

APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S5

PROPRIETARY NAMES AND DOSAGE FORM:

XANOR[®] 0,25 mg tablet

XANOR[®] 0,5 mg tablet

XANOR[®] 1,0 mg tablet

XANOR[®] 2,0 mg tablet

XANOR[®] SR 0,5 mg tablet

XANOR[®] SR 1,0 mg tablet

XANOR[®] SR 2,0 mg tablet

Read this leaflet carefully before you start taking XANOR:

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- XANOR has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

1. WHAT XANOR CONTAINS

The active ingredient of XANOR is alprazolam.

XANOR contains the following inactive ingredients:

XANOR tablets: Colloidal silicon dioxide, docusate sodium with sodium benzoate, lactose hydrous, magnesium stearate, microcrystalline cellulose and starch with erythrosine sodium or FD and C blue as colourants.

XANOR SR tablets: Cellulose methylhydroxypropyl, lactose anhydrous, magnesium stearate, and silicon colloidal dioxide with FD & C blue as colourant.

2. WHAT XANOR IS USED FOR

XANOR belongs to a group of medicines known as benzodiazepines. It is used in the treatment of anxiety, certain types of depression and panic disorders.

3. BEFORE YOU TAKE XANOR

Do not take XANOR if you:

have ever had any unusual or allergic reaction to alprazolam or to any of the ingredients of XANOR or other similar medications. Also tell your doctor if you are allergic to any other substances such as foods, preservatives or dyes.

- are pregnant, trying to become pregnant or breastfeeding. Your baby may become dependent on this medicine or experience breathing problems, difficulty in feeding, body temperature problems or muscle weakness. Breastfed babies may become drowsy as XANOR may pass into the breast milk.
- suffer from schizophrenia
- are using ketoconazole

Take special care with XANOR:

- if you suffer from kidney or liver disease – this may increase the chances of experiencing side effects with XANOR
- if you have a serious condition affecting your breathing
- if you have a history of alcohol abuse
- when used in children under 18 years as these patients are more sensitive than adults to the effects of XANOR
- if you have a history of drug abuse or dependence – dependence on XANOR may occur
- if you have epilepsy or a history of seizures – the risk of seizures may be increased when starting or suddenly stopping XANOR treatment
- when stopping your XANOR medication too quickly or abruptly – you may experience withdrawal symptoms like inability to sleep, stomach or muscle cramps, vomiting, sweating, convulsions/seizures.
- if you have severe mental illness
- if you suffer from depression unless there is some anxiety with the depression

Pregnancy and Breastfeeding:

Your doctor will decide if XANOR is appropriate for you.

If you are pregnant or breastfeeding your baby while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

Important information about some of the ingredients of XANOR:

Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

Driving and using machinery:

XANOR may cause drowsiness or dizziness. If you feel drowsy, do not drive or do anything that requires you to be alert.

Taking other medicines with XANOR:

Imipramine and desipramine: XANOR may increase the levels of these medicines in the body if taken together

- Do not take XANOR with ketoconazole, itraconazole or other azole antifungal medicines (used to treat fungal infections)
- It is recommended that the dose of XANOR be decreased when given with nefazodone, fluvoxamine or cimetidine – higher blood levels of XANOR may occur and this can lead to more side effects. Your doctor may want to change the dose of XANOR or give you a different medicine.
- Caution is recommended when XANOR is given with any of the following medicines: fluoxetine, oral contraceptives (birth control pill), sertraline, diltiazem or macrolide antibiotics (e.g. erythromycin)

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of XANOR with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.

4. HOW TO TAKE XANOR

Always take XANOR exactly as your doctor has instructed you. Your doctor will decide what dose is right for you. Check with your doctor or pharmacist if you are unsure.

The usual dose of XANOR varies from one person to another. In patients who require higher doses, your doctor will choose the right dose for you.

XANOR tablets:

A. For anxiety:

The usual starting dose is 0,25 mg to 0,5 mg taken three times a day. Your doctor may increase your dose if needed. However, the dose usually is not more than 4 mg a day.

B. For mixed anxiety/depression:

The usual starting dose is 0,5 mg taken three times a day. Your doctor may increase your dose if needed. However, the dose usually is not more than 4,5 mg a day.

C. For panic disorders:

The usual starting dose is 0,5 mg to 1,0 mg given at bedtime or 0,5 mg taken three times a day. Your doctor may increase your dose if needed. However, the dose usually is not more than 10 mg a day.

D. For elderly patients:

The usual starting dose is 0,25 mg taken two or three times a day. Your doctor may increase your dose if needed. However, the dose usually is not more than 0,75 mg a day.

XANOR SR tablets:

The tablets should be taken intact; they should not be chewed, crushed or broken.

A. For anxiety or mixed anxiety/depression:

The usual starting dose is 1 mg daily in one or two doses. Your doctor may increase your dose if needed. However, the dose usually is not more than 4 mg a day.

B. For panic disorders:

The usual starting dose is 0,5 mg to 1,0 mg given at bedtime or 0,5 mg taken two times a day. Your doctor may increase your dose if needed. However, the dose usually is not more than 10 mg a day.

C. For elderly patients:

The usual starting dose is 0,5 mg to 1,0 mg taken one or two times a day. Your doctor may increase your dose if needed. However, the dose usually is not more than 1 mg a day.

Do not alter the dose yourself without your doctor's advice. Do not stop taking XANOR unless told to do so by your doctor. Should you need to stop taking XANOR, your doctor will have decided the best method for you.

If you take more XANOR than you should:

If you take more XANOR than you should, it can become habit-forming (causing mental or physical dependence). Call your doctor immediately. If you cannot call your doctor go to the nearest hospital or poison control centre at once. Always take the labelled medicine package with you, whether there are any XANOR left or not.

These are the possible signs and symptoms of over dosage: slurred speech or confusion, severe drowsiness, staggering or walking unsteadily, difficulty breathing or coma.

If you forget to take XANOR:

If you forget to take a dose, take it as soon as you remember. Then take any remaining doses for that day at regular spaced intervals. **Do not take two doses at the same time.** If you forget to take your medicine for more than one week, call your doctor before taking any more medicine.

5. POSSIBLE SIDE EFFECTS

XANOR can have side effects. Some side effects of XANOR include the following and should also be discussed with your doctor if they occur:

Frequency unknown: peripheral oedema (swelling of hands and feet due to the retained fluids) and angioedema (swelling beneath the skin).

Frequent: anorexia (lack or loss of appetite for food), confusion (more common in the elderly), depression, irritability, changes in sexual desire, dizziness, headache, lack of memory, blurred vision (not seeing clearly), constipation, nausea, feeling tired, dry mouth.

Less frequent: aggressive behaviour, insomnia (inability to sleep), mood changes, nervousness, amnesia (lack of memory), tremor (shakiness), diarrhoea, vomiting, muscle twitching or weakness, changes in menstrual period, changes in weight.

Less frequent: hallucinations (seeing, hearing or feeling things that are not there), agitation, rage (uncontrolled anger), slurred speech, itching.

Not all side effects reported for XANOR are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice. If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

6. STORING AND DISPOSING OF XANOR TABLETS

Store at or below 30 °C. Keep tablets packed in bottles tightly closed.

Keep all medicines out of the reach and sight of children.

Do not use XANOR after the expiry date which is printed on the label. Return all unused medicine to your pharmacist. DO not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. PRESENTATION OF XANOR

XANOR 0,25 mg and 1,0 mg are packed in blister packs of 30 and 100 tablets.

XANOR 0,5 mg is packed in blister packs of 30 and 100 tablets and in bottles containing 500 tablets.

XANOR 2,0 mg is packed in bottles containing 30 and 100 tablets.

XANOR SR tablets are packed in foil blisters of 60 tablets.

8. IDENTIFICATION OF XANOR

XANOR 0,25 mg tablets are white, ovoid shaped, embossed with "Upjohn 29" on the one side and scored on the other side.

XANOR 0,5 mg tablets are pink, ovoid shaped, embossed with "Upjohn 55" on the one side and scored on the other side.

XANOR 1,0 mg tablets are lavender, ovoid shaped, embossed with "Upjohn 90" on the one side and scored on the other side.

XANOR 2,0 mg tablets are white capsule shaped, three scored tablets, embossed with "U94".

XANOR SR 0,5 mg tablets are light blue, round deep oval shape, embossed with "Upjohn 57".

XANOR SR 1,0 mg tablets are white, round deep oval shape, embossed with "Upjohn 59".

XANOR SR 2,0 mg tablets are light blue, pentagonal deep oval shape, embossed with "Upjohn 66".

9. REGISTRATION NUMBERS / REFERENCE NUMBERS

XANOR 0,25 mg tablets: M/2.6/233

XANOR 0,5 mg tablets: M/2.6/234

XANOR 1,0 mg tablets: M/2.6/235

XANOR 2,0 mg tablets: 27/2.6/96

XANOR SR 0,5 mg tablets: 29/2.6/0504

XANOR SR 1,0 mg tablets: 29/2.6/0505

XANOR SR 2,0 mg tablets: 29/2.6/0506

10. NAME AND ADDRESS OF REGISTRATION HOLDER

Pfizer Laboratories (Pty) Ltd

85 Bute Lane

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11. DATE OF PUBLICATION

07 March 2014