

CLAIMS

- 1) A method of treating moderate or severe hypertriglyceridemia in a subject in need thereof, comprising administering to the patient a therapeutically effective amount of pemafibrate or a pharmaceutically acceptable salt thereof.
- 2) A method of treating severe hypertriglyceridemia in a subject in need thereof, comprising:
(a) identifying a subject having a fasting baseline triglyceride level of about 500 mg/dl (5.65 mmol/L) and over, and (b) administering to the subject a pharmaceutical composition comprising pemafibrate or a pharmaceutically acceptable salt thereof.
- 3) A method of treating severe hypertriglyceridemia in a subject in need thereof, comprising:
(a) identifying a subject having a fasting baseline triglyceride level of about 500 mg/dl (5.65 mmol/L) to about 2000 mg/dl (22.6 mmol/L), and (b) administering to the subject a pharmaceutical composition comprising pemafibrate or a pharmaceutically acceptable salt thereof.
- 4) The method according to any one of claims 1 to 3, wherein the therapeutically effective amount of pemafibrate or pharmaceutically acceptable salt thereof is from 0.2 to 1.0 mg, administered orally per day.
- 5) The method according to any one of claims 1 to 3, wherein the therapeutically effective amount of pemafibrate or pharmaceutically acceptable salt thereof is 0.4 mg, administered orally per day.
- 6) The method according to claim 5, wherein the therapeutically effective amount of pemafibrate or pharmaceutically acceptable salt thereof is administered twice daily.
- 7) The method according to any one of claims 1 to 3, wherein the therapeutically effective amount of pemafibrate or a pharmaceutically acceptable salt thereof is 0.2 mg, administered orally per day.
- 8) The method according to claim 7, wherein the therapeutically effective amount of pemafibrate or pharmaceutically acceptable salt thereof is administered twice daily.
- 9) The method according to any one of claims 1 to 3, wherein the patient has normal renal function.
- 10) The method according to any one of claims 1 to 3, wherein the patient has mild or moderate renal impairment.
- 11) The method according to any one of claims 1 to 8, wherein the patient has severe renal impairment.

- 12) The method of any one of claims 1 to 11, wherein the patient is on high intensity statin therapy and aged ≥ 21 years with clinical ASCVD selected from a history of acute coronary syndrome or myocardial infarction, stable or unstable angina, coronary revascularization, stroke, transient ischemic attack [TIA] of atherosclerotic origin, or peripheral arterial disease or revascularization.
- 13) The method of any one of claims 1 to 11, wherein the patient is on high intensity statin therapy and aged ≥ 21 years with a history of LDL-C ≥ 190 mg/dL, which is not due to secondary modifiable causes.
- 14) The method of any one of claims 1 to 11, wherein the patient is on moderate or high intensity statin therapy and aged 40 to 75 years, inclusive, without clinical ASCVD but with type-2 diabetes and a history of LDL-C of 70 to 189 mg/dL, inclusive.
- 15) The method of any one of claims 1 to 11, wherein the patient is on moderate or high intensity statin therapy and aged 40 to 75 years, inclusive, without clinical ASCVD or diabetes, with a history of LDL-C of 70 to 189 mg/dL, inclusive, with estimated 10-year risk for ASCVD of $\geq 7.5\%$ by the Pooled Cohort Equation.
- 16) The method of any one of claims 1 to 15, wherein the subject has one or a combination of low HDL-C levels, elevated LDL-C levels, elevated non-HDL-C levels, or elevated Total Cholesterol levels.
- 17) The method of any one of claims 1 to 16, wherein said subject is an adult and not on statin therapy, comprising administering 0.2 mg of pemafibrate or a pharmaceutically acceptable salt thereof twice daily to said subject, further comprising administering 0.2 mg of pemafibrate or a pharmaceutically acceptable salt thereof to a second adult subject on moderate or high intensity statin therapy with moderate or severe hypertriglyceridemia.
- 18) The method of claim 17, wherein said second adult subject is on high intensity statin therapy.
- 19) The method of any one of claims 1 to 17, wherein said subject is an adult and not renally impaired, comprising administering 0.2 mg of pemafibrate or a pharmaceutically acceptable salt thereof twice daily to said subject, further comprising administering 0.2 mg of pemafibrate or a pharmaceutically acceptable salt thereof to a second adult subject who is renally impaired with moderate or severe hypertriglyceridemia.
- 20) The method of claim 19, wherein said second subject has mild to moderate renal impairment.

- 21) The method according to any one of claims 1 to 20, wherein the subject has a fasting baseline triglyceride level of greater than 750 mg/dl (8.475 mmol/L).
- 22) The method according to any one of claims 1 to 20, wherein the subject has a fasting baseline triglyceride level of greater than 1000 mg/dl (11.3 mmol/L).
- 23) The method according to any one of claims 1 to 20, wherein the subject has a fasting baseline triglyceride level of greater than 1500 mg/dl (16.95 mmol/L).
- 24) A method of treating dyslipidemia in a renally impaired adult patient and a non-renally impaired adult patient comprising administering to both patients 0.2 mg of pemafibrate or a pharmaceutically acceptable salt thereof twice daily.
- 25) The method of claim 24 wherein the renally impaired patient is mildly to moderately renally impaired.
- 26) The method of claim 24 wherein the renally impaired patient is severely renally impaired.
- 27) The method of any one of claims 1 to 26, wherein the subject or renally impaired patient has an HDL-C concentration of less than 40 mg/dL.
- 28) The method of any one of claims 1 to 26, wherein the subject or renally impaired patient is on moderate or high intensity statin therapy.
- 29) The method of any one of claims 1 to 26, wherein the subject has an LDL-C concentration less than 70 mg/dL.
- 30) The method of any one of claims 1 to 26, wherein the subject or renally impaired patient has an HDL-C concentration of less than 40 mg/dL and is on moderate to high intensity statin therapy.
- 31) The method of any one of claims 1 to 26, wherein the subject or renally impaired patient has an HDL-C concentration of less than 40 mg/dL and has an LDL-C concentration less than 70 mg/dL.
- 32) The method of claim 1 wherein the subject or renally impaired patient has an HDL-C concentration of less than 40 mg/dL and is on moderate to high intensity statin therapy and has a triglyceride concentration of from 200 to 500 mg/dL.
- 33) The method of claim 1 wherein the subject or renally impaired patient has an HDL-C concentration of less than 40 mg/dL and has an LDL-C concentration less than 70 mg/dL and has a triglyceride concentration of from 200 to 500 mg/dL.
- 34) The method of any one of claims 1 to 33, wherein the method prevents a cardiovascular event selected from nonfatal myocardial infarction, nonfatal ischemic stroke,

hospitalization for unstable angina requiring unplanned coronary revascularization, cardiovascular death, and combinations thereof.