paliperidone (pa-li-per-i-done)

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Classification

Therapeutic: antipsychotics
Pharmacologic: benzisoxazoles

Pregnancy Category C

Indications

PO, IM: Acute and maintenance treatment of schizophrenia. PO: Acute treatment of schizoaffective disorder (as monotherapy or as adjunct to mood stabilizers and/or antidepressants).

Action

May act by antagonizing dopamine and serotonin in the CNS. Paliperidone is the active metabolite of risperidone.

Therapeutic Effects:

Decreased manifestations of schizophrenia. Decreased manifestations of schizoaffective disorder.

Pharmacokinetics

Absorption: 28% absorbed following oral administration; food inhibits absorption; slowly absorbed after IM administration (concentrations higher and more rapidly achieved with administration into deltoid muscle).

Distribution: Unknown.

Metabolism and Excretion: 59% excreted unchanged in urine; 32% excreted in urine as metabolites.

Half-life: 23 hr (PO); 25–49 days (IM).

TIME/ACTION PROFILE (blood levels)

ROUTE ONSET PEAK DURATION
PO unknown 24 hr 24 hr
IM unknown 13 days 1 mo

Contraindications/Precautions

Contraindicated in: Hypersensitivity to paliperidone or risperidone; Concurrent use of drugs known to cause QTc prolongation (including quinidine, procainamide, sotalol, amiodarone, chlorpromazine, disopyramide, metoprolol); History of con- genital QTc prolongation or other cardiac abnormalities; Bradycardia, hypokalemia, hypomagnesemia (↑ risk of QTc prolongation). Pre-existing severe GI narrowing (due to nature of tablet formulation). GG ↓ < 50 mL/min (for IM). Lactation: Discontinue drug or breastfeed.

Use Cautiously in: Patients with Parkinson’s disease or dementia with Lewy Bodies (↑ sensitivity to effects of antipsychotics); History of suicide attempts; Patients at risk for aspiration pneumonia; Concurrent use of drugs known to cause QTc prolongation include quinidine, procainamide, sotalol, amiodarone, chlorpromazine, thioridazine, moxifloxacin; History of congenital QTc prolongation or other cardiac abnormalities; Bradycardia, hypokalemia, hypomagnesemia (↑ risk of QTc prolongation); Pre-existing severe GI narrowing (due to nature of tablet formulation). Conditions which may ↑ body temperature (intensive exercise, exposure to extreme heat, concurrent use of antibiotics or of other drugs known to cause hyperthermia or risk of dehydration); ↓ GI motility (due to risk of GI obstruction); ↓ GI motility (due to risk of GI obstruction); ↓ GI motility (due to risk of GI obstruction); ↓ GI motility (due to risk of GI obstruction); ↓ GI motility (due to risk of GI obstruction).

Adverse Reactions/Side Effects

CNS: NEUROLEPTIC MALIGNANT SYNDROME, SUICIDAL THOUGHTS, drowsiness, extrapyramidal disorders (dose related), headache, insomnia, anxiety, confusion, dizziness, dysarthria, fatigue, syncope, tardive dyskinesia, weakness.

EENT: blurred vision.

Resp: dyspnea, cough.

CV: palpitations, tachycardia (dose related), bradycardia, orthostatic hypotension, QTc interval prolongation.

GI: abdominal pain, dry mouth, dyspepsia, nausea, swollen tongue.

GU: impotence, priapism.

Endo: amenorrhea, dyslipidemia, galactorrhea, gynecomastia, hyperglycemia, weight gain.

Hemat: agranulocytosis, leukopenia, neutropenia.

MS: back pain, dystonia (dose related).

Neuro: akathisia, dyskinesia, tremor (dose related).

Misc: fever.

Interactions

Drug-Drug: ↑ risk of CNS depression with other CNS depressants including alcohol, antihistamines, sedative/hypnotics, or opioid analgesics. May antagonize the effects of levodopa or other dopamine agonists. ↑ risk of orthostatic hypotension with antihypertensives, nitrates, or other agents that lower BP. Carbamazepine may ↓ levels/effects.

Other Effects:

- ♦ = Drug name
- ♣ = Genetic Implication
- OPT (organ); age-related effects may be significant. The following indicate most frequent. The following indicate most frequent. The following indicate most frequent. The following indicate most frequent. The following indicate most frequent.
Route/Dosage

**Schizophrenia**
- **PO (Adults):** 6 mg once daily; may titrate by 3 mg/day at intervals of at least 5 days (range 3–12 mg/day).
- **PO (Children 12–17 yr):** 3 mg once daily; may titrate by 3 mg/day at intervals of at least 5 days (not to exceed 6 mg if <51 kg or 12 mg if ≥51 kg).
- **IM (Adults):** 2.34 mg initially, then 1.56 mg one week later; continue with monthly maintenance dose of 0.78 mg (range 0.39–2.34 mg based on efficacy and/or tolerability).

**Renal Impairment**
- **PO (Adults):** CCr 50–79 mL/min—3 mg/day initially; dose may be ↑ to maximum of 6 mg/day; CCr 10–50 mL/min—1.5 mg/day initially; dose may be ↑ to maximum of 3 mg/day.
- **IM (Adults):** CCr 50–79 mL/min—1.17 mg initially, then 0.78 mg one week later; continue with monthly maintenance dose of 0.4 mg; CCr ≤50 mL/min—Contraindicated.

**Schizoaffective Disorder**
- **PO (Adults):** 6 mg/day; may titrate by 3 mg/day at intervals of at least 4 days (range 3–12 mg/day).
- **Renal Impairment**
  - **PO (Adults):** CCr 50–79 mL/min—3 mg/day initially; dose may be ↑ to maximum of 6 mg/day; CCr 10–50 mL/min—1.5 mg/day initially; dose may be ↑ to maximum of 3 mg/day.

**NURSING IMPLICATIONS**

- **Assessment**
  - Monitor patient's mental status (orientation, mood, behavior) before and periodically during therapy.
  - Monitor closely for notable changes in behavior that could indicate the emergence or worsening of suicidal thoughts or behavior, especially during early therapy. Restrict amount of drug available to patient.
  - Assess weight and BMI initially and throughout therapy.
  - Monitor BP (sitting, standing, lying down) and pulse before and periodically during therapy. May cause prolonged Q-T interval, tachycardia, and orthostatic hypotension.
  - Observe patient when administering medication to ensure that medication is actually swallowed and not hoarded or chewed.
  - Monitor patient for onset of extrapyramidal side effects (akathisia—restlessness; dystonia—muscle spasms and twisting motions; or pseudoparkinsonism—mask-like face, rigidity, tremors, drooling, shuffling gait, dysphagia). Report these symptoms; reduction of dose or discontinuation of medication may be necessary.
  - Monitor for tardive dyskinesia (involuntary rhythmic movement of mouth, face, and extremities). Reversibility may be irreversible.
  - Monitor for development of neuroleptic malignant syndrome (fever, respiratory distress, mydriasis, daunorubicin, hypertension, glycosuria, rigidity, tremors, shuffling gait, severe muscle aches). Discontinue paliperidone and notify health care professional immediately if these symptoms occur.
  - Monitor for symptoms related to hyperprolactinemia (menstrual abnormalities, galactorrhea, sexual dysfunction).
  - Lab Test Considerations: Monitor fasting blood glucose and cholesterol levels before and periodically during therapy.
  - Monitor serum prolactin prior to and periodically during therapy. May cause ↑ serum prolactin levels.
  - Monitor CBC frequently during initial months of therapy in patients with pre-existing or history of low WBC. May cause leukopenia, neutropenia, or agranulocytosis. Discontinue therapy if these occur.

**Potential Nursing Diagnoses**

- Risk for self-directed violence (Indications) (Adverse Reactions)
- Disturbed sensory perception (specify: visual, auditory, kinesthetic, gustatory, tactile, olfactory) (Indications)

**Implementation**

- **PO:** Administer once daily in the morning without regard to food. Tablets should be swallowed whole; do not crush, break, or chew.
- **IM:** Administer initial and second doses in deltoid using a 1 1/2-inch, 22 gauge needle for patients ≤90 kg (<200 lb) or 1-inch, 23 gauge needle for patients ≥90 kg (>200 lb). Monthly maintenance doses can be administered in either deltoid.
paliperidone

or gluteal sites. For gluteal injection, use 1 1/2-inch, 22 gauge needle regardless of patient weight. To avoid missed dose, may give second dose 4 days before or after the one-week timepoint. Monthly doses may be given up to 7 days before or after the monthly timepoint. After the second dose at 1 week, avoid injection within 1 wk of scheduled dose. If missed dose is within 1 wk of scheduled dose, administer 2nd dose of 156 mg as soon as possible. If a 1st dose of 117 mg is either delayed or gluteal injection is given, may give 1st dose at any time. Then return to normal monthly injections in either deltoid or gluteal muscle. If delayed more than 7 days since 1st injection, resume by administering 156 mg dose in deltoid as soon as possible, a second 156 mg dose in deltoid or gluteal in 5 wk, followed by monthly doses in deltoid or gluteal sites. For injection, administer using initial dosing schedule. During regular monthly dose schedule, if delayed since last injection, administer previously stabilized dose as soon as possible, then monthly. If 6 months since last injection, resume dose previously stabilized on, unless stabilized at 234 mg (then 1st two injections should be 156 mg). Administer 1 dose in deltoid as soon as possible, then another deltoid injection of same dose 1 week later, then resume regular monthly schedule. If delayed since last injection, administer using initial dosing schedule.

Patient/Family Teaching

- Instruct patient to take medication as directed. Advise patient that appearance of tablets in stool is normal and not of concern.
- Advise patient to notify health care professional if thoughts about suicide or dying, attempts to commit suicide; new or worse depression; new or worse anxiety; feeling very agitated or restless; panic attacks; trouble sleeping; new or worse irritability; acting aggressive; being angry or violent; acting on dangerous impulses; an extreme increase in activity and talking, other unusual changes in behavior or mood occur.
- Advise patient to seek medical treatment if和尚sleep, weight, or medical revaluation is needed for weight gain or decreased/decreased.
- Inform patient to notify health care professional promptly if delayed, fever, unusual bleeding or bruising, rash, ulcers, menstrual abnormalities, galactorrhea, or sexual dysfunction occur.
- Advise patient to notify health care professional of all prescription or OTC medications, vitamins, or herbal products being taken and to consult with health care professional before taking other medications and alcohol.
- Advise patient to seek medical treatment for weight gain or decreased/decreased.
- Instruct patient how to prevent or stop seizures.
- Advise patient to notify health care professional of medication regimen before treatment or surgery.
- Advise female patients to notify health care professional if pregnancy is planned or suspected, or if breast feeding or planning to breast feed.
- Emphasize the importance of routine follow-up exams to monitor side effects and continued participation in psychotherapy to improve coping skills.

Evaluation/Desired Outcomes

- Decrease in excited, manic behavior.
- Decrease in positive symptoms (delusions, hallucinations) of schizophrenia.
- Decrease in negative symptoms (social withdrawal, flat, blunted affect) of schizophrenia.

Why was this drug prescribed for your patient?