

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S5**

BIOTECH TRAZODONE 50, 50 mg capsules

BIOTECH TRAZODONE 100, 100 mg capsules

Trazodone hydrochloride

Contains sugar (lactose monohydrate):

BIOTECH TRAZODONE 50: 77, 66 mg per capsule

BIOTECH TRAZODONE 100: 155,32 mg per capsule.

Please read all of this leaflet carefully before you start taking BIOTECH TRAZODONE

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

1. What BIOTECH TRAZODONE is and what it is used for

BIOTECH TRAZODONE is an antidepressant and is used for the treatment of:

- Depression
- Mixed anxiety and depression

2. What you need to know before you take BIOTECH TRAZODONE

Do not take BIOTECH TRAZODONE:

- if you are hypersensitive (allergic) to trazodone hydrochloride or any of the other ingredients of BIOTECH TRAZODONE (listed in section 6)
- if you are recovering from a myocardial infarction (heart attack)
- if you are a heavy drinker or are taking any other antidepressants or sleeping tablets
- if you are pregnant or breastfeeding

Warnings and precautions

Take special care with BIOTECH TRAZODONE:

Tell your doctor immediately:

- If you have thoughts of harming or killing yourself. These thoughts may be increased when first starting treatment, since BIOTECH TRAZODONE takes 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. There is an increased risk of suicidal behaviour in adults aged less than 25 years with psychiatric conditions who were treated with an antidepressant.

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.

Also tell your doctor:

- If you have heart problems such as coronary artery disease (condition that affects the supply of blood to the heart) and problems with the heart rhythm
- If you suffer from epilepsy (fits or seizures)
- If you have severe kidney or liver problems.
- If you have an overactive thyroid gland (hyperthyroidism)
- If you have problems passing water or needing to pass water (urine) more frequently
- If you have narrow angle glaucoma (an eye disease)
- If you have porphyria
- If you have schizophrenia or another type of mental disorder
- If you are elderly, since you may be more prone to side effects, especially when taking other medicines at the same time as BIOTECH TRAZODONE or if you have some other diseases
- If you have high blood pressure, as your doctor may need to reduce the dose of the antihypertensive medicine
- If you are taking opioids and BIOTECH TRAZODONE together – this can cause a dangerous condition called serotonin syndrome, which can be life-threatening
- If you have depression or other conditions that are treated with antidepressants. The use of these medicines together with BIOTECH TRAZODONE can lead to serotonin syndrome, a potentially life-threatening condition (see “Other medicines and BIOTECH TRAZODONE capsules”). Symptoms of serotonin syndrome may include mental-status changes, autonomic instability, neuromuscular abnormalities, and/or gastrointestinal symptoms.

Children and adolescents

BIOTECH TRAZODONE is not recommended for use in children and adolescents under 18 years old.

If any of these apply to you, tell your doctor before you take BIOTECH TRAZODONE.

Other medicines and BIOTECH TRAZODONE

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines)

It is especially important to tell your doctor if you are taking any of the following medicines:

BIOTECH TRAZODONE may enhance the central nervous system depressant effects such as drowsiness, dry mouth, tachycardia, blurred vision and constipation of:

- Other antidepressants such as amitriptyline or fluoxetine
- Muscle relaxants and inhaled anaesthetics
- Phenothiazines e.g., chlorpromazine, fluphenazine, levomepromazine, perphenazine (for treating schizophrenia)
- Antihistamines (for e.g., chlorpheniramine)
- Sleeping tablets and tranquilizers
- Barbiturates (used to treat depression)
- Pimozide (for treating uncontrolled movements, tics)
- Alcohol
- Levodopa (used for Parkinson's disease)
- Anxiolytics.

BIOTECH TRAZODONE may increase plasma concentrations of:

- Digoxin
- Carbamazepine, phenytoin (used in treatment of epilepsy).
- MAOI (Mono Amine Oxidase Inhibitors) medicines such as tranylecypromine, phenelzine and isocarboxazid (for depression) or selegiline (for Parkinson's disease). Tell your doctor or pharmacist if you are taking them now or have taken them in the last 2 weeks
- If you are taking opioids and BIOTECH TRAZODONE together – this can cause a dangerous condition

called serotonin syndrome, which can be life-threatening

- Amiodarone
- Medicines used to treat high blood pressure (e.g., clonidine)
- Medicines used to treat fungal infections such as ketoconazole and itraconazole
- Erythromycin (antibiotic used to treat infections)
- Warfarin (a medicine used to stop blood from clotting)
- Some medicines used to treat HIV such as ritonavir, indinavir and nefazodone
- St. John's Wort (a herbal medicine)
- Oral contraceptives
- Cimetidine (inhibits stomach acid production)
- Other antipsychotics
- Lithium (to treat major depressive disorder and bipolar disorder)

Anaesthetics

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

BIOTECH TRAZODONE with food, drink and alcohol

BIOTECH TRAZODONE should be taken with food.

You should avoid drinking alcohol while taking BIOTECH TRAZODONE. This is because BIOTECH TRAZODONE can change the way alcohol affects you.

Driving and using machines

BIOTECH TRAZODONE may cause drowsiness, headaches, dizziness and impaired concentration.

It is not always possible to predict to what extent BIOTECH TRAZODONE may interfere with the daily

activities of a patient. So, before you drive a vehicle or use machinery make sure you know how you react to the effects of BIOTECH TRAZODONE.

Pregnancy and breastfeeding

Safety in pregnancy and lactation has not been established.

Pregnant women should not use BIOTECH TRAZODONE.

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 BIOTECH TRAZODONE.

If you take BIOTECH TRAZODONE, you should not breastfeed your baby.

No data available in fertility.

BIOTECH TRAZODONE contains lactose.

Patients with the rare hereditary conditions of lactose or galactose intolerance should not take BIOTECH TRAZODONE.

3. How to take BIOTECH TRAZODONE

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

Always take BIOTECH TRAZODONE exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. Your doctor will tell you how long your treatment with BIOTECH TRAZODONE will last. If you have the impression that the effect of BIOTECH TRAZODONE is too strong or too weak, tell your doctor or pharmacist.

Do not exceed the recommended dosage. BIOTECH TRAZODONE is for oral use only. Your doctor will prescribe a dose for your specific condition and your response to the treatment.

For treatment of depression:

The doctor might start with a lower dose and then gradually increase the dosage for your needs or response. The usual dosage will be 300 – 400 mg per day in three divided doses. A usual starting dose of 150 mg per day is suggested for the first week, gradually increased to 300 mg per day.

For treatment of mixed anxiety or depression:

The doctor might start with a lower dose and then gradually increase the dosage for your needs or response. The usual starting dose is 100 – 150 mg per day. When depression is predominant the dose might be increased to 300 – 400 mg per day.

If you take more BIOTECH TRAZODONE than you should

You may experience the following symptoms:

- drowsiness,
- nausea,
- vomiting,
- dizziness,
- fainting,
- fits (seizures),
- painful, prolonged penile erection,
- confusion,
- problems with your heart or breathing.

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

Take the remaining capsules with you so that the doctor will know what the patient has taken. There is no specific antidote for BIOTECH TRAZODONE.

If you forget to take BIOTECH TRAZODONE

If you forget to take a dose of BIOTECH TRAZODONE, carry on with the next dose at the usual time. Do not take a double dose to make up for forgotten individual doses.

Effects when treatment with BIOTECH TRAZODONE is stopped

Treatment with BIOTECH TRAZODONE should not be stopped immediately but should be withdrawn gradually in consultation with your doctor.

Stopping your medicine too quickly could cause sleep problems, leave you feeling more irritable than usual and cause you to sweat more than usual.

4. Possible side effects

BIOTECH TRAZODONE can have side effects.

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

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

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching
- fainting

- yellowing of the skin and eyes, also called jaundice

These are all serious side effects. If you have them, you may have had a serious reaction to BIOTECH TRAZODONE. 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:

- bruising more easily than usual. This could be because of a blood disorder (thrombocytopenia)
- getting more infections than usual (sore throat, skin infections) which may indicate a blood disorder (agranulocytosis)
- frequent infections with high temperature, severe chills, sore throat or mouth ulcers. These could be signs of a blood problem called leukopenia
- 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
- fast, slow or irregular heartbeat
- painful erection of the penis, unrelated to sexual activity, that will not go away (priapism)
- severe abdominal pain and bloating, which may be accompanied by vomiting or constipation. These may be signs that your intestine is not working properly (paralytic ilius)

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

Tell your doctor if you notice any of the following:

Frequent:

- headache
- dizziness
- drowsiness
- nausea
- vomiting

Each capsule contains: trazodone hydrochloride 50 mg
and 100 mg respectively

- dry mouth, an unpleasant taste

Less frequent:

- confusion
- unusual excitement
- low blood pressure
- tremors
- blurred vision
- constipation
- diarrhoea

Frequency not known:

- feeling tired, faint, dizzy, having pale skin. These could be signs of anaemia
- body is retaining water due to high levels of a hormone (SIADH)
- weight loss and loss of appetite
- increased appetite
- 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.
- convulsions
- thoughts of harming or killing yourself
- feeling anxious or more nervous than usual, feeling agitated
- overactive behaviour or thoughts (mania), believing things that are not true (delusions), memory disturbance
- spinning feeling (vertigo)
- nightmares
- decreased sex drive

Each capsule contains: trazodone hydrochloride 50 mg
and 100 mg respectively

- decreased alertness
- jerking movements that you cannot control, mainly in of the arms and legs, uncontrolled muscle movements or twitches
- difficulty with speaking
- feeling very unwell possibly with shortness of breath (dyspnoea), difficulty in walking or walking with a shuffling gait, shaking, uncontrolled muscle twitching, and a high temperature (above 36 °C). This could be a rare condition known as Neuroleptic Malignant Syndrome
- unusual skin sensations such as numbness, tingling, pricking, burning or creeping on the skin (paraesthesia)
- muscle tremors
- abnormal muscle tone and posture
- restlessness
- irritability
- sleeplessness
- slow heartbeat
- feeling dizzy or light-headed on standing or sitting up quickly (postural hypotension), fainting (syncope)
- high blood pressure
- blocked nose
- indigestion
- stomach pain
- infectious diarrhoea
- increased amounts of saliva
- severe liver disorders such as severe liver function impairment or hepatitis
- liver failure with potentially fatal outcome
- sweating more than usual

- pain in limbs, back pain, pain in your muscles, pain in your joints
- disturbances of emptying of the bladder
- weakness
- water retention which may cause swollen arms or legs
- high temperature
- flu type symptoms
- chest pain
- tiredness
- high levels of liver enzymes in your blood (shown by a blood test)

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 BIOTECH TRAZODONE.

5. How to store BIOTECH TRAZODONE

Store in a cool dry place at or below 25 °C and protect from light.

Keep the capsules in the blister in the outer carton until required for use.

Do not take BIOTECH TRAZODONE after the expiry date shown on the pack.

Do not use any BIOTECH TRAZODONE pack that is damaged or shows signs of tampering.

Store all medicines out of reach of children.

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 BIOTECH TRAZODONE contains:

BIOTECH TRAZODONE 50: Each capsule contains 50 mg of the active substance trazodone hydrochloride.

The other ingredients are colloidal silica anhydrous, lactose monohydrate, magnesium stearate and a gelatine capsule shell containing the following colourants: erythrosine, indigo carmine, patent blue V, titanium dioxide and yellow iron oxide.

BIOTECH TRAZODONE 100: Each capsule contains 100 mg of the active substance trazodone hydrochloride.

The other ingredients are colloidal silica anhydrous, lactose monohydrate, magnesium stearate and a gelatine capsule shell containing the following colourants: erythrosine, patent blue V, titanium dioxide and yellow iron oxide.

What BIOTECH TRAZODONE looks like and contents of the pack

BIOTECH TRAZODONE 50: Hard gelatine size '3' capsule with green body, violet cap containing white powder.

BIOTECH TRAZODONE 100: Hard gelatine size '2' capsule with yellow body, violet cap containing white powder.

Clear PVC/PVdC and silver aluminium foil blister strips each containing 10, 12 or 14 capsules per strip. The strips are packed in an outer carton.

Holder of Certificate of Registration

BIOTECH LABORATORIES (PTY) LTD.

Block K West

Central Park

400 16th Road

Biotech Laboratories (Pty) Ltd
Biotech Trazodone 50 & 100, Capsules (43/1.2/0698 &
0699)
Each capsule contains: trazodone hydrochloride 50 mg
and 100 mg respectively

1.3.2 Patient Information Leaflet

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