablet according to any one of claims 1 to 7, characterized in that the disintegrant is selected from the group consisting of: sodium croscarmellose, sodium carboxymethyl starch, calcium carboxymethylcellulose, microcrystalline cellulose, calcium carbonate, magnesium aluminum silicate, sodium starch glycolate, pregelatinized starch, sodium alginate, alginic acid, guar gum and their mixtures.

9. The film-coated tablet according to any one of claims 1 to 7, wherein the disintegrant is sodium croscarmellose.

10. The film-coated tablet according to any one of claims 1 to 9, characterized in that the lubricant is selected from the group consisting of: magnesium stearate, calcium stearate, stearic acid, sodium stearyl fumarate, sucrose fatty acid ester, talc, and mixtures thereof, preferably the lubricant is magnesium stearate.

11. The film-coated tablet according to any one of claims 1 to 10, characterized in that hydroxypropylcellulose is the sole binder present in the tablet.

12. The film-coated tablet according to any one of claims 1 to 11, characterized in that it comprises:

- triazine derivative: at least 85 wt.%
- binder(s): 1.5-4.5 wt.%

- disintegrant(s): 1.5-3 wt.%
- glidant(s): 0.8-2.5 wt.%
- lubricant(s): 0.5-1.5 wt.%
- coating: 2-3 wt.%

provided that the total content of the above ingredients amounts to 100 wt.%.

13. The film-coated tablet according to any one of claims 1 to 12, wherein the triazine derivative is 2-amino-3,6-dihydro-4-dimethylamino-6-methyl-1,3,5-triazine or hydrochloride salt thereof, the binder is hydroxypropyl cellulose, the disintegrant is sodium croscarmellose, the lubricant is magnesium stearate and the glidant is anhydrous colloidal silica.

14. The film-coated tablet of any one of claims 1 to 13, which is devoid of povidone and crospovidone.

15. An oral film-coated tablet having an inner core and an external coating, wherein the tablet comprises:

• at least 85 wt.% of 2-amino-3,6-dihydro-4-dimethylamino-6-methyl-1,3,5-triazine or hydrochloride salt thereof

• at least 1.5% wt.% of hydroxypropylcellulose,

• from 1.5 to 3 wt.% of sodium croscarmellose,

• from 0.8 to 2.5 wt.% of anhydrous colloidal silica,

• from 0.5 to 1.5 wt.% of magnesium stearate

• from 2 to 3 wt.% of the external coating comprising at least one water-soluble film-forming agent,

the percentage being relative to the total weight of the tablet,

and wherein the inner core is devoid of crospovidone and povidone.

16. A process for the manufacture of the film-coated tablet according to any one of claims 1 to 15, comprising the following successive steps:

1) wet granulating the triazine derivative with hydroxypropylcellulose and optionally part of the glidant, in a high-shear mixer, using water as a granulation aid,

2) drying the granules,

3) mixing the granules with the remaining excipients,

4) compressing the resulting mixture on a tableting machine, and

5) coating the tablets thus obtained.

17. The film-coated tablet according to any one of claims 1 to 13 for use as a medicament.

18. Use of the film-coated tablet according to any one of claims 1 to 13 in the manufacture of a medicament for the treatment of diabetes and/or complications thereof.