Rapine®

Mirtazapine

Description

Rapine® is a preparation of Mirtazapine which is a centrally acting presynaptic alpha2-antagonist, which increases central noradrenergic and serotonergic neurotransmission. The enhancement of serotonergic neurotransmission is specially mediated via 5-HT1 receptors, because 5-HT2 and 5-HT3 receptors are blocked by Mirtazapine. Both enantiomers of Mirtazapine are presumed to contribute to the antidepressant activity, the S(+) enantiomer by blocking a2 and 5-HT2 receptors and the R(-) enantiomer by blocking 5-HT3 receptor.

Indications

Rapine® is indicated for the treatment of major depression.

Dosage and administration

Adults:

Initially 1-2 tablets (15–30 mg) daily at bedtime increased within 2–4 weeks according to response; max. 3 tablets (45 mg) daily as a single dose at bedtime or in 2 divided doses.

Children under 18 years: not recommended.

Use in pregnancy and lactation

There are no adequate and well-controlled studies in pregnant women and Mirtazapine should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers: It is recommended that women receiving Mirtazapine should not breast feed.

Side Effects

The common side effects of Mirtazapine are dry mouth, weight gain, somnolence, sedation, headache, increased appetite, nausea, vomiting, diarrhea, and fatigue. Less common side effects are paraesthesia, restless legs, syncope, hypotension, nightmares & agitation.

Precautions

Caution should be taken in patient of elderly, cardiac disorders, hypotension, history of urinary retention, susceptibility to angle-closure glaucoma, diabetes mellitus, psychoses, history of seizures or bipolar depression.

Reversible agranulocytosis has been reported as a rare occurrence in clinical studies with Mirtazapine. Agranulocytosis have been reported, mostly reversible, but in some cases fatal. Fatal cases mostly concerned patients with an age above 65. If symptoms like fever, sore throat, stomatitis or other signs of infection occur, treatment should be stopped and blood counts taken. Treatment should be discontinued if jaundice occurs. As with other antidepressant care should be taken in patient with

micturition disturbance like prostate hypertrophy, acute narrow angle glaucoma and increased intraocular pressure.

Contraindications

It is contraindicated in patients with known hypersensitivity to active ingredient or any component of the product.

Drug interaction

Mirtazapine may increase the CNS depressant effect of alcohol. It should not be concomitantly administered with MAO inhibitors or within two weeks of cessation of therapy with these agents. It may potentiate the sedative effects of benzodiazepines. Co-administration of the potent CYP3A4 inhibitor, ketoconazole increased the peak plasma levels and the AUC of Mirtazapine by approximately 40 % and 50 % respectively. Caution should be needed and dose may be decreased when strong CYP3A4 inhibitors, HIV protease inhibitors, azole antifungals, erythromycin and nefazodone are co-administered with Mirtazapine. Cimetidine co-administered with Mirtazapine, the mean plasma concentration of Mirtazapine may increase more than 50 %.

Overdose

Present experience concerning overdose with Mirtazapine alone indicates that symptoms are usually mild. Depressions of the central nervous system with disorientation and prolonged sedation have been reported, together with tachycardia and mild hypertension or hypotension. However, there is a possibility of more serious outcomes (including fatalities) at dosages much higher than the therapeutic dose, especially with mixed overdoses.

Pharmaceutical precautions

Store in a cool, dry place. Protect from light. Keep out reach of children

Presentation

Rapine® 15mg tablet: Each film coated tablet contains Mirtazapine BP 15 mg.

Package quantities

Rapine® 15mg tablet: Carton of 30 tablets per pack.

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ACI Limited