

Approved Patient Information Leaflet for Medicines for Human Use:

ZADOPAX 50 mg, 100 mg

SCHEDULING STATUS: S5

ZADOPAX 50 mg Hard gelatin capsules

ZADOPAX 100 mg Hard gelatin capsules

Trazodone Hydrochloride

Contains sugar (Lactose monohydrate)

Each ZADOPAX 50 mg Hard gelatin capsules contains 80 mg of lactose monohydrate.

Each ZADOPAX 100 mg Hard gelatin capsules contains 160 mg of lactose monohydrate.

Read all of this leaflet carefully before you start taking ZADOPAX

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist, nurse or other health care provider.
- ZADOPAX 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 ZADOPAX is and what it is used for
2. What you need to know before you take ZADOPAX
3. How to take ZADOPAX

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

1. What ZADOPAX is and what it is used for

ZADOPAX contains the active substance Trazodone Hydrochloride which belongs to a group of medicines called Psychoanaleptics (antidepressants).

ZADOPAX is used for the treatment of depression and mixed anxiety and depression.

2. What you need to know before you take ZADOPAX

Do not take ZADOPAX

- if you are allergic (hypersensitive) to trazodone hydrochloride or any of the other ingredients of ZADOPAX (listed in Section 6).
- if you are taking a medicine called a monoamine oxidase inhibitor (MAOI) or if you have taken them in the last 2 weeks. You should not receive MAOI's within 1 week of stopping ZADOPAX.
- if you are taking any other psychotropic medicine which your doctor may not know of.
- if you have recently had a heart attack.
- if you are a heavy drinker or are taking sleeping tablets.

Warnings and precautions

Talk to your doctor or health care provider before taking ZADOPAX

Take special care with ZADOPAX

Thoughts of suicide and worsening of your depression or anxiety disorder

If you are depressed and/or have anxiety disorders you can sometimes have thoughts of harming or killing yourself. These may be increased when first starting antidepressants, since these medicines all take time to work, usually about two weeks but sometimes longer.

You may be more likely to think like this:

- If you have previously had thoughts about killing or harming yourself.
- If you are a young adult. Information from clinical trials has shown an increased risk of suicidal behaviour in adults aged less than 25 years with psychiatric conditions who were treated with an antidepressant.

If you have thoughts of harming or killing yourself at any time, contact your doctor or go to a hospital straight away.

You may find it helpful to tell a relative or close friend that you are depressed or have an anxiety disorder and ask them to read this leaflet. You might ask them to tell you if they think your depression or anxiety is getting worse, or if they are worried about changes in your behaviour.

Check with your doctor or pharmacist before taking this medicine if you:

- Have or have ever had fits or seizures (epilepsy)
- Have severe liver, kidney or heart problems
- Are pregnant, trying to become pregnant or are breast-feeding
- Have an overactive thyroid gland (hyperthyroidism)
- Have problems passing water or need to pass water (urine) frequently
- Have narrow angle glaucoma (an eye disorder)
- Have schizophrenia or other type of mental disorder
- Are elderly, as you may be more prone to side effects

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking ZADOPAX.

Children and adolescents

ZADOPAX should not be used in children and adolescents under 18 years of age.

Other medicines and ZADOPAX

Tell your doctor if you are taking, have recently taken or might take any other medicines.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines you buy without a prescription, including herbal medicines. This is because ZADOPAX can affect the way some other medicines work. Also, some medicines can affect the way ZADOPAX work.

Tell your doctor if you are taking any of the following medicines:

- MAOI (Monoamine Oxidase Inhibitors) medicines such as tranylcypromine, phenelzine and isocarboxazide (for depression) or selegiline (for Parkinson's disease), or have taken them in the last 2 weeks
- Other antidepressants (such as amitriptyline or fluoxetine)
- Sedatives (such as tranquilizers or sleeping pills)
- Medicines used to treat epilepsy such as carbamazepine and phenytoin
- Medicines used to treat high blood pressure, for example, clonidine
- Digoxin (used to treat heart problems)
- Medicines used to treat fungal infections such as ketoconazole and itraconazole
- Some medicines used to treat HIV such as ritonavir and indinavir
- Erythromycin, an antibiotic used to treat infections
- Levodopa (used to treat Parkinson's disease)
- St. John's Wort (a herbal remedy)
- Warfarin (used to stop your blood from clotting)

Anaesthetics

If you are going to have an anaesthetic (for an operation), tell your doctor or dentist that you are taking ZADOPAX.

ZADOPAX with drink and alcohol

You should avoid drinking alcohol while taking ZADOPAX.

Pregnancy and breastfeeding and fertility

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 ZADOPAX.

Taking ZADOPAX in the late stages of pregnancy may lead to your baby experiencing withdrawal symptoms when they are born.

Driving and using machines

ZADOPAX may make you feel sleepy or dizzy. If this happens do not drive or use any tools or machines.

ZADOPAX contains lactose

If you have been told that you cannot digest or tolerate some sugars, talk to your doctor before taking ZADOPAX.

3. How to take ZADOPAX

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

Always take ZADOPAX exactly as your doctor or pharmacist has instructed you. Check with your doctor or pharmacist if you are not sure.

Adults:

Depression

- Adults usually start by taking 150 mg each day
- Your doctor may increase the dose to 300 mg each day depending on your condition
- For adults in hospital the dose may be as high as 600 mg each day

Anxiety

- Adults usually start by taking 75 mg each day
- Your doctor may increase the dose to 300 mg each day

Elderly

- Older people or those who are frail will usually be given a starting dose of 100 mg each day

Children

Children and adolescents under 18 years should not take ZADOPAX.

If you feel the effect of your medicine is too weak or strong, do not change the dose yourself, but ask your doctor

Method of administration

- Take this medicine by mouth.
- Swallow the capsules whole with a drink of water.

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- Take with or after food. This can help lower the chances of side effects.
- If you have been told to take ZADOPAX only once each day then you should take it before going to bed.

If you take more ZADOPAX than you should

If you take more ZADOPAX than you should, tell a doctor or go to a hospital casualty department straight away. Take the medicine pack with you. This is so the doctor knows what you have taken.

The following effects may happen feeling sick or being sick, feeling sleepy, dizzy or faint, fits (seizures), confusion, breathing or heart problems.

If you forget to take ZADOPAX

If you forget to take a dose, take it as soon as you remember it. However, if it is nearly time for the next dose, skip the missed dose.

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

If you stop taking ZADOPAX

Keep taking ZADOPAX until your doctor tells you to stop. Do not stop taking ZADOPAX just because you feel better. When your doctor tells you to stop taking these capsules, he/she will help you to stop taking them gradually.

4. Possible side effects

ZADOPAX can have side effects.

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

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

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching
- fainting
- painful erection of the penis, unrelated to sexual activity, that will not go away (priapism)
- yellowing of the skin and eyes, dark urine, and tiredness which may be symptoms of liver problems
- fits or seizures
- a combination of high temperature (fever), sweating, stiff muscles, feeling very drowsy or faint, large increase in blood pressure or heartbeat (a disorder called “Neuroleptic Malignant Syndrome”)
- getting infections more easily than usual. This could be because of a blood disorder (agranulocytosis)
- bruising more easily than usual. This could be because of a blood disorder (thrombocytopenia)
- severe abdominal pain and bloating, are being sick (vomiting) and have constipation. These may be signs that your intestine is not working properly (paralyticilius)

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

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- having thoughts of harming or killing yourself
- feeling tired, faint, dizzy, having pale skin. These could be signs of anaemia
- unusual skin sensations such as numbness, tingling, pricking, burning or creeping on the skin (parasthesia)

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- feeling confused, restless, sweating, shaking, shivering, hallucinations (strange visions or sounds), sudden jerks of the muscles or a fast heartbeat, you may have something called Serotonin syndrome.
- very fast or slow or irregular heartbeat.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- drowsiness
- headache, dizziness, confusion, shaking (tremor), excitement
- nausea (feeling sick), vomiting, dry mouth.

Less frequent side effects:

- constipation or diarrhoea
- weakness
- blurred vision
- skin rash
- feeling dizzy or light-headed on standing or sitting up quickly (orthostatic hypotension)

Side effects with frequency unknown:

- feeling less alert, irritability or agitation, feeling restless, difficulty sleeping (insomnia)
- altered taste
- weight loss
- indigestion, increased amounts of saliva, stomach pain
- unexpected swelling (fluid retention), chest pain
- fainting (syncope)
- blocked nose
- itching, sweating more than usual
- pain in limbs, back pain, pain in your muscles, pain in your joints

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- jerking movements that you cannot control, mainly in the arms and legs, uncontrolled muscle movements or twitches, difficulty with speaking
- feeling anxious or more nervous than usual, feeling agitated
- overactive behaviour or thoughts (mania), believing things that are not true (delusions), memory disturbance
- nightmares
- decreased sex drive
- high blood pressure
- feeling flush, high temperature
- higher than normal number of white blood cells or liver enzymes (shown by a blood test)
- feeling tired, weak and confused, having muscle that ache, are stiff or do not work well. There may also be headache, loss of appetite, nausea or vomiting, convulsion. This may be due to low sodium levels in your blood.

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 ZADOPAX.

5. How to store ZADOPAX

Store all medicines out of reach of children.

Store at or below 25 °C.

Store in the original package.

Keep the blisters in the outer carton.

There are no special storage instructions for ZADOPAX.

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Do not use this medicine after the expiry date which is stated on the carton and blister after 'EXP'. The expiry date refers to the last day of that month.

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 ZADOPAX contains

The active substance is Trazodone Hydrochloride.

ZADOPAX 50 mg:

Each Hard gelatin capsule contains 50 mg of Trazodone Hydrochloride.

ZADOPAX 100 mg:

Each Hard gelatin capsule contains 100 mg of Trazodone Hydrochloride.

The other ingredients are: Lactose monohydrate and magnesium stearate.

What ZADOPAX looks like and contents of the pack

ZADOPAX are hard gelatin capsules.

ZADOPAX 50 mg: Size "3" opaque green body, printed "50" in black and violet cap.

ZADOPAX 100 mg: Size "2" light yellow body, printed "100" in black and violet cap.

ZADOPAX 50 mg and ZADOPAX 100 mg are available Alu-PVC/PVDC blister packs and Alu-PVC/PE/PVDC blister packs. The blister packs are packed into cardboard cartons in pack sizes of 5 x 10's and 10 x 10's respectively.

ZADOPAX 50 mg and ZADOPAX 100 mg are available in colourless, transparent polypropylene polymer plastic packs of 50's and 100's tablets.

Not all pack sizes may be marketed.

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Holder of Certificate of Registration

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ZADOPAX 100 mg: 54/1.2/0521

Access to the corresponding Professional Information

Professional Information for this medicine is available on the following URL: <https://austell.co.za/product-info/>

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