Melev® 20

Tablet

Description

Melev 20 tablet contains Paroxetine Hydrochloride. Paroxetine is a potent selective serotonin reuptake inhibitor (SSRI). Paroxetine selectively inhibits neuronal reuptake of serotonin (5-Hydroxy Tryptamine, 5-HT) which potentiates serotonergic activity in the central nervous system, which appears to be associated with antidepressant activity. Studies at clinically relevant doses in humans have demonstrated that Paroxetine blocks the uptake of serotonin into human platelets. In vitro studies in animals also suggest that Paroxetine has only very weak effects on norepinephrine and dopamine neuronal reuptake.

Indications

Major depressive disorder, obsessive compulsive disorder, panic disorder, social anxiety disorder, generalised anxiety disorder & post-traumatic stress disorder.

Dosage and Administration

Major depressive disorder : Usual initial dose is one Melev 20 tablet as a single daily dose with or without food, usually in the morning. Some patients not responding to a 20 mg dose may benefit from dose increment, in 10 mg/day increment up to a maximum of 50 mg/day. Dose changes should occur at intervals of at least 1 week. *Maintenance therapy :* Efficacy of Paroxetine Hydrochloride is maintained for periods of up to 1 year with doses that averaged about 30 mg.

Obsessive compulsive disorder (OCD) : Usual initial dosage is 20 mg/day and the dose can be increased weekly in 10 mg/day increments. *Maintenance therapy :* Efficacy of Paroxetine Hydrochloride is maintained for periods of up to 1 year with doses that averaged about 30 mg.

Panic disorder : Usual initial dosage is one Melev 20 tablet as a single daily dose with or without food, usually in the morning. The target dose in the treatment of panic disorder is 40 mg/day. Patients should be started on 10 mg/day. Dose changes should occur in 10 mg/day increments and at intervals of at least 1 week. The maximum dosage should not exceed 60

mg/day. *Maintenance therapy :* Dosage adjustments should be made to maintain the patient on the lowest effective dosage and patients should be periodically reassessed to determine the need for continued treatment.

Social anxiety disorder (SAD) : Usual initial dose is one Melev 20 tablet as a single daily dose with or without food, usually in the morning. Dose may be increased after 2 weeks if necessary by increments of 10 mg at weekly intervals to a maximum of 50 mg daily.

Generalised anxiety disorder (GAD) : The recommended starting dosage and the established effective dosage is 20 mg/day.

Posttraumatic stress disorder (PTSD) : The recommended starting dosage and the established effective dosage is 20 mg/day. Dose changes, if indicated, should occur in 10 mg/day increments and at intervals of at least 1 week.

Dosage for elderly or debilitated patients and patients with severe renal or hepatic impairment : The recommended initial dose is 10 mg/day for elderly patients, debilitated patients and/or patients with severe renal or hepatic impairment. Increases may be made if indicated. Dosage should not exceed 40 mg/day.

Contraindications

Paroxetine is contraindicated in patients with hypersensitivity to Paroxetine. Concomitant use in patients taking either monoamine oxidase inhibitors (MAOIs) or Thioridazine is contraindicated.

Precautions

Cardiac conditions : Caution is advised when treating patients with cardiac conditions. *Epilepsy :* Paroxetine should be used with caution in patients with epilepsy (avoid if poorly controlled, discontinue if convulsions develop). *Seizures :* Overall the incidence of seizures is < 0.1% in patients treated with Paroxetine. Paroxetine should be discontinued in any patient who develops seizures after ECT. *History of mania :* Caution is advised when treating patient with mania.

Paroxetine may impair performance of skilled tasks (e.g., driving). Abrupt withdrawal of Proxetine should be avoided. Discontinuation of treatment should be gradual to reduce the risk of withdrawal symptoms (i.e., decrease in the daily dose by 10 mg/day at weekly intervals).

Drug Interactions

Food/Antacids : The absorption and pharmacokinetics of Paroxetine are not affected by food or antacids.

Tryptophan : An interaction between Paroxetine and Tryptophan may occur, resulting in a serotonin syndrome suggested by a combination of agitation, restlessness and gastrointestinal symptoms including diarrhoea.

Drug metabolising enzyme inducers/inhibitors : The metabolism and pharmacokinetics of Paroxetine may be affected by drugs, which induce or inhibit hepatic drug metabolising enzymes. When Paroxetine is to be co-administered with a known drug metabolising inhibitor, consideration should be given to using doses at the lower end of the range.

Alcohol : Although Paroxetine does not increase the impairment of mental and motor skill caused by alcohol, the concomitant use of Paroxetine and alcohol in depressed patients is not advised.

Haloperidol/Amylobarbitone/Oxazepam : Paroxetine does not increase the sedation and drowsiness associated with haloperidol, amylobarbitone or oxazepam when given in combination.

MAOIs : An interaction between Paroxetine and monoamine oxidase (MAO) inhibitors may occur. Treatment with Paroxetine should not be started until 2 weeks after stopping an MAOI.

Lithium : The concurrent administration of Paroxetine and Lithium should be undertaken with caution. Lithium levels should be monitored.

Phenytoin/Anticonvulsants : Co-administration of Paroxetine and Phenytoin is associated with an increased incidence of adverse experiences.

Warfarin : Preliminary data suggest that there may be a pharmacodynamic, interaction between Paroxetine and Warfarin, which may result in increased bleeding in the presence of unaltered prothrombin times. Paroxetine should therefore be administered with great caution to patients receiving oral anticoagulants.

Side Effects

Major depressive disorder : Asthenia, sweating, nausea, decreased appetite, somnolence, dizziness, insomnia, tremor, nervousness, ejaculatory disturbance and other male genital disorders. *Obsessive compulsive disorder:* Nausea, dry mouth, decreased appetite, constipation, dizziness, somnolence, tremor, sweating, impotence and abnormal ejaculation. *Panic disorder :* Asthenia, sweating, decreased appetite, decreased libido , tremor, abnormal ejaculation, female genital disorders and impotence. *Social anxiety disorder :* Sweating, nausea, dry mouth, constipation, decreased appetite, somnolence, tremor, decreased libido, yawn, abnormal ejaculation, female genital disorders and impotence. *Generalised anxiety disorder :* Asthenia, infection, constipation, decreased appetite, dry mouth, nausea, decreased libido, somnolence, tremor, sweating and abnormal ejaculation. *Post-traumatic stress disorder :* Asthenia, sweating nausea, dry mouth, diarrhoea, decreased appetite, somnolence, decreased libido, abnormal ejaculation, female genital disorders and impotence.

Use in Special Populations

Pregnancy : This drug should be used during pregnancy only if the potential benefit justifies the potential risk to the foetus.

Lactation : Like many other drugs Paroxetine is secreted in human milk and caution should be exercised when Paroxetine Hydrochloride is administered in a nursing mother.

Commercial Pack

Melev® 20 Tablet : Each box containing 30 tablets in 3x10's blister strips. Each tablet contains Paroxetine Hydrochloride USP equivalent to 20 mg Paroxetine.