

PATIENT INFORMATION LEAFLET

Paroxetine 12.5/ 25/ 37.5 mg Extended-Release Tablets

DEPNOX ER 12.5/25/37.5

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

1. What DEPNOX ER is and what it is used for
2. What you need to know before you take DEPNOX ER
3. How to take DEPNOX ER
4. Possible side effects
5. How to store DEPNOX ER
6. Contents of the pack and other information

1. What DEPNOX ER is and what it is used for

DEPNOX ER contain active ingredient called Paroxetine (as Paroxetine Hydrochloride Hemihydrate) which belongs to a group of medicines called Selective Serotonin Re-uptake Inhibitors (SSRIs). Paroxetine Tablets are used in adults to treat:

- ❖ Major Depression
- ❖ Obsessive Compulsive Disorder
- ❖ Panic Disorder with or without Agoraphobia (Fear of open spaces or new situations)
- ❖ Social Anxiety Disorders/Social Phobias
- ❖ Anxiety after Traumatic Experience (Post-Traumatic Stress Disorder)
- ❖ Generalised Anxiety Disorder.

How DEPNOX ER works

Low levels of the hormone called serotonin are thought to be a cause of depression and other related conditions. Paroxetine work by inhibiting the reuptake of serotonin, thereby increasing serotonin activity.

2. What you need to know before you take DEPNOX ER

Do not take DEPNOX ER if:

- ❖ If you are allergic to Paroxetine
- ❖ If you are taking medicines called monoamine oxidase inhibitors (MAOIs, including moclobemide, linezolid and methylthionium chloride (methylene blue)), or have taken them at any time within the last two weeks. Your doctor will advise you how you should begin taking Paroxetine once you have stopped taking the MAOI.
- ❖ If you are taking anti-psychotic medicines called thioridazine or pimozide.

Do not take Paroxetine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Paroxetine.

Warnings and precautions

Talk to your doctor or pharmacist before taking Paroxetine:

- ❖ If you are taking tamoxifen to treat breast cancer or fertility problems. Paroxetine may make tamoxifen less effective, so your doctor may recommend you take another antidepressant.
- ❖ If you are taking any other medicines. If you have kidney, liver or heart trouble.
- ❖ If you have an abnormality of your heart tracing after an electrocardiogram (ECG) known as prolonged QT interval.
- ❖ If you have a family history of QT prolongation, heart disease such as heart failure, low heart rate, or low potassium levels or low magnesium levels.
- ❖ If you have epilepsy or have a history of fits or seizures.
- ❖ If you have ever had episodes of mania (overactive behaviour or thoughts).
- ❖ If you are having electro-convulsive therapy (ECT).
- ❖ If you have a history of bleeding disorders, or you are taking other medicines that

may increase the risk of bleeding (these include medicines used to thin the blood, such as warfarin, anti-psychotics such as perphenazine or clozapine, tricyclic antidepressants, medicines used for pain and inflammation called non-steroidal anti-inflammatory drugs or NSAIDs, such as acetylsalicylic acid, ibuprofen, celecoxib, etodolac, diclofenac, meloxicam).

- ❖ If you have diabetes.
- ❖ If you are on a low sodium diet.
- ❖ If you have glaucoma (pressure in the eye).
- ❖ If you are pregnant or planning to get pregnant
- ❖ If you are under 18 years old

If you answer YES to any of these questions, and you have not already discussed them with your doctor, go back to your doctor and ask what to do about taking Paroxetine. Medicines like Paroxetine Tablets (so called SSRIs) may cause symptoms of sexual dysfunction (see section 4). In some cases, these symptoms have continued after stopping treatment.

Children and adolescents

DEPNOX ER should not be used for children and adolescents under 18 years. Patients under 18 have an increased risk of side-effects such as suicide attempt, suicidal thoughts and hostility (predominantly aggression, oppositional behaviour and anger) when they take this class of medicines.

Pregnancy and Breast-feeding

If you are pregnant or breast-feeding, think you might be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. Paroxetine is not recommended during pregnancy as it may cause harm to the baby. Your doctor may decide that it is better for you to change to another treatment or to gradually stop taking paroxetine while you are pregnant. When taken during pregnancy, particularly in the last 3 months of pregnancy, medicines like Paroxetine may increase the risk of a serious condition in babies, called persistent pulmonary hypertension of the newborn (PPHN), making the baby breathe faster and appear bluish. These symptoms usually begin during the first 24 hours after the baby is born. If this happens to your baby you should contact your doctor immediately. Paroxetine may pass into breast milk in very small amounts. If you are taking Paroxetine, talk to your doctor before you start breast-feeding

DEPNOX ER with food, drink and alcohol

Do not drink alcohol while you are taking Paroxetine. Alcohol may make your symptoms or side effects worse. Taking Paroxetine in the morning with food will reduce the likelihood of you feeling sick (nausea).

Driving and using machines

DEPNOX ER may cause dizziness, confusion or changes in eyesight. If you are affected by these side effects, do not drive or use machinery.

3. How to take DEPNOX ER

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Take your tablets in the morning with food. Do not chew the tablets but swallow them whole with a glass of water.

How much to take

The amount of DEPNOX ER that you will take varies depending on your condition and your doctor will advise you what dose to take when you first start taking DEPNOX ER Tablets.

Recommended starting and maximum daily dosage:

Indication	Starting Dose	Maximum Dose
MDD	25 mg/day	62.5 mg/day
PD	12.5 mg/day	75 mg/day
SAD	12.5 mg/day	37.5 mg/day
MDD	12.5 mg/day	25 mg/day

If you take more DEPNOX ER than you should

If you take more DEPNOX ER tablets than you should have, you may experience the following symptoms such as being sick, widening of the pupils, fever, headache,

uncontrollable tightening of the muscles and increase in heart rate. If this happens to you, tell your doctor or go to a hospital straight away.

If you forget to take DEPNOX ER

Take your medicine at the same time every day.

If you miss a dose, take it as soon as you remember. If you do not remember until it is time for your next dose, skip the missed dose and go back to your regular schedule. Do not take a double dose of DEPNOX ER to make up for a forgotten dose. Never take two doses at the same time.

If you stop taking DEPNOX ER

Keep taking DEPNOX ER until your doctor tells you to stop. When stopping DEPNOX ER, your doctor will help you to reduce your dose

4. What are the possible side effects of DEPNOX ER

Like all prescription medicines, DEPNOX ER may cause side effects. Tell your doctor if you notice or have any of the following:

Uncommon (may affect up to 1 in 100 people): Unusual bruising or bleeding, including vomiting blood or passing blood in your stools, being unable to pass water.

Rare (may affect up to 1 in 1000 people): Seizures (fits), restlessness or you may have a serious condition called akathisia.

Very rare (may affect up to 1 in 10,000 people): Allergic reactions which may be severe (red and lumpy skin rash, swelling of eyelids, face, lips, mouth or tongue, have difficulty breathing or swallowing and feel weak or lightheaded resulting in collapse or loss of consciousness), skin rash which may be blister and looks like small targets (central dark spots surrounded by a paler area, with a dark ring around the edge) called erythema multiforme, a widespread rash with blisters and skin peeling, particularly around the mouth, nose, eyes and genitals (Stevens- Johnson Syndrome), syndrome of inappropriate antidiuretic hormone production (SIADH) which is a condition in which the body develops an excess of water and a decrease in sodium (salt) concentration, as a result of improper chemical signals. Patients with SIADH may become severely ill or may have no symptoms at all.

Other possible side effects during treatment

Very common (may affect more than 1 in 10 people): Feeling sick (nausea), taking your medicine in the morning with food will reduce the chance of this happening. Change in sex drive or sexual function (lack of orgasm, abnormal erection and ejaculation).

Common (may affect up to 1 in 10 people): Increases in the level of cholesterol in the blood, lack of appetite, not sleeping well (insomnia) or feeling sleepy, abnormal dreams (including nightmares), feeling dizzy or shaky (tremors), headache, difficulty in concentration, feeling agitated, feeling unusually weak, blurred vision, yawning, dry mouth, diarrhoea or constipation, vomiting, weight gain.

Uncommon (may affect up to 1 in 100 people): A brief increase in blood pressure, or a brief decrease that may make you feel dizzy or faint when you stand up suddenly, a faster than normal heartbeat, lack of movement, stiffness, shaking or abnormal movements in the mouth and tongue, dilated pupils, skin rashes, feeling confused, having hallucinations (strange visions or sounds), an inability to urinate (urinary retention) or an uncontrollable, involuntary passing of urine (urinary incontinence). If you are a diabetic patient you may notice a loss of control of your blood sugar levels while taking DEPNOX ER. Please speak to your doctor about adjusting the dosage of your insulin or diabetes medications.

Rare (may affect up to 1 in 1000 people): Abnormal production of breast milk in men and women, a slow heartbeat, Effects on the liver showing up in blood tests of your liver function, Panic attacks, overactive behaviour or thoughts (mania), feeling

detached from yourself (depersonalisation), feeling anxious, Irresistible urge to move the legs (Restless Legs Syndrome), Pain in the joints or muscles.

Very rare (may affect up to 1 in 10,000 people): Fluid or water retention which may cause swelling of the arms or legs, painful erection of the penis that won't go away, unexpected bleeding, e.g bleeding gums, blood in urine or in vomit, or the appearance of unexpected bruises or broken blood vessels (broken veins).

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

5. How to store DEPNOX ER

Keep this medicine out of the sight and reach of children. Do not use this medicine after the expiry date which is stated on the blister and carton after EXP.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

The expiry date refers to the last day of that month.

Store this medicine below 25 °C.

6. Contents of the pack and other information

What DEPNOX ER contains

The active substance is Paroxetine.

DEPNOX ER 12.5

Each enteric coated extended-release tablet contains: Paroxetine Hydrochloride Hemihydrate USP equivalent to Paroxetine 12.5 mg
Colours: Titanium Dioxide

DEPNOX ER 25

Each enteric coated extended-release tablet contains: Paroxetine Hydrochloride Hemihydrate USP equivalent to Paroxetine 25 mg
Colours: Titanium Dioxide

DEPNOX ER 37.5

Each enteric coated extended-release tablet contains: Paroxetine Hydrochloride Hemihydrate USP equivalent to Paroxetine 37.5 mg
Colours: Iron Oxide Yellow & Titanium Dioxide

What DEPNOX ER looks like and contents of the pack

DEPNOX ER 12.5 Tablets are White, Round, Biconvex and Enteric coated extended-release tablets. Tablets are packed into Strip. The pack size is 10 x 10 packed in a printed paper carton.

DEPNOX ER 25 Tablets are White, Round, Biconvex and Enteric coated extended-release tablets. Tablets are packed into Strip. The pack size is 10 x 10 packed in a printed paper carton.

DEPNOX ER 37.5 Tablets are Light yellow, Round, Biconvex and Enteric coated extended-release tablets. Tablets are packed into Strip. The pack size is 10 x 10 packed in a printed paper carton.



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