CLAIMS

1. Use of a therapeutically effective amount of a pharmaceutical composition comprising ethyl eicosapentanoate (EPA-E), eicosapentaenoic acid (EPA), or pharmaceutically acceptable amides, salts, ester or phospholipids of EPA in the manufacture of a medicament for treating a fatty liver disease or disorder in a subject in need thereof, wherein the subject is selected to have or suspected of having a fatty liver disease or disorder, wherein the subject is non diabetic, pre- diabetic, or mildly diabetic, and wherein the medicament is to be administered into the subject in need thereof and comprises a self-emulsifying composition comprising 50 to 95% by weight of a omega-3 polyunsaturated fatty acid or a pharmaceutically acceptable amide, salt, phospholipid or ester thereof.
2. The use of claim 1, wherein the fatty liver disease or disorder is selected from the group consisting of Non-Alcoholic Fatty Liver Disease (NAFLD) and Non-Alcoholic Steatohepatits (NASH).
3. The use of claim 1, wherein selection of a subject having or suspected of having a fatty liver disease or disorder comprises selecting a subject having a score selected from the group consisting of: a NAS score greater than or equal to 3, a steatosis score equal to or greater than 1, a lobular inflammation score equal to or greater than 1, a ballooning score equal to or greater than 1 and a fibrosis score equal to or greater than 1.
4. The use of claim 1, wherein fatty liver disease is characterized by the baseline pretreatment level in the subject of at least one criteria selected from the group consisting of ALT in a range of 10 to 300 IU/L, AST in a range of 10 to 250 IU/L, HDL/C in a range of 25 to 55 mg/dl, LDL-C in a range of 100 to 200 mg/dl, triglycerides in a range of 100 to 1000 mg/dl, TC in a range of 170 to 300 mg/dl, High TG and low HDL-C, TG/HDL-C ratio in a range of 3.75 to 10, non-HDL-C in a range of 100 to 250 mg/dl, Free fatty acid in a range of 400 to 1000 μ Eq/L, HOMA-IR in a range of 1.5 to 5, HbA1c in a range of 5.7 to 10%, Fasting plasma glucose in a range of 100 to 200 mg/dl, impaired glucose tolerance and metabolic syndrome.
5. The use of claim 1, wherein a therapeutically effective amount of EPA-E to be administered to the subject is an amount between about 1800 and about 2700 mg per day.
6. The use of claim 1, wherein a therapeutically effective amount of EPA-E to be administered to the subject is at least 1800 mg per day.
7. The use of claim 1, wherein a therapeutically effective amount of EPA-E to be administered to the subject is at least 2700 mg per day.

8. The use of claim 1, wherein the medicament comprises a self-emulsifying composition comprising 50 to 95% by weight, of EPA-E, EPA or pharmaceutically acceptable amides, salts, esters or phospholipids of EPA.
9. The use of claim 1, wherein the medicament comprises 5 to 50% by weight of an emulsifier having a hydrophilic lipophilic balance of at least 10.
10. The use of claim 9, wherein the medicament comprises ethanol content up to 4% by weight in relation to the total content of the compound and the emulsifier.
11. The use of claim 9, wherein the emulsifier is at least one member selected from the group consisting of polyoxyethylene hydrogenated castor oil, polyoxyethylene sorbitan fatty acid ester, polyoxyethylene castor oil, polyethylene glycol fatty acid ester, polyoxyethylene polyoxypropylene glycol, sucrose fatty acid ester, sorbitan fatty acid ester, glycerin fatty acid ester and lecithin.
12. The use of claim 9, wherein the medicament contains a lecithin.
13. The use of claim 9, wherein the medicament contains a polyhydric alcohol.
14. The use of claim 1, wherein the medicament contains at least one member selected from the group consisting of eicosapentaenoic acid, docosahexaenoic acid, and their pharmaceutically acceptable amides, salts, esters and phospholipids.
15. The use of claim 1, wherein EPA-E, EPA or pharmaceutically acceptable amides, salts, esters or phospholipids of EPA present in the medicament is at least 40% by weight in total of the fatty acids and derivatives.
16. The use of claim 1, wherein the subject's HbA1c level is equal to or less than 6.4%, or the subject's fasting serum glucose level is equal to or less than 125 mg/dl.