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,
- ~~at least one binder comprising~~ 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, ~~hydroxypropylcellulose,~~ calcium carboxymethylcellulose, microcrystalline cellulose, calcium carbonate, magnesium aluminum silicate, sodium starch glycolate, pregelatinized starch, sodium alginate, alginic acid, guar gum and their mixtures~~, preferably the disintegrant is sodium croscarmellose~~.

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

~~9~~10. The film-coated tablet according to any one of claims 1 to ~~8~~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.

~~10~~11. The film-coated tablet according to any one of claims 1 to ~~9~~10, characterized in that ~~the binder consists of~~ hydroxypropylcellulose is the sole binder present in the tablet.

~~11~~12. The film-coated tablet according to any one of claims 1 to ~~10~~11, characterized in that it ~~consists of~~comprises:

- triazine derivative: at least 85~~-95~~ 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.

~~12~~16. A process for the manufacture of the film-coated tablet according to any one of claims 1 to ~~11~~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.

~~13~~17. The film-coated tablet according to any one of claims 1 to ~~11~~ 13 for use as a medicament.

~~14~~18. Use of the film-coated tablet according to any one of claims 1 to ~~11~~ 13 in the manufacture of a medicament for the treatment of diabetes and/or complications thereof.