CLAIMS

1. A solid unfractionated unit comprising a dose of 5 to 500 mg of fexofenadine and/or of at least one pharmaceutically acceptable salt thereof, the composition of which is the following:
    - 45% to 92% by weight of fexofenadine and/or of at least one pharmaceutically acceptable salt thereof, optionally in combination with at least one other active ingredient,
    - 4% to 20% by weight of a hot-melt excipient or mixture of hot-melt excipients, said hot-melt excipient(s) being chosen from polyethylene glycol and stearic acid, and
    - 4% to 50% by weight of an additional excipient or of a plurality of additional excipients,

    the percentages by weight being expressed relative to the total weight of the composition.

2. The solid unfractionated unit as claimed in claim 1, wherein the percentage by weight of fexofenadine and/or of at least one pharmaceutically acceptable salt thereof is between 55% and 92%.

3. The solid unfractionated unit as claimed in claims 1 or 2, wherein the percentage by weight of the hot-melt excipient(s) is included in the range of from 4% to 17% by weight.

4. The solid unfractionated unit as claimed in any one of the preceding claims, wherein the percentage by weight of the additional excipient(s) is included in the range of from 4% to 35%.

5. The solid unfractionated unit as claimed in any one of the preceding claims, wherein the additional excipient(s) is (are) chosen from the group consisting of disintegrants, flow agents, lubricants and/or diluents.

6. The solid unfractionated unit as claimed in any one of the preceding claims, wherein total weight of the solid unit, including any coating or film-coating, is less than 400 mg, for a fexofenadine content of 180 mg.

7. The solid unfractionated unit as claimed in claims 1 to 6, for use as a medicament, in particular as an antihistamine, a bronchodilator, and/or for the treatment of allergies and/or urticarial.

8. The solid unfractionated unit according to claim 1, having the following composition:

- 70% to 92% by weight of fexofenadine and/or of at least one pharmaceutically acceptable salt thereof, optionally in combination with at least one other active ingredient,
- 4% to 15% by weight of a hot-melt excipient or mixture of hot-melt excipients, said hot-melt excipient(s) being chosen from polyethylene glycol and stearic acid, and
- 4% to 15% by weight of an additional excipient or of a plurality of additional excipients,

the percentages by weight being expressed relative to the total weight of the composition.

9. The solid unfractionated unit according to claim 1, having the following composition:

- 60% to 92% by weight of fexofenadine and/or of at least one pharmaceutically acceptable salt thereof, optionally in combination with at least one other active ingredient;
- 4% to 10% by weight of a hot-melt excipient or mixture of hot-melt excipients, said hot-melt excipient(s) being chosen from polyethylene glycol and stearic acid, and
- 4% to 30% by weight of an additional excipient or of a plurality of additional excipients

the percentages by weight being expressed relative to the total weight of the composition.

10. A process for manufacturing a solid unfractionated unit comprising 5 to 500 mg

of fexofenadine and/or of at least one pharmaceutically acceptable salt thereof, comprising at least the following steps:

(i) the mixing of:

- 45% to 92% by weight of fexofenadine and/or of at least one pharmaceutically acceptable salt thereof, optionally in combination with at least one other active ingredient, with
- 4% to 20% by weight of a hot-melt excipient or of a mixture of hot-melt excipients, said hot-melt excipient(s) being chosen from polyethylene glycol and stearic acid,

(ii) the granulation of the mixture obtained in step (i) at a temperature which allows the hot-melt excipient(s) to melt or to soften,

(iii) the cooling of the grains resulting from step (ii),

(iv) the calibration of the grains,

(v) the homogenization of the calibrated grains in order to obtain a homogeneous mixture, and

(vi) the forming of a solid unfractionated unit from the homogeneous mixture,

the percentages by weight being expressed relative to the total weight of the composition.

11. The process as claimed in claim 10, wherein the solid unfractionated unit comprises an additional excipient or a plurality of additional excipients, in a content of from 4% to 50% by weight relative to the weight of the solid unit.

12. The process as claimed in claim 11, wherein the additional excipient(s) is (are) chosen from the group consisting of disintegrants, flow agents, lubricants and/or diluents, and can be added during the calibration step (iv) and/or during the homogenization step (v).

13. The process as claimed in claim 11 or 12, wherein the additional excipient(s) comprise(s) at least one disintegrant, it being possible for a part of the at least one disintegrant to also be introduced into the mixture during step (i).

14. The process as claimed in any one of claims 10 to 13, comprising, after step (v), a step of coating or film-coating the solid unit.