Palimax® ER

Paliperidone

Description

Palimax® ER is a preparation of Paliperidone which is an antipsychotic agent. Paliperidone is the major active metabolite of Risperidone. It is a centrally active dopamine D2 antagonist with predominant serotonergic 5-HT2A antagonistic activity. It is also active as an antagonist at α1, α2 adrenergic receptors and H1 histaminergic receptors.

Indications and usage

Palimax® ER is indicated for-

- Schizophrenia, including acute treatment and recurrence prevention
- Treatment of acute exacerbations of schizoaffective disorder as monotherapy and in combination with antidepressants or mood stabilizers (Lithium and Valproate)

Dosage & administration

Schizophrenia & schizoaffective disorder

Adult

The recommended dose of Paliperidone for the treatment of schizophrenia & Schizoaffective disorder is 6 mg once daily, administered in the morning. Initial dose titration is not required; adjusted if necessary in increments of 3 mg over at least 5 days; usual range 3-12 mg daily.

Adolescents (12-17 years of age)

The recommended starting dose of Paliperidone for the treatment of schizophrenia is 3 mg administered once daily. Initial dose titration is not required. Dose increases, if considered necessary, should be made only after clinical reassessment and should occur at increments of 3 mg/day at intervals of more than 5 days; usual range 3-12 mg daily.

Elderly

The recommended dosing for elderly patients with normal renal function is the same as for adolescent patients with normal renal function. As elderly patients may have diminished renal function, dose adjustments may be required according to their renal function status. For patients with moderate to severe renal impairment (creatinine clearance 10 mL/min to < 50 mL/min), the maximum recommended dose of Paliperidone is 3 mg once daily.

Renal Impairment

Dosing must be individualized according to the patient's renal function status. For patients with mild renal impairment (creatinine clearance > 50 mL/min to < 80 mL/min), the recommended initial dose of Paliperidone is 3 mg once daily. The dose may then be increased to a maximum of 6 mg once daily based on clinical response and tolerability. For patients with moderate to severe renal impairment (creatinine clearance > 10 mL/min to < 50 mL/min), the recommended initial dose of Paliperidone is 1.5 mg once daily, which may be increased to a maximum of 3 mg once daily after clinical reassessment. In patients with creatinine clearance below 10 mL/min, use of Paliperidone is not recommended in such patients.

Hepatic Impairment

For patients with mild to moderate hepatic impairment, (Child-Pugh Classification A and B), no dose adjustment is recommended.

Use in pregnancy and lactation

Pregnancy: Paliperidone is pregnancy category C. The safety of Paliperidone during pregnancy has not been established. It should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Lactation: Paliperidone is excreted in human breast milk. The known benefits of breastfeeding should be weighed against the unknown risks of infant exposure to Paliperidone.

Side effects
The most common side effects of Paliperidone are hypertension, anaphylactic reactions, respiratory disorders, epistaxis, appetite changes, sleep disorders, anxiety, depression, malaise, urinary disorders, arthralgia, myalgia, toothache, and edema.

Contraindications
Paliperidone is contraindicated in patients with a known hypersensitivity to either Paliperidone or Risperidone, or to any of the excipients in the Paliperidone formulation.

Precautions
Patients with schizoaffective disorder treated with Paliperidone should be carefully monitored for a potential switch from manic to depressive symptoms. Caution should be exercised when Paliperidone is prescribed in patients with known cardiovascular disease or family history of QT prolongation and in neuroleptic malignant syndrome, tardive dyskinesia, leukopenia, neutropenia, hyperglycemia and diabetes mellitus, dyslipidemia, weight gain, hyperprolactinaemia, seizures, conditions with decreased gastro-intestinal transit time, renal impairment, hepatic impairment, elderly patients with dementia and risk factors of stroke, parkinson's disease.

Drug interaction
Concomitant use of Paliperidone with oral Risperidone is not recommended as Paliperidone is the active metabolite of Risperidone. Caution is advised when prescribing Paliperidone with medicines known to prolong the QT interval e.g. quinidine, disopyramide, amiodarone, sotalol, mefloquine, anxiolytics, hypnotics and opiates. Paliperidone may antagonise the effect of levodopa and other dopamine agonists. Caution is advised if Paliperidone is combined with other medicines known to lower the seizure threshold (i.e. phenothiazines or butyrophenones, clozapine, tricyclics, SSRIs, tramadol and mefloquine).

Overdose
Overdose of Paliperidone is limited; there is no specific antidote to Paliperidone. If overdose occurs general supportive & symptomatic measures should be employed.

Pharmaceutical precautions
Store in a cool (below 25°C) and dry place. Protect from light. Keep out of the reach of children.

Presentation
Palimax® ER 1.5 tablet: Each extended release tablet contains Paliperidone INN 1.5 mg.
Palimax® ER 3 tablet: Each extended release tablet contains Paliperidone INN 3 mg.
Palimax® ER 6 tablet: Each extended release tablet contains Paliperidone INN 6 mg.

Package quantities
Palimax® ER 1.5 tablet: Carton of 50 tablets in blister pack.
Palimax® ER 3 tablet: Carton of 50 tablets in blister pack.
Palimax® ER 6 tablet: Carton of 30 tablets in blister pack.

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