

## PATIENT INFORMATION LEAFLET

**SCHEDULING STATUS:** S5

**XANOR® 0,25 mg tablets**

**XANOR® 0,5 mg tablets**

**XANOR® 1,0 mg tablets**

**XANOR® 2,0 mg tablets**

**XANOR® SR 0,5 mg tablets**

**XANOR® SR 1,0 mg tablets**

**XANOR® SR 2,0 mg tablets**

**Alprazolam**

**Contains sugar (lactose monohydrate)**

Each XANOR 0,25 mg, 0,5 mg and 1,0 mg tablet contains 96,0 mg lactose monohydrate.

Each XANOR 2,0 mg tablet contains 192,0 mg lactose monohydrate.

Each XANOR SR 0,5 mg, 1,0 mg or 2,0 mg tablet contains 221,7 mg lactose monohydrate.

### **Read all of 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, pharmacist, nurse or other health care provider.
- 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.

### **What is in this leaflet**

1. What XANOR is and what it is used for
2. What you need to know before you take XANOR

3. How to take XANOR
4. Possible side effects
5. How to store XANOR
6. Contents of the pack and other information

### **1. What XANOR is and what it 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.

### **2. What you need to know 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 medicines. Also tell your doctor if you are allergic to any other substances such as foods, preservatives or dyes.
- If you are pregnant, trying to become pregnant or breastfeeding. Your baby may become dependent on XANOR 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.
- If you suffer from schizophrenia.
- If you are using ketoconazole and itraconazole.
- When used in children below 18 years of age, as these patients are more sensitive than adults to the effects of XANOR.
- If you suffer from a disease called 'myasthenia gravis' where you suffer from very weak and tired muscles.
- If you have severe chest problems or breathing difficulties (e.g. chronic bronchitis or emphysema).
- If you have 'sleep apnoea' – this is a condition where your breathing becomes irregular, even stopping for short periods, while you are asleep.
- If you have severe liver problems.

#### **Warnings and precautions**

**Take special care with XANOR:**

- Benzodiazepines and related products should be used with caution in elderly, due to the risk of sedation and/or musculoskeletal weakness that can promote falls, often with serious consequences in this population.
- 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 suffer from anxiety together with underlying depression
- If you are taking sedatives (barbiturates).
- If you have a history of using too much alcohol regularly, or alcohol abuse.
- If you have a history of drug abuse or dependence – as dependence on XANOR may occur more easily.
- 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 medicine 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 anxiety forms part of the depression.
- If you have ever felt so depressed that you have thoughts about taking your own life.
- Concomitant use of XANOR and opioids (strong pain killers, medicines for substitution therapy and some cough medicines) increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life-threatening. Because of this, concomitant use should only be considered when other treatment options are not possible. However, if your doctor does prescribe XANOR together with opioids, the dosage and duration of concomitant treatment should be limited by your doctor. Please tell your doctor about all opioid medicines you are taking and follow your doctor's dosage recommendation closely. It could be helpful to inform friends or relatives to be aware of sign and symptoms stated above. Contact your doctor when experiencing such symptoms.

- If you experience memory loss (amnesia). Tell your doctor straight away.
- If you feel that XANOR is not working anymore. Some loss of effectiveness of XANOR may occur after repeated use for a few weeks.

### **Other medicines and XANOR**

Always tell your health care provider if you are taking any other medicine. (This includes complementary or traditional medicines). The use of XANOR with these medicines may cause undesirable interactions.

- Imipramine and desipramine: XANOR may increase the levels of these medicines in the body if taken together.
- Some strong pain killers (e.g. opioids such as morphine, codeine or propoxyphene): using these medicines together with XANOR increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life-threatening.
- Antipsychotic medicines used to treat mental illnesses like schizophrenia.
- Do not take XANOR with ketoconazole, itraconazole or other azole antifungal medicines (used to treat fungal infections).
- Your dose of XANOR should be decreased if/when you are given 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.
- Take special care if/when you are given XANOR with any of the following medicines: fluoxetine, oral contraceptives (birth control pill), sertraline, diltiazem or macrolide antibiotics (e.g. erythromycin and troleandomycin).
- Ritonavir or other similar medicines used for treating HIV.
- Digoxin (used to treat various heart conditions).

### **XANOR with alcohol**

It is important not to drink any alcohol while you are taking XANOR, as alcohol increases the effects of the medicine.

### **Pregnancy and breastfeeding**

Your doctor will decide if XANOR is appropriate for you.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking XANOR.

### **Driving and using machines**

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

It is not always possible to predict to what extent XANOR may interfere with your daily activities. You should ensure that you do not engage in activities that require you to be alert until you are aware of the measure to which XANOR affects them.

### **XANOR contains lactose and sodium benzoate**

#### *Lactose*

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

#### *Sodium benzoate*

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

## **3. How to take XANOR**

Do not share medicines prescribed for you with any other person.

Always take XANOR exactly as your doctor has told you. Your doctor will decide what dose is right for you. Check with your doctor or pharmacist if you are not sure.

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**

Your doctor will decide what is the usual or appropriate dose for your condition.

#### *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 usual dose for this 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 is usually 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 usual dose 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 is usually not more than 0,75 mg a day.

**XANOR SR tablets**

These tablets should not be chewed, crushed or broken. They should be swallowed whole.

*A. For anxiety or mixed anxiety/depression*

The usual starting dose is 1 mg daily, taken in one or two doses. Your doctor may increase your dose if needed. However, the dose is usually 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.

Your doctor will tell you how long your treatment with XANOR will last. 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 have the impression that the effect of XANOR is too strong or too weak for you, tell your doctor or pharmacist.

**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). In the event of overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. Always take the labelled medicine package with you,

whether there are any XANOR left or not.

These are the possible signs and symptoms of overdosage: 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 your dose of XANOR, 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 XANOR for more than one week, call your doctor before taking any more medicine.

#### **4. Possible side effects**

XANOR can have side effects.

Some side effects of XANOR include the following, and should be discussed with your doctor if they occur:

##### *Frequency unknown:*

- Peripheral oedema (swelling of hands and feet due to the retained fluids).
- Angioedema (swelling beneath the skin).

##### *Frequent side effects:*

- 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 side effects:*

- Aggressive behaviour.
- Insomnia (inability to sleep).
- Mood changes.
- Nervousness.
- Amnesia (loss of memory).
- Tremor (trembling or shakiness).
- Diarrhoea.
- Vomiting.
- Muscle twitching or weakness.
- Changes in menstrual cycle.
- Changes in weight.
- 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 or if you experience any untoward effects while taking XANOR, please consult your health care provider for advice.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

**Reporting of side effects**

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more

information on the safety of XANOR.

## **5. How to store XANOR**

XANOR 0,25 mg, 0,5 mg, 1,0 mg, 2,0 mg tablets: Store at or below 30 °C.

XANOR SR 0,5 mg, 1,0 mg, 2,0 mg tablets: Store at or below 25 °C.

Keep tablets packed in bottles tightly closed.

Store all medicines out of reach of children.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

## **6. Contents of the pack and other information**

### **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 monohydrate, magnesium stearate, microcrystalline cellulose and starch with erythrosine sodium or FD & C blue as colourants.

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

### **What XANOR looks like and contents of the pack**

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 round, blue, convex tablets with "P&U 57" on one side.

XANOR SR 1,0 mg tablets are round, white, convex tablets with "P&U 59" on one side.

XANOR SR 2,0 mg tablets are pentagonal, blue tablets with "P&U 66" on one side.

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.

#### **Holder of Certificate of Registration**

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#### **This leaflet was last revised in**

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

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