PROXETIN®
20 mg Capsules

Dear patient,
Please read the following instructions carefully. They contain important information about the use of this medicine. If you have any further questions, please ask your doctor or pharmacist.

Information about PROXETIN
Each PROXETIN capsule for oral administration contains fluoxetine hydrochloride equivalent to 20 mg fluoxetine.
Fluoxetine is a selective serotonin reuptake inhibitor (SSRI).
PROXETIN is indicated in the following conditions:
- Treatment of major depressive disorder in adults and pediatric patients (8 years of age and over)
- Treatment of obsessions and compulsions in adults and pediatric patients (7 years of age and older) with obsessive-compulsive disorder
- Treatment of panic disorder in adults, with or without agoraphobia
- Treatment of bulimia nervosa
- Treatment of premenstrual dysphoric disorder in adults: PROXETIN produces beneficial effects in controlling both the psychological and somatic symptoms of women with premenstrual syndrome

The way to take PROXETIN
Take PROXETIN as directed by your physician. Do not discontinue the treatment without consulting your doctor.
Dosage and duration of treatment are individualized and adjusted according to the condition under treatment and the response obtained.
The usual recommended doses are:

Indication	**Adult dose**	**Pediatric dose**
Major depressive Disorder	The usual initial dose is 20 mg (1 capsule) once daily in the morning. A gradual dose increase may be considered after several weeks if insufficient clinical improvement is observed, up to a maximum of 80 mg daily. Doses above 20 mg daily may be given in 2 divided doses, for example in the morning and at noon, or as a once daily dose.	The usual initial recommended dose is 10 or 20 mg per day. After one week at 10mg per day, the dose should be increased to 20mg per day
Obsessive Compulsive disorder	The usual initial dose is 20 mg (1 capsule) once daily in the morning. A dose increase may be considered after several weeks if insufficient clinical improvement is observed. A dose range of 20 to 60 mg/day is recommended. The maximum dose is 80 mg/day. Doses above 20 mg/day may be administered on a once-a-day or twice-a-day schedule (for example morning and noon)	The starting dose is 10 mg daily; - In low-weight children the dose is increased after several weeks to 20 to 30 mg daily, if required. - Adolescents and higher-weight children may be increased to 20 mg daily after 2 weeks; further increases to 60 mg daily may be made after several weeks, as necessary.
Panic disorder	The usual initial dose is 10 mg once	-

	daily. After a week the dose should be increased to 20 mg (1 capsule) daily; further increases to 60 mg daily may be considered after several weeks if no improvement is seen.	
Bulimia nervosa	60 mg (3 capsules of 20 mg) once daily in the morning	-
Premenstrual dysphoric disorder	The usual recommended dose is 20 mg (1 capsule) daily. Intermittent dosing is also permitted: for each new cycle, fluoxetine should be started 14 days before the onset of menstruation and continued until the first full day of menstruation. Treatment may be continued for 6 months; benefit should then be reassessed before continuing further.	-

A lower or less frequent dosage is recommended in elderly patients and in case of liver impairment.

Duration of treatment

Duration of treatment is determined according to the disease under treatment.

As with other drugs effective in the treatment of depression, the full effect may be delayed until 4 weeks of treatment or longer.

Acute episodes of psychiatric disorders require several months or longer of sustained therapy beyond response to initial treatment.

Patients should be periodically reassessed to determine the need for maintenance treatment.

In case of overdose

In case of intake of high doses of this medication, inform your doctor at once and seek emergency medical attention. General measures should be adopted.

In case of missed dose

If you miss a dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

Contraindications

This drug is contraindicated in case of:

- History of hypersensitivity to any of the components
- Concomitant use with monoamine oxidase inhibitors (MAOIs)
- Thioridazine

Precautions

- Antidepressants are associated with an increased risk of potentially suicidal thinking and behavior when used for the treatment of psychiatric disorders in children and adolescents. All pediatric patients being treated with antidepressants should be observed closely for unusual changes in behavior.
- The possibility of a suicide attempt is inherent in major depressive disorder and may persist until significant remission occurs. Close supervision of high-risk patients should accompany initial drug therapy until significant improvement in depression is observed.
- This drug should be used with care in patients with a seizure disorder, diabetes, liver or renal disease.
- Do not stop taking this medicine without first checking with your doctor. He may want you to reduce gradually the amount you are taking before stopping completely. Antidepressants should be withdrawn gradually to reduce the risk of withdrawal symptoms.
- The doctor should be informed in case of emergence of anxiety, agitation, panic attacks, insomnia, irritability, hostility, aggressiveness or other unusual changes in the patient's behavior.

- Caution should be taken when driving a car or operating dangerous machinery until you are reasonably certain that your performance is not affected.
- Consult your doctor before using this medication in case of pregnancy or lactation. This drug should be used during pregnancy only if clearly needed. Nursing is not recommended during treatment with this drug.

Associations with other medications

Please inform your doctor if other medicines are being taken or have been taken recently.
This drug should not be used in combination with a MAOI, or within 14 days of discontinuing treatment with a MAOI.
Thioridazine should not be administered with fluoxetine or within a minimum of 5 weeks after fluoxetine has been discontinued
Caution should be used when administered concomitantly with NSAIDs, aspirin, oral anticoagulants or other drugs that affect coagulation.
Use with caution with sumatriptan, flecainide, digitoxin, tryptophan, methadone, phenytoin, carbamazepine, diazepam, alprazolam, pimozide, lithium, haloperidol, clozapine, tricyclic antidepressants, and other central nervous system active drugs.

Adverse reactions

The most reported adverse reactions include, headache, insomnia, anxiety, nervousness, altered appetite, nausea, vomiting, tremor, diarrhea, dyspepsia, dry mouth, dizziness, fatigue, and somnolence.
Rarely reported adverse reactions include hyponatremia, weight modification, abnormal ejaculation, increased sweating, rash, pruritus, activation of mania, and convulsions.
Inform your doctor if any side effect appears or becomes bothersome.

Storage

Store at controlled room temperature (up to 30°C), protected from light and humidity, beyond the reach of children.
The expiry date is printed on the pack; don’t use this medicine after this date.

Pack Presentation

PROXETIN, fluoxetine 20 mg, pack of 14 capsules

Revision date: 01/2010
PROC2/005