Claims

1. Use of paliperidone palmitate in the manufacture of a medicament for the treatment of psychosis, schizophrenia, schizoaffective disorder, schizophreniform disorder, or bipolar disorder in a patient in need thereof who has been administered a first dose of a first paliperidone palmitate extended-release injectable suspension having a six month dosing interval ("PP6M") (first suspension), wherein the use comprises:

a re-initiation loading dose of a second paliperidone palmitate extended-release injectable suspension having a one month dosing interval ("PP1M") (second suspension) to be administered in a deltoid muscle of the patient at a time that is more than six months and three weeks after administration of said first dose of the first suspension but less than eight months after administration of said first dose of the first suspension; and

a maintenance dose of the first suspension to be administered in the deltoid or gluteal muscle of the patient at a time that is about one month (± 7 days) after administration of the re-initiation loading dose of the second suspension,

wherein there are no intervening doses of paliperidone palmitate between the first dose and the re-initiation loading dose.

2. The use of claim 1, wherein the first dose of the first suspension comprises about 1092 mg of paliperidone palmitate; the re-initiation loading dose of the second suspension comprises about 156 mg of paliperidone palmitate; and the maintenance dose of the first suspension comprises about 1092 mg of paliperidone palmitate.

3. The use of claim 1, wherein the first dose of the first suspension comprises about 1560 mg of paliperidone palmitate; the re-initiation loading dose of the second suspension comprises about 234 mg of paliperidone palmitate; and the maintenance dose of the first suspension comprises about 1560 mg of paliperidone palmitate.

4. Use of paliperidone palmitate in a manufacture of a medicament for the treatment of psychosis, schizophrenia, schizoaffective disorder, schizophreniform disorder, or bipolar disorder in a patient in need thereof who has been administered a first dose of a first paliperidone

palmitate extended-release injectable suspension having a six month dosing interval ("PP6M") (first suspension), wherein the use comprises:

a first re-initiation loading dose of about 156 mg paliperidone palmitate of a second paliperidone palmitate extended-release injectable suspension having a one month dosing interval ("PP1M") (second suspension) to be administered to the deltoid muscle of the patient at a time that is from 8 months up to and including 11 months after administration of the first dose of the first suspension;

a second re-initiation loading dose of about 156 mg paliperidone palmitate of the second suspension to be administered in the deltoid muscle of the patient on about day 8 (± 4 days) after administration of the first re-initiation loading dose of the second suspension; and

from about 1092 mg to about 1560 mg paliperidone palmitate of a maintenance dose of the first suspension to be administered in the deltoid or gluteal muscle of the patient about 1 month (±7 days) after administration of the second re-initiation loading dose of the second suspension,

wherein there are no intervening doses of paliperidone palmitate between the first dose and the first re-initiation loading dose.

5. The use of claim 4, wherein the first dose of the first suspension comprises about 1092 mg paliperidone palmitate and the maintenance dose of the first suspension comprises about 1092 mg paliperidone palmitate.

6. The use of claim 4, wherein the first dose of the first suspension comprises about 1560 mg paliperidone palmitate and the maintenance dose of the first suspension comprises about 1560 mg paliperidone palmitate.

7. Use of paliperidone palmitate in a manufacture of a medicament for the treatment of psychosis, schizophrenia, schizoaffective disorder, schizophreniform disorder, or bipolar disorder in a patient in need thereof who has been administered a first dose of a first paliperidone palmitate extended-release injectable suspension having a six month dosing interval ("PP6M") (first suspension), wherein the use comprises:

(1) a first re-initiation loading dose of about 234 mg paliperidone palmitate of a second paliperidone palmitate extended-release injectable suspension having a one month dosing interval ("PP1M") (second suspension) to be administered in the deltoid muscle of the patient at a time that is more than 11 months after administration of the first dose of the first suspension;

(2) a second re-initiation loading dose of about 156 mg paliperidone palmitate of the second suspension to be administered in the deltoid muscle of the patient on about day 8 (± 4 days) after administration of the first re-initiation loading dose of the second suspension;

(3) a first re-initiation maintenance dose of about 39 mg to about 234 mg paliperidone palmitate of the second suspension to be administered in the deltoid or gluteal muscle of the patient about 1 month (±7 days) after administration of the second re-initiation loading dose of the second suspension;

(4) a second re-initiation maintenance dose of from about 39 mg to about 234 mg paliperidone palmitate of the second suspension to be administered in the deltoid or gluteal muscle of the patient about 1 month (±7 days) after administration of the first re-initiation maintenance dose of the second suspension;

(5) a third re-initiation maintenance dose of from about 39 mg to about 234 mg paliperidone palmitate of the second suspension to be administrated in the deltoid or gluteal muscle of the patient about 1 month (±7 days) after administration of the second re-initiation maintenance dose of the second suspension; and

(6) from about 1092 mg to about 1560 mg paliperidone palmitate of a maintenance dose of the first suspension to be administered in the deltoid or gluteal muscle of the patient about 1 month (±7 days) after administration of the third re-initiation maintenance dose of the second suspension,

wherein there are no intervening doses of paliperidone palmitate between the first dose and the first re-initiation loading dose.

8. The use of claim 7, wherein the first dose of the first suspension comprises about 1092 mg paliperidone palmitate and the maintenance dose of the first suspension comprises about 1092 mg paliperidone palmitate.

9. The use of claim 7, wherein the first dose of the first suspension comprises about 1560 mg paliperidone palmitate and the maintenance dose of the first suspension comprises about 1560 mg paliperidone palmitate.

10. The use of any one of the preceding claims wherein the first dose of the first suspension and the maintenance dose of the first suspension is to be administered in the gluteal muscle.

11. The use of any one of the preceding claims, wherein the patient is in need of treatment for schizophrenia.

12. The use of any one of the preceding claims, wherein the first suspension comprises:
about 280 mg/mL to about 350 mg/mL of the paliperidone palmitate;
about 8 mg/mL to about 12 mg/mL of a wetting agent;
one or more buffering agents;
about 65 mg/mL to about 85 mg/mL of a suspending agent; and
water q.s. ad 100%.

13. The use of claim 12, wherein the first suspension is from about pH 6.0 to about pH 8.0.

14. The use of claim 12 or claim 13, wherein the one or more buffering agents comprise citric acid monohydrate, sodium dihydrogen phosphate monohydrate, disodium hydrogen phosphate anhydrous, or sodium hydroxide.

15. The use of claim 12, wherein the first suspension comprises:
about 312 mg/mL of paliperidone palmitate;
about 10 mg/mL of polysorbate 20; and
about 75 mg/mL of polyethylene glycol 4000.

16. The use of any one of the preceding claims, wherein the second suspension comprises:
about 140 mg/mL to about 180 mg/ml of the paliperidone palmitate;

about 8 mg/mL to about 16 mg/ml of a wetting agent;
one or more buffering agents;
about 20 mg/mL to about 40 mg/ml of a suspending agent; and
water q.s. ad 100%.

17. The use of claim 16, wherein the second suspension is from about pH 6.0 to about pH 8.0.

18. The use of claim 16 or claim 17, wherein the one or more buffering agents comprise citric acid monohydrate, sodium dihydrogen phosphate monohydrate, disodium hydrogen phosphate anhydrous, or sodium hydroxide.

19. The use of claim 16, wherein the second suspension comprises:
about 156 mg/mL of paliperidone palmitate;
about 12 mg/mL of polysorbate 20; and
about 30 mg/mL of polyethylene glycol 4000.