CLAIMS

1. An oral solid dosage form, comprising:

i) elafibranor or a pharmaceutically acceptable salt or ester thereof;

ii) a filler selected in the group consisting of mannitol, microcrystalline cellulose and lactose monohydrate;

iii) a disintegrating agent selected in the group consisting of crospovidone and croscarmellose sodium;

iv) a binder selected in the group consisting of hydroxypropylcellulose, copovidone, povidone and hydroxypropylmethyl cellulose.

2. The oral solid dosage form according to claim 1, wherein elafibranor or a pharmaceutically acceptable salt or ester thereof is micronized.

3. The oral solid dosage form according to claim 1 or 2, wherein elafibranor or a pharmaceutically acceptable salt or ester thereof is in the form of particles, and wherein at least 90% of the particles have a diameter of 15 μm or less.

4. The oral solid dosage form according to any one of claims 1 to 3, wherein at least 50% of the particles have a diameter of 5 μm or less.

5. The oral solid dosage form according to any one of claims 1 to 4, wherein the dosage form comprises from 20 to 60 % by weight of elafibranor or a pharmaceutically acceptable salt or ester thereof.

6. The oral solid dosage form according to any onf of claims 1 to 5, wherein the dosage form comprises from 35 to 40% by weight of elafibranor or a pharmaceutically acceptable salt or ester thereof.

7. The oral solid dosage form according to any one of claims 1 to 6, wherein the dosage form comprises from 35 mg to 180 mg of elafibranor or a pharmaceutically acceptable salt or ester thereof.

8. The oral solid dosage form according to any one of claims 1 to 7, wherein the dosage form comprises from 40 mg to 120 mg of elafibranor or a pharmaceutically acceptable salt or ester thereof.

9. The oral solid dosage form according to any one of claims 1 to 8, said dosage form being a tablet.

10. The oral solid dosage form according to any one of claims 1 to 9, said dosage form being a tablet comprising:

(a) an internal phase comprising:

(i) from 30% to 60 % by weight of elafibranor or a pharmaceutically acceptable salt or ester thereof;

(ii) from 20% to 55 % by weight of microcrystalline cellulose;

(iii) from 0.8% to 6 % by weight of croscarmellose sodium; and

(iv) from 2% to 6 % by weight of povidone; and

(b) an external phase comprising:

from 0.2% to 4 % by weight of croscarmellose sodium;

from 0.1% to 0.4 % by weight of colloidal silica; and

from 0.1% to 2% by weight of magnesium stearate;

relative to the total weight of the tablet.

11. The oral solid dosage form according to claim 9 or 10, wherein the tablet is obtained by carried out a step of wet granulation followed by tablet compression and optionnaly coating.

12. The oral solid dosage form according to any one of claims 9 to 11, said dosage form comprising an external coating.

13. The oral solid dosage form according to claim 12, wherein the external coating comprises a coloring agent.

14. The oral solid dosage form of any of claims 1 to 13, for use in treating or preventing primary biliary cholangitis (PBC), primary sclerosing cholangitis (PSC), nonalcoholic fatty liver disease (NAFLD), nonalcoholic steatohepatitis (NASH), cirrhosis, hepatitis C infection, alcoholic liver disease, liver damage due to progressive fibrosis, liver fibrosis or cirrhosis in a patient in need thereof.

15. The oral solid dosage form for use according to claim 14, wherein said composition is for oral administration once a day.

16. Use of the oral solid dosage form of any of claims 1 to 13, in the manufacture of a medicament for treating or preventing primary biliary cholangitis (PBC), primary sclerosing cholangitis (PSC), nonalcoholic fatty liver disease (NAFLD), nonalcoholic steatohepatitis (NASH), cirrhosis, hepatitis C infection, alcoholic liver disease, liver damage due to progressive fibrosis, liver fibrosis or cirrhosis in a patient in need thereof.

17. Use according to claim 16, wherein said composition is for oral administration once a day.