HCP-MEPPO
Publishers of MEPPO and MODERN MEDICINE
08-15

MIRZAGEN® F.C. Tablets 15 mg, 30 mg & 45 mg

RIYADH PHARMA

Suicidality in Children and Adolescents:

- Antidepressants increased the risk of suicidal thinking and behavior (suicidality) in short-term studies in children and adolescents with Major Depressive Disorder (MDD) and other psychiatric disorders. Anyone considering the use of mirtazapine or any other antidepressant in a child or adolescent must balance this risk with the clinical need. Patients who are started on therapy should be observed closely for clinical worsening, suicidality or unusual changes in behavior. Families and caregivers should be advised of the need for close observation and communication with the prescriber. Mirtazapine is not approved for use in paediatric patients.
- Pooled analysis of short-term (4 to 16 weeks) placebo-controlled trials of 9 antidepressant drugs (SSRIs and others) in children and adolescents with Major Depressive Disorder (MDD), Obsessive Compulsive Disorder (OCD) or other psychiatric disorders (a total of 24 trials involving over 4400 patients) have revealed a greater risk of adverse events representing suicidal thinking or behavior (suicidality) during the first few months of treatment in those receiving antidepressants. The average risk of such events in patients receiving antidepressants was 4%, twice the placebo risk of 2%. No suicides occurred in these trials.

COMPOSITION:

Tablets: Each film coated tablet contains Mirtazapine (USP) 15 mg, 30 mg or 45 mg.

Other ingredients: Lactose Anhydrous, Maize Starch, Colloidal Anhydrous Silica, Low Substituted HPC, Magnesium Stearate and coating material: (Opadry yellow for 15 mg), (Opadry Buff for 30 mg) and (Opadry White for 45 mg).

CLINICAL PHARMACOLOGY:

Mirtazapine is a tetracyclic antidepressant that works by it's central presynaptic alpha$_2$-adrenergic antagonist effects, which results in increased release of norepinephrine and serotonin. It is also a potent antagonist of 5-HT$_2$ and 5-HT$_3$ serotonin receptors and H$_1$ histamine receptors and a moderate peripheral alpha$_1$-adrenergic and a very little antimuscarinic activity.

INDICATIONS:

MIRZAGEN is indicated for the treatment of depression.

CONTRAINDICATIONS:

Hypersensitivity to mirtazapine or any component of the formulation.

Mirtazapine should not be used in combination with monoamine oxidase inhibitors (MAOI) or within 2 weeks of discontinuing MAOI.

PRECAUTIONS:

Caution should be taken in patients with epilepsy, hepatic and renal impairment.

Caution should be taken in patients with hypotension, diabetes mellitus, psychoses and in those with a history of bipolar disorder or urinary retention.

Use with caution in patients with cardiac disorders such as conduction disturbances, angina pectoris and recent myocardial infarction.

Caution should be exercised in patients with micturition disturbances, angle-closure glaucoma and raised intra-ocular pressure.

Patients should be advised to report any of the symptoms during treatment: fever, sore throat, stomatitis or other sign of infection, treatment should be stopped and blood count performed.

The incidence of sexual dysfunction with mirtazapine is generally lower than with SSRIs.

Mirtazapine should be withdrawn gradually to reduce the risk of withdrawal symptoms.

Safety and efficacy of mirtazapine in children has not been established.

ADVERSE REACTIONS:

Increased appetite and weight gain, oedema, sedation,

less commonly dizziness, headache, rarely postural hypotension, abnormal dreams, mania, convulsions, tremor, myoclonus, paraesthesia, arthralgia, myalgia, akathisia, rash and reversible agranulocytosis.

DRUG INTERACTIONS:
Use of mirtazapine with alcohol or benzodiazepines may potentiate sedative effects.

CYP1A2 inhibitors such as: amiodarone, ciprofloxacin, fluvoxamine, ketoconazole, norfloxacin, ofloxacin and rofecoxib may increase the effects of mirtazapine.

CYP2D6 inhibitors such as: chlorpromazine, delavirdine, fluoxetine, miconazole, paroxetine, pergolide, quinidine, quinine, ritonavir and ropinirole may increase the effects of mirtazapine.

CYP3A4 inhibitors such as: azole antifungals, clarithromycin, diclofenac, doxycycline, erythromycin, isoniazid and verapamil may increase the effects of mirtazapine.

CYP1A2 inducers such as: aminoglutethimide, carbamazepine, Phenobarbital and rifampin may decrease the effects of mirtazapine.

CYP3A4 inducers such as: nafcillin, phenytoin and rifamycin may decrease the effects of mirtazapine.

USE DURING PREGNANCY AND LACTATION:
Mirtazapine should be avoided during pregnancy.

Pregnancy factor C: (animal studies indicate a risk but there is no safety data in humans).

Mirtazapine present in milk of animal studies, so should be avoided during lactation.

DOSAGE:
Children & Adolescent: under 18 years not recommended.

Adults: in the treatment of depression, MIRZAGEN is given by mouth in an initial daily dose of 15 mg at bedtime increased within 2-4 weeks according to response. Maximum dose is 45 mg daily as a single dose at bedtime or in 2 divided doses.

Note: Mirtazapine should be withdrawn gradually to reduce the risk of withdrawal symptoms.

STORAGE:
Store at room temperature (15-25)°C.

Do not use the drug after the expiry date printed on the package.

PRESENTATION:
Tablets:

Packs contain (30) film coated tablets of MIRZAGEN 15 mg, 30 mg or 45 mg.

Hospital packs of MIRZAGEN 15 mg, 30 mg or 45 mg film coated tablets.