PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S5

NOVAPRAZ XR 0,5 (0,5 mg extended release tablets)

NOVAPRAZ XR 1 (1,0 mg extended release tablets)

NOVAPRAZ XR 2 (2,0 mg extended release tablets)

Alprazolam

Contains sugar (lactose monohydrate).

Read all of this leaflet carefully before you start taking NOVAPRAZ XR

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- NOVAPRAZ XR 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 NOVAPRAZ XR is and what it is used for
2. What you need to know before you take NOVAPRAZ XR
3. How to take NOVAPRAZ XR
4. Possible side effects
5. How to store NOVAPRAZ XR
6. Contents of the pack and other information

1. What NOVAPRAZ XR is and what it is used for

NOVAPRAZ XR is a tranquiliser containing the active ingredient alprazolam. Alprazolam belongs to one of a group of medicines called benzodiazepines. Benzodiazepines affect chemical activity in the brain to promote sleep and to reduce anxiety and worry.

NOVAPRAZ XR tablets are used in the treatment of anxiety, and panic disorder.

2. What you need to know before you take NOVAPRAZ XR

Do not take NOVAPRAZ XR:

- if you are hypersensitive (allergic) to alprazolam or other similar benzodiazepine medicine, or to any of the other ingredients of NOVAPRAZ XR
- if you have been primarily diagnosed with schizophrenia
- if you are taking antiretroviral protease inhibitors used in the treatment of HIV and ketoconazole used in the treatment of fungal infections, as the elimination of NOVAPRAZ XR tablets are delayed several fold and may become toxic.
- if you suffer from a disease called 'myastenia 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 NOVAPRAZ XR and talk to your doctor or pharmacist before taking NOVAPRAZ XR

- if you have problems with your lungs, kidneys or liver.
- if you have abused drugs or alcohol in the past or find it difficult to stop taking medicines, drinking or taking drugs. Your doctor may want to give you special help when you need to stop taking these tablets.
- if you have ever felt so depressed that you have thought about taking your own life.
- if you have ever suffered any mental illness that required hospital treatment.
- if you have a serious condition affecting your breathing.
- do not stop taking this medication abruptly or decrease the dose without consulting your doctor, since withdrawal symptoms can occur such as inability to sleep, stomach or muscle cramps, vomiting, sweating, convulsions/seizures.

- some patients may find it very difficult to discontinue treatment with NOVAPRAZ XR due to severe emotional and physical dependence. Discontinuation symptoms, including possible seizures, may occur following discontinuation from any dose, but the risk may be increased with extended use at doses greater than 4 mg/day, especially if discontinuation is too abrupt. It is important that you seek advice from your doctor to discontinue treatment in a careful and safe manner. Proper discontinuation will help to decrease the possibility of withdrawal reactions that can range from mild reactions to severe reactions such as seizure.
- if you experience memory loss.
- inform your doctor if you are pregnant, if you are planning to have a child, or if you become pregnant while you are taking NOVAPRAZ XR or if you are breastfeeding your child (see "Pregnancy and breastfeeding below").

Elderly patients

NOVAPRAZ XR should be used with caution if you are an elderly patient, due to the risk of sedation and / or musculoskeletal weakness that can promote falls, often with serious consequences.

Children and adolescents

NOVAPRAZ XR should not be used by children and adolescents below the age of 18 years because safety and efficacy have not been established.

Other medicines and NOVAPRAZ XR

Always tell your healthcare professional if you are taking any other medicine (this includes all complementary or traditional medicines.), especially medicines listed below, as the effect of NOVAPRAZ XR or the other medicine may change when taken at the same time:

- Any other medicine to treat anxiety or depression or to help you sleep (e.g. imipramine, desimipramine, nefazodone, fluvoxamine, fluoxetine, sertraline)
- *Diltiazem* (for treating high blood pressure, angina and certain heart rhythm disorders)
- *Oral contraceptives ("the pill")*
- *Cimetidine (for treating stomach ulcers)*

- Macrolide antibiotics (erythromycin and troleandomycin) to treat bacterial infections

Taking NOVAPRAZ XR with food and drink

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

Pregnancy and breastfeeding

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 healthcare provider for advice before taking NOVAPRAZ XR.

Do not take NOVAPRAZ XR if you are pregnant.

Do not breastfeed while taking NOVAPRAZ XR, as the medicine is passed into your breast milk.

Driving and using machinery

NOVAPRAZ XR can make you feel sleepy or woozy and make you lose concentration, so it is very important that you do not operate machinery until you know how the tablets affect you.

It is not always possible to predict to what extent NOVAPRAZ XR may interfere with your daily activities. You should ensure that you do not engage in driving or using machinery until you are aware of the measure to which NOVAPRAZ XR affects you.

NOVAPRAZ XR contains lactose

NOVAPRAZ XR contains an ingredient known as lactose which is a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking NOVAPRAZ XR.

3. HOW TO TAKE NOVAPRAZ XR

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

Do not chew the tablets.

Always take NOVAPRAZ XR exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Your doctor will decide on the correct dose of NOVAPRAZ XR for you.

You will be periodically re-assessed by your doctor and dosage adjustments made, as appropriate.

The optimum dose for you will be individualised based upon the severity of your symptoms and your response to the treatment.

If you require a higher dosage, the dosage should be increased cautiously to avoid side effects.

To discontinue your treatment with NOVAPRAZ XR the dosage should be reduced slowly by your doctor.

Your doctor will tell you how long your treatment with NOVAPRAZ XR will last. Do not stop treatment unless your doctor advises you to.

If you have the impression that the effect of NOVAPRAZ XR is too strong or too weak, tell your doctor or pharmacist.

If you take more NOVAPRAZ XR than you should

It is important that you do not take more tablets than you are told to. If you do accidentally take too many tablets you may experience drowsiness, confusion, feeling cold, slurred speech, drop in blood pressure and difficulty breathing.

In the event of overdosage, consult your doctor or pharmacist. If neither is available contact the nearest hospital or poison control centre.

If possible, show them the NOVAPRAZ XR pack.

If you forget to take a dose of NOVAPRAZ XR

If you miss a dose, take it as soon as you remember unless it is time for your next dose.

Do not take a double dose to make up for forgotten individual doses.

If you stop taking NOVAPRAZ XR

Take NOVAPRAZ XR for as long as your doctor recommends. Don't stop unless your doctor advises you to. Always see your doctor before you stop taking NOVAPRAZ XR as the dose needs to be reduced gradually. If you stop taking the tablets or reduce the dose suddenly you can get 'rebound' effects which might cause you to become temporarily more anxious or restless or to have difficulty sleeping. These symptoms will go away as your body re-adjusts. If you are worried, your doctor can tell you more about this.

Severity of withdrawal seizures which may occur with rapid dose reduction or abrupt discontinuation.

4. Possible side effects

NOVAPRAZ XR can have side effects.

Not all side effects reported for NOVAPRAZ XR are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking NOVAPRAZ XR, please consult your healthcare provider for advice.

If any of the following happens, stop taking NOVAPRAZ XR and tell your doctor immediately or go to the casualty department of your nearest hospital:

- skin rash or itching
- swelling of the hands, feet, ankles, face, lips and mouth or throat (angioedema), which may cause difficulty in swallowing or breathing
- fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to NOVAPRAZ XR. You may need urgent medical attention or hospitalisation.

If you get any of these symptoms see your doctor straight away as treatment will need to be discontinued. Your doctor will then advise how treatment will be stopped.

- serious behavioural or psychiatric effects - for example agitation, restlessness, aggressiveness, irritability, violent anger, false beliefs, nightmares and hallucinations or other inappropriate behaviour.
- memory loss (amnesia)
- yellowing of the skin and white of the eyes (jaundice)

Tell your doctor if you notice any of the following:

Frequent side effects

- decreased appetite
- confusion and disorientation
- depression
- irritability
- decreased sex drive
- sleepiness and drowsiness
- problems with balance and unsteadiness
- slurred speech
- dizziness
- headache
- inability to remember bits of information
- excessive tiredness
- inability to stay awake, feeling sluggish
- double or blurred vision
- constipation
- feeling sick (nausea)
- dry mouth
- tiredness

Less frequent side effects:

- feeling hostile or aggressive
- inability to sleep or disturbed sleep
- loss of sex drive
- disturbance in your mood
- nervousness or feeling anxious or agitated
- seeing or hearing things that do not exist
- feeling agitated or very angry
- memory loss
- being hyperactive
- shakiness or trembling
- loss of alertness or concentration
- increased pressure in the eyes, which can also affect your vision
- diarrhoea
- being sick (vomiting)
- problems with your liver function
- skin irritation
- twisting or jerking movements
- muscle weakness
- incontinence or bladder control problems
- urinating frequently
- difficulty urinating
- in women irregular periods, or production of too much prolactin (the hormone that stimulates milk production)
- weight decrease
- weight increase
- feeling elated or over-excited, which causes unusual behaviour
- involuntary muscle contractions

- rapid swelling of the deep layers of the skin

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, pharmacist or nurse. 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 NOVAPRAZ XR.

5. How to store NOVAPRAZ XR

Store at or below 25 °C.

Store all medicines out of reach of children.

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

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 NOVAPRAZ XR contains

The active substance is alprazolam. Each tablet contains 0,5 mg; 1 mg or 2 mg alprazolam respectively.

The other ingredients are colloidal silicon dioxide, hypromellose, lactose monohydrate, magnesium stearate.

What NOVAPRAZ XR looks like and contents of the pack

NOVAPRAZ XR 0,5: White to off-white, round, biconvex tablets with bevelled edge debossed with 'X' on one side and '70' on the other side.

NOVAPRAZ XR 1: Yellow coloured, round, biconvex tablets with bevelled edge debossed with 'X' on one side and '73' on the other side. The tablets may be mottled.

NOVAPRAZ XR 2: Blue coloured, round, biconvex tablets with bevelled edge debossed with ‘X’ on one side and ‘74’ on the other side. The tablets may be mottled.

NOVAPRAZ XR 0,5, NOVAPRAZ XR 1 and NOVAPRAZ XR 2 are packed in white opaque round HDPE containers closed with white opaque polypropylene child resistant closures with wad having induction sealing liner. The HDPE containers also contain 2 g silica gel sachets and a cotton coil. The HDPE container is further packed in a pre-printed outer carton.

Pack size: 60 tablets.

Holder of Certificate of Registration

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