Mirapro™

Mirtazapine USP

Composition

Mirapro™ 7.5 Tablet: Each film coated Tablet contains Mirtazapine USP 7.5 mg.

Mirapro™ 15 Tablet: Each film coated Tablet contains Mirtazapine USP 15 mg.

Pharmacology

The mechanism of action of Mirtazapine as with other drugs effective in the treatment of major depressive disorder, is unknown.

Evidence gathered in preclinical studies suggests that Mirtazapine enhances central noradrenergic and serotonergic activity. These studies have shown that Mirtazapine acts as an antagonist at central presynaptic α_2-adrenergic inhibitory autoreceptors and heteroreceptors, an action that is postulated to result in an increase in central noradrenergic and serotonergic activity.

Mirtazapine is a potent antagonist of 5-HT_2 and 5-HT_3 receptors. Mirtazapine has no significant affinity for the 5-HT_{1A} and 5-HT_{1B} receptors. Mirtazapine is a potent antagonist of histamine (H_1) receptors, a property that may explain its prominent sedative effects. Mirtazapine is a moderate peripheral α_1-adrenergic antagonist, a property that may explain the occasional orthostatic hypotension reported in association with its use. Mirtazapine is a moderate antagonist at muscarinic receptors, a property that may explain the relatively low incidence of anticholinergic side effects associated with its use.

Indications

Mirapro™ (Mirtazapine) Tablets are indicated for the treatment of major depressive disorder (MDD).

Dosage & Administration

The recommended starting dose for **Mirapro**™ is 15 mg/day, administered in a single dose, preferably in the evening prior to sleep. It is generally agreed that acute episodes of depression require several months or longer of sustained pharmacological therapy beyond response to the acute episode. Systematic evaluation of **Mirapro**™ has demonstrated that its efficacy in major depressive disorder is maintained for periods of up to 40 weeks following 8 to 12 weeks of initial treatment at a dose of 15 to 45 mg/day.

Contraindication

Hypersensitivity

Mirtazapine is contraindicated in patients with a known hypersensitivity to Mirtazapine or to any of the excipients.

Monoamine Oxidase Inhibitors

The concomitant use of Mirtazapine and a monoamine oxidase (MAO) inhibitor is contraindicated. Mirtazapine should not be used within 14 days of initiating or discontinuing therapy with a monoamine oxidase inhibitor (MAOI)

Side Effects

The most common side effects of Mirtazapine are dizziness, drowsiness, dry mouth, increased appetite, weight gain etc.

Precaution

Patients, their families, and their caregivers should be encouraged to be alert to the emergence of anxiety, agitation, panic attacks, insomnia, irritability, hostility, aggressiveness, impulsivity, akathisia (psychomotor restlessness), hypomania, mania, other unusual changes in behavior, worsening of depression, and suicidal ideation, especially early during antidepressant treatment and when the dose is adjusted up or down.

Patients who are to receive Mirtazapine should be warned about the risk of developing agranulocytosis. Mirtazapine may impair judgment, thinking, and particularly, motor skills, because of its prominent sedative effect. Clinically significant ALT (SGPT) elevations (≥ 3 times the upper limit of the normal range) may occur.

Pregnancy & lactation

Pregnancy Category-C. Patients should be advised to notify their physician if they become pregnant or intend to become pregnant during Mirtazapine therapy.

Patients should be advised to notify their physician if they are breastfeeding an infant.

Drug interaction

Mirtazapine has clinically significant drug-drug interactions with Monoamine Oxidase Inhibitors (MAOI) & other serotonergic drugs such as tryptophan, triptans, linezolid, serotonin reuptake inhibitors, venlafaxine, lithium, tramadol, or St. John's wort. Mirtazapine may interrupt the metabolism or activity of Carbamazepine, Phenytoin or Cimetidine. Patient should avoid Alcohol & Diazepam while taking Mirtazapine.

Storage

Keep away from light and moisture. Store below 30° C. Keep all medicine out of the reach of children.

How supplied

Mirapro™ 7.5 Tablet: Each box contains 30 Tablets in Alu-PVDC blister pack.

Mirapro™ 15 Tablet: Each box contains 30 Tablets in Alu-PVDC blister pack.

Manufactured by

SQUARE

PHARMACEUTICALS LTD.

BANGLADESH