

We claims:

1. An orally disintegrating pharmaceutical dosage form comprising a therapeutically effective amount of apixaban or a pharmaceutically acceptable salt or a prodrug thereof and at least one disintegrating excipient wherein the dosage form has hardness of about 10N to about 200N and a disintegration time of less than about 3 minutes.
2. The orally disintegrating pharmaceutical dosage form according to claim 1 wherein the dosage form has a hardness of about 15N to about 150N, preferably about 30N to about 110N, or more preferably about 40N to about 90N.
3. The orally disintegrating pharmaceutical dosage form according to claim 1, wherein the dosage form has disintegration time of less than about 3 minutes, preferably less than about 60 seconds, preferably less than about 45 seconds, or more preferably less than about 30 seconds.
4. The orally disintegrating pharmaceutical dosage form according to claim 1, wherein the disintegrating excipient is selected from group consisting of low-substituted hydroxypropyl cellulose, microcrystalline cellulose, alginic acid, calcium carbonate, potato starch, tapioca starch, corn starch, pre-gelatinized starch, sodium starch glycolate, crospovidone, croscarmellose sodium, croscarmellose calcium,

soy polysaccharides, calcium silicate, inorganic salts of 2-Methyl-2-propenoic acid polymer with divinylbenzene and styrene-divinylbenzene copolymers or a like thereof.

5. The orally disintegrating pharmaceutical dosage form according to claims 1 to 4, wherein the disintegrating excipient optionally comprises one or more additional excipient selected from the group consisting of diluent, binder, surfactant, lubricant, glidant, or a like thereof.
6. The orally disintegrating pharmaceutical dosage form according to claim 5, wherein the additional excipient is selected from the group consisting of mannitol, lactose, xylitol, fructose, sorbitol, anhydrous dibasic calcium phosphate, microcrystalline cellulose, crospovidone, magnesium aluminosilicate, colloidal silicon dioxide, carmellose or a like thereof.
7. The orally disintegrating pharmaceutical dosage form according to claim 1, wherein the said dosage form is selected from the group consisting of tablet, mini-tablet, granules, pellets, capsules or a like thereof.
8. An orally disintegrating pharmaceutical dosage form comprising a therapeutically effective amount of apixaban or a pharmaceutically acceptable salt or a prodrug

thereof and at least one disintegrating excipient characterized in that the weight ratio of apixaban to disintegrating excipient is from about 1:0.2 to about 1:95.

9. The orally disintegrating pharmaceutical dosage form according to claim 8 wherein the dosage form has a hardness of about 10N to about 200N, preferably about 15N to about 150N, preferably about 30N to about 110N, or more preferably about 40N to about 90N.
10. The orally disintegrating pharmaceutical dosage form according to claim 8, wherein the dosage form has disintegration time of less than about 3 minutes, preferably less than about 60 seconds, preferably less than about 45 seconds, or more preferably less than about 30 seconds.
11. The orally disintegrating pharmaceutical dosage form according to claim 8, wherein the weight ratio of apixaban to disintegrating excipient is from about 1:0.2 to about 1:95, preferably from about 1:5 to about 1:60, or more preferably from about 1:10 to about 1:40.
12. The orally disintegrating pharmaceutical dosage form according to claim 8, wherein disintegrating excipient is selected from group comprising low-substituted hydroxypropyl cellulose, microcrystalline cellulose, alginic acid, calcium carbonate, potato starch, tapioca starch, corn starch, pre-gelatinized starch, sodium

starch glycolate, crospovidone, croscarmellose sodium, croscarmellose calcium, soy polysaccharides, calcium silicate, inorganic salts of 2-Methyl-2-propenoic acid polymer with divinylbenzene and styrene-divinylbenzene copolymers or a like thereof.

13. The orally disintegrating pharmaceutical dosage form according to claims 8 and 11-12, wherein the disintegrating excipient optionally comprises one or more additional excipient selected from the group comprising diluent, binder, disintegrant, surfactant, lubricant, glidant or a like thereof.
14. The orally disintegrating pharmaceutical dosage form according to claim 13, wherein the additional excipient is selected from the group comprising mannitol, lactose, xylitol, fructose, sorbitol, anhydrous dibasic calcium phosphate, microcrystalline cellulose, crospovidone, magnesium aluminosilicate, colloidal silicon dioxide, carmellose or a like thereof.
15. The orally disintegrating pharmaceutical dosage form according to claim 8, wherein the said dosage form is selected from the group consisting of tablet, mini-tablet, granules, pellets, capsules or a like thereof.
16. An orally disintegrating pharmaceutical dosage form comprising a therapeutically effective amount of apixaban or a pharmaceutically acceptable salt or a prodrug

thereof in an amount from about 0.5% w/w to about 50% w/w of total composition, at least one disintegrating excipient in an amount from about 0.5% w/w to about 95% w/w of total composition and optionally one or more pharmaceutically acceptable excipients thereof wherein apixaban and disintegrating excipient are in the weight ratio from about 1:0.2 to about 1:95.

17. The orally disintegrating pharmaceutical dosage form according to claim 16, wherein apixaban or a pharmaceutically acceptable salt or a prodrug thereof is present in an amount from about 0.5% w/w to about 50% w/w, preferably about 2% w/w to about 20% w/w, or more preferably about 2.5% w/w to about 15% w/w.
18. The orally disintegrating pharmaceutical dosage form according to claim 16, wherein at least one disintegrating excipient is present in an amount from about 5% w/w to 90% w/w, preferably from about 10% w/w to about 80% w/w, or more preferably from about 15% w/w to about 70% w/w.
19. The orally disintegrating pharmaceutical dosage form according to claim 16 wherein the dosage form has a hardness of about 10N to about 200N, preferably about 15N to about 150N, preferably about 30N to about 110N, more preferably about 40N to about 90N.

20. The orally disintegrating pharmaceutical dosage form according to claim 16, wherein the dosage form has disintegration time of less than about 2 minutes, preferably less than about 60 seconds, preferably less than about 45 seconds, more preferably less than about 30 seconds.
21. The orally disintegrating pharmaceutical dosage form according to claim 16, wherein disintegrating excipient is selected from group comprising low-substituted hydroxypropyl cellulose, microcrystalline cellulose, alginic acid, calcium carbonate, potato starch, tapioca starch, corn starch, pre-gelatinized starch, sodium starch glycolate, crospovidone, croscarmellose sodium, croscarmellose calcium, soy polysaccharides, calcium silicate, inorganic salts of 2-Methyl-2-propenoic acid polymer with divinylbenzene and styrene-divinylbenzene copolymers or a like thereof.
22. The orally disintegrating pharmaceutical dosage form according to claims 16 and 20-21, wherein the disintegrating excipient optionally comprises one or more additional excipient selected from the group comprising diluent, binder, disintegrant, surfactant, lubricant, glidant or a like thereof.
23. The orally disintegrating pharmaceutical dosage form according to claim 22, wherein the additional excipient is selected from the group comprising mannitol, lactose, xylitol, fructose, sorbitol, anhydrous dibasic calcium phosphate,

microcrystalline cellulose, crospovidone, magnesium aluminosilicate, colloidal silicon dioxide, carmellose or a like thereof.

24. The orally disintegrating pharmaceutical dosage form according to claim 16, wherein the said dosage form is selected from the group consisting of tablet, mini-tablet, granules, pellets, capsules or a like thereof.

25. An orally disintegrating pharmaceutical dosage form according to any preceding claims comprising

- (a) 0.5% w/w to 50% w/w of apixaban;
- (b) 0.5% w/w to 95% w/w of disintegrating excipient;
- (c) 1% w/w to 98% w/w of diluent;
- (d) 1% w/w to 90% w/w of binder;
- (e) 0.01% w/w to 5% w/w lubricant;
- (f) 0.01% w/w to 5% w/w glidant;
- (g) 0.01% w/w to 5% w/w sweetener;
- (h) 0.1% w/w to 1.0% w/w flavouring agent;
- (i) 0.001% w/w to 10% w/w surfactant;

26. An orally disintegrating pharmaceutical dosage form according to claim 25 comprising 2-4% w/w apixaban; 30-40% w/w mannitol; 5-10% w/w starch; 20-30% w/w lactose; 10-20% w/w microcrystalline cellulose; 5-15% w/w crospovidone;

0.5-2% w/w sodium lauryl sulfate; 0.5-5% w/w magnesium stearate; 0.1-0.5% w/w of talc; 0.1-2% w/w peppermint flavour; 0.1-2% w/w aspartame.

27. The orally disintegrating pharmaceutical dosage form according to according to any preceding claims wherein the dosage form at pH from about 6.5 to about 7.5 exhibits at least one of the following dissolution profile:
- after 5 minutes, at least about about 55% of the apixaban content is dissolved; and after 30 minutes, more than about 80% of the apixaban content is dissolved.
28. The orally disintegrating pharmaceutical dosage form according to according to any preceding claims wherein upon oral administration the dosage form provides a plasma concentration $C_{\max}$ of apixaban between about 90 ng/ml to about 275 ng/ml and total drug exposure (AUC_{0-t}) of apixaban between about 800 ng.hr/ml to about 2400 ng.hr/ml.
29. An orally disintegrating dosage form for use in the treatment of thromboembolic disorder comprising therapeutically effective amount of apixaban or a pharmaceutically acceptable salt or a prodrug thereof and at least one disintegrating excipient characterized in that the weight ratio of apixaban to disintegrating excipient is from about 1:0.2 to about 1:95 wherein the thromboembolic disorder is selected from the group consisting of arterial and venous cardiovascular thromboembolic disorders, and thromboembolic disorders of the heart.

30. An orally disintegrating dosage form for use in the treatment of thromboembolic disorder according to claim 29, wherein the thromboembolic disorder is selected from deep vein thrombosis, venous thrombosis, arterial embolism, pulmonary embolism, peripheral artery disease, venous thromboembolic events in adults who have undergone elective hip or knee surgery, non-valvular arterial fibrillation.
31. A process for the preparation of an orally disintegrating dosage form as defined in any one of the preceding claims comprising the step of:
- (a) mixing together apixaban and at least one pharmaceutically acceptable excipient; and
 - (b) directly compressing the mixture into the dosage form.
32. A process for the preparation of an orally disintegrating dosage form as defined in any one of the preceding claims comprising the step of:
- (a) mixing together apixaban and at least one pharmaceutically acceptable excipient;
 - (b) granulating the mixture of step (a) by addition of liquid to obtain wet granules;
 - (c) drying the wet granules of step (b)
 - (d) optionally mixing the dry granules of step (c) with one or more pharmaceutically acceptable excipients selected from the group comprising diluent, binder, disintegrant, surfactant, lubricant and glidant;

(e) compressing the mixture obtained in step (c) or (d) to into the dosage form.

33. A process for the preparation of an orally disintegrating dosage form as defined in any one of the preceding claims comprising the step of:

- (a) mixing together apixaban and at least one pharmaceutically acceptable excipient;
- (b) compacting and sizing the mixture of step (a) to obtain dry granules;
- (c) optionally mixing the dry granules of step (b) with one or more pharmaceutically acceptable excipients selected from the group comprising diluent, binder, disintegrant, surfactant, lubricant and glidant;
- (d) compressing the mixture obtained in step (c) or (d) to into the dosage form.