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MIRTAZAPINE

DEZINE 30®

30 mg uncoated orally disintegrating tablet
Antidepressant

PRODUCT DESCRIPTION:

Light blue, round, biconvex uncoated tablet with breakline scored on one side.

FORMULATION/COMPOSITION:

Each uncoated orally disintegrating tablet contains:
Mirtazapine USP.....30 mg

INDICATIONS:

Treatment of major depressive disorder.

DOSAGE AND ADMINSTRATION:

Adult dose: The recommended starting dose for Mirtazapine tablets is 15 mg/day, administered in a single dose, preferably in the evening or prior to sleep. The effective dose range was generally 15 to 45 mg/day and the patients not responding to the initial 15 mg dose may benefit from dose increases up to a 30 mg to maximum of 45 mg/day. Mirtazapine has an elimination half-life of approximately 20 to 40 hours; therefore, dose changes should be made at intervals of less than 1 to 2 weeks in order to allow sufficient time for the therapeutic response to a given dose.

Use in children: Use in children are not recommended to Mirtazapine.

Missed Dose: If anyone misses a dose of mirtazapine, take it as soon as remember unless it is close to when the next dose is due. If anyone missed a dose of medication and it is close to the time of next dose, skip the missed dose and should take next dose at the regularly scheduled time. One should not take double or more than prescribed dose.

CONTRAINDICATIONS:

Hypersensitivity to the active ingredient or any excipients

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.

SPECIAL WARNING AND PRECAUTIONS:

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 AND 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.

SIDE EFFECTS:

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

PHARMACOLOGICAL PROPERTIES:

Pharmacodynamic properties:
Pharmacotherapeutic group: antidepressants, selective serotonin reuptake inhibitor
ATC-code: N 06 AB 10

Mechanism of action
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 α2-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- HT2 and 5-HT3 receptors. Mirtazapine has no significant affinity for the 5-HT1A and 5-HT1B receptors. Mirtazapine is a potent antagonist of histamine (H1) receptors, a property that may explain its prominent sedative effects. Mirtazapine is a moderate peripheral α1-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.

Pharmacokinetic properties:

After oral administration of Mirtazapine tablets, the active constituent mirtazapine is rapidly and well-absorbed, reaching peak plasma levels after about 2 hours. Binding of mirtazapine to plasma proteins is approximately 85%. The mean half-life of elimination is 20-40 hours; (26 hours in males, 37 hours in females). The half-life of elimination is sufficient to justify once-a-day dosing. Mirtazapine displays linear pharmacokinetics within the recommended dose range. Mirtazapine is extensively metabolized and eliminated via the urine and faeces four days. Major pathways of biotransformation are demethylation and oxidation followed by conjugation.

STORAGE CONDITION:
Store at or below 25^{0}C

AVAILABILITY:
Alu-Alu blister pack x 10's (Box of 150's)

MANUFACTURED BY:
Quest Pharmaceuticals Pvt. Ltd.
Chhatapipara, Bara, Nepal

MARKETING AUTHORIZATION HOLDER:
Quest Pharmaceuticals Pvt. Ltd.
Daan Sadan, Teku, Kathmandu, Nepal