

## DEPROX® Tablets

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 DEPROX

DEPROX is available in 20 mg and 40 mg tablet for oral administration containing respectively paroxetine hydrochloride equivalent to 20 mg paroxetine and 40 mg paroxetine. Other ingredients are: dibasic calcium phosphate, sodium starch glycolate, magnesium stearate

Paroxetine is antidepressant (SSRI); its action is related to specific and potent inhibition of serotonin re-uptake in the brain neurons.

DEPROX is indicated in the treatment of the following conditions:

- Major depressive disorder
- Obsessions and compulsions in patients with obsessive-compulsive disorder (OCD)
- Panic disorder, with or without agoraphobia
- Social anxiety disorder (also known as social phobia)
- Generalized anxiety disorder (GAD)
- Posttraumatic stress disorder (PTSD)

### The way to take DEPROX

Take DEPROX 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.

DEPROX is given as a single dose in the morning with or without food.

The usual recommended doses are:

Indication	Adult dose
Major depressive Disorder	The recommended initial dose is 20mg daily; the dose range is 20 to 50 mg/day.
Obsessive-Compulsive disorder	The recommended dose is 40 mg daily; Patients should be started on 20 mg/day and the dose can be increased in 10-mg/day increments and at intervals of at least 1 week to the maximum dosage of 60 mg/day
Panic disorder	The target dose is 40 mg daily; Patients should be started on 10 mg/day and the dose can be increased in 10-mg/day increments and at intervals of at least 1 week to the maximum dosage of 60 mg/day
Social anxiety disorder	The recommended initial dose is 20mg daily; the dose range is 20 to 60 mg/day.
Generalized anxiety disorder	The recommended initial dose is 20mg daily; the dose range is 20 to 50 mg/day
Posttraumatic stress disorder	The recommended initial dose is 20mg daily; the dose range is 20 to 50 mg/day

Dose changes, if indicated, should occur in 10 mg/day increments and at intervals of at least 1 week to the maximum recommended dose.

In elderly and patients with severe renal or hepatic impairment, the recommended initial dose is 10mg daily; dosage should not exceed 40 mg/day.

### Duration of treatment

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

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 continued 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)
- Concomitant use with pimozide and thioridazine

**Precautions**

-Depression and certain other psychiatric disorders are themselves associated with increases in the risk of suicide. All patients being treated with antidepressants for any indication should be monitored appropriately and observed closely for clinical worsening, suicidality and unusual changes in behavior, especially during the initial few months of a course of drug therapy, or at times of dose changes, either increases or decreases.

-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.

-This drug should be used with caution in patients with a history of epilepsy, in patients with a history of bleeding disorders or with hypomania or mania.

-Do not stop taking this medicine without first checking with your doctor. Antidepressants should be withdrawn gradually to reduce the risk of withdrawal symptoms.

-This drug should be used with caution in patients with hepatic or renal impairment; dosage adjustment may be necessary.

-Caution should be taken when driving a car or operating dangerous machinery until you know how you respond to the drug.

-Inform your doctor before using this medication in case of pregnancy or lactation. This drug should be used during pregnancy only when strictly indicated. This drug should not be used in nursing mothers.

**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.

The concomitant use of this drug and alcohol and tryptophan is not recommended.

The concomitant use with pimozide and thioridazine is contra-indicated.

Caution should be used when administered concomitantly with NSAIDs, aspirin, oral anticoagulants or other drugs that affect coagulation, cimetidine, digoxin, theophylline, anti-epileptic drugs, lithium, tricyclic antidepressants, triptans, tramadol, or other serotonergic agents and central nervous system drugs.

**Adverse reactions**

The most reported adverse reactions include asthenia, sweating, nausea, decreased appetite, dry mouth, constipation, somnolence, dizziness, insomnia, tremor, nervousness, ejaculatory disturbance and genital disorders

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**

DEPROX 20, Paroxetine 20 mg, pack of 30 tablets

DEPROX 40, Paroxetine 40 mg, pack of 30 tablets

**Issue date: 04/2011**

DEOT2/001