Depram F.C.Tablets
Citalopram Hydrobromide

COMPOSITION:
Each Depram 20 mg tablet contains: Citalopram hydrobromide 25 mg corresponding to 20 mg citalopram base.
Each Depram 40 mg tablet contains: Citalopram hydrobromide 50 mg corresponding to 40 mg citalopram base.

CLINICAL PHARMACOLOGY:
Citalopram is a potent inhibitor of serotonin re-uptake.
Citalopram is the most selective serotonin reuptake inhibitor. It has no or minimal noradrenaline (NA), dopamine (DA) and gamma amino butyric acid (GABA) inhibition.

PHARMACOKINETIC:
Absorption: Is almost complete and independent of food.
Distribution: The plasma protein binding is 80% of citalopram and its metabolites.
Elimination: Citalopram is excreted mainly via the liver (85%) and the kidney (15%).

INDICATIONS:
- Treatment of depression and prevention of relapse and recurrence.
- Panic attack.
- Obsessive compulsive disorder (OCD).

WARNINGS AND PRECAUTIONS:
- Patients with congestive heart failure, bradyarrhythmias, myocardial infarction or predisposition to hypokalemia or hypomagnesaemia because of concomitant illness or drugs, are at higher risk of developing Torsade de Pointes.
- Health care professionals should consider more frequent electrocardiogram (ECG) monitoring in patients with congestive heart failure, bradyarrhythmias.
- Hypokalemia and hypomagnesaemia should be corrected before administering citalopram. Electrolytes should be monitored as clinically indicated.
- Patients should contact a healthcare professional immediately if they experience signs and symptoms of an abnormal heart rate or rhythm while taking citalopram.
- Patients should be advised not to stop taking citalopram or change or reduce the dose without first consulting their health care professional, as withdrawal symptoms may occur when citalopram treatment is discontinued, particularly if this is abrupt.

DOSAGE AND ADMINISTRATION:
- Remove the dose recommendation of 60 mg per day. Citalopram should no longer be prescribed at doses greater than 40 mg per day.
- 20 mg per day is the maximum recommended dose for patients with hepatic impairment, who are greater than 60 years of age, who are CYP 2C19 poor metabolizers, or who are taking concomitant cimetidine (Tagamet®), because these drug factors lead to increased blood levels of citalopram, increasing the risk of QT interval prolongation and Torsade de Points.

Depression: Depram should be administered at initial dose of 20 mg once daily generally with an increase to a dose of 40 mg per day.
Dose increases should usually occur in increments of 20 mg at intervals of not less than one week.

Panic Disorder: Single oral dose 10 mg in the first week increased to 20 mg. May be increased to 40 mg daily.

OCD: An initial dose 20 mg may be increased to 40 mg daily.

Special population: 20 mg is the recommended dose for most of elderly patients and patients with hepatic impairment.

Renal patients: No dosage adjustment is required in mild or moderate renal impairment.

SIDE EFFECTS:
Mild and Transient: Headache - tremor - dry mouth - nausea - sweating - rash - diarrhea - vomiting - abdominal pain - dyspepsia.

DRUG-DRUG INTERACTION:
Monoamine Oxidase Inhibitors (MAOIs) non selective and selective: Treatment with citalopram must be instituted 14 days after discontinuation of non selective (MAOIs).

CONTRAINDICATIONS:
- Do not use citalopram with other medicinal products known to prolong the QT interval.
- Citalopram is contraindicated in patients with congenital long QT syndrome.
- Hypersensitivity to the drug or any of its components.
- Concomitant treatment with MAOIs.
- Pregnancy: Clinical experience of use in pregnancy is limited.
- Lactation: Excretion of citalopram into breast milk in minimum amount may produce risk to the child.

PACKAGE AND STORAGE:
Depram 20 mg: Pack of 20 F.C. tablets.
Depram 40 mg: Pack of 10 F.C. tablets.
Store at temperature not exceeding 30 °C.

Keep All Medicines Out of Reach of Children

Manufactured by: Apex Pharma - S.A.E - Badr City- Egypt.
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