

Package leaflet: Information for the user

Trazodone hydrochloride 50 mg/5 ml oral solution trazodone hydrochloride

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What trazodone is and what it is used for
2. What you need to know before you take trazodone
3. How to take trazodone hydrochloride oral solution
4. Possible side effects
5. How to store trazodone
6. Contents of the pack and other information

1 What trazodone is and what it is used for

The name of your medicine is Trazodone hydrochloride 50 mg/5 ml oral solution (called trazodone in this leaflet). This belongs to a group of medicines called antidepressants.

Trazodone can be used to treat anxiety and depression.

2 What you need to know before you take trazodone

Do not take trazodone:

- if you are allergic to trazodone hydrochloride or any of the other ingredients of this medicine (listed in section 6). Signs of an allergic reaction can include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- if you have recently had a heart attack.
- if you are a heavy drinker or are taking sleeping tablets.
- if you are under 18 years of age.

Do not take this medicine if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking trazodone.

Warnings and precautions

Talk to your doctor before taking trazodone if you have:

- The use of Buprenorphine together with trazodone can lead to serotonin syndrome, a potentially life-threatening condition (see “Other medicines and trazodone oral solution”).

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.

Children and adolescents

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

Patients under 18 have increased risk of side effects such as suicide attempt, suicidal thoughts and hostility (predominantly aggression, oppositional behaviour and anger) when they take antidepressant medicines. Moreover, there are no data available on the long-term safety on children and adolescents regarding growth, maturation and cognitive and behavioural development.

If you are elderly, you may be more prone to side effects; increased caution is necessary especially when taking other medicines at the same time as Trazodone or you have some other diseases.

Check with your doctor or pharmacist before taking this medicine:

- if you have or have ever had fits or seizures (epilepsy).
- if you have severe liver, kidney or heart problems.
- if you are pregnant, trying to become pregnant or are breast-feeding.
- if you have an overactive thyroid gland (hyperthyroidism).
- if you have problems passing water or need to pass water (urine) frequently.
- if you have narrow angle glaucoma (an eye disorder).
- if you have schizophrenia or other type of mental disorder.
- if you 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 trazodone.

Other medicines and Trazodone

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

Some medicines may increase the side effects of trazodone and may sometimes cause very serious reactions. Do not take any other medicines whilst taking trazodone without first talking to your doctor, especially:

- buprenorphine/opioids. These medicines may interact with trazodone and you may experience symptoms such as involuntary, rhythmic contractions of muscles, including the muscles that control movement of the eye, agitation, hallucinations, coma, excessive sweating, tremor, exaggeration of reflexes, increased muscle tension, body temperature above 38°C. Contact your doctor when experiencing such symptoms.

In particular, tell your doctor if you are taking any of the following medicines:

- MAOI (MonoAmine Oxidase Inhibitors) medicines such as tranylcypromine, phenelzine and isocarboxazid (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 trazodone.

Taking trazodone with alcohol

You should avoid drinking alcohol while taking trazodone.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

Avoid taking trazodone hydrochloride during the first trimester of your pregnancy.

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

Breast-feeding

Talk to your doctor if you are breast-feeding or intend to breast-feed. Your doctor will explain to you, whether you should continue/discontinue breast-feeding or continue/discontinue taking trazodone.

Driving and using machines

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

Trazodone contains sorbitol

This medicine contains 1225 mg sorbitol in each 5 ml, which is equivalent to 245 mg/ml. Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine.

Sorbitol may cause gastrointestinal discomfort and mild laxative effect.

Trazodone contains glycerol

May cause headache, stomach upset and diarrhoea.

Trazodone contains benzoic acid

This medicine contains 0.5 mg benzoic acid in 5 ml, which is equivalent to 0.1 mg/ml.

Information on sodium content

This medicine contains less than 1 mmol sodium (23 mg) per 5 ml oral solution, i.e. is essentially 'sodium-free'.

3 How to take trazodone hydrochloride oral solution

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

Taking this medicine

- Take this medicine by mouth.
- Take with or after food. This can help lower the chances of getting side effects.
- If you have been told to take trazodone only once each day, then you should take it before going to bed.
- If you feel the effect of your medicine is too weak or strong, do not change the dose yourself, but ask your doctor.

The recommended doses are:

To treat depression

Adults: the starting dose is 150 mg (15 ml) each day. Your doctor may increase the dose to 300 mg (30 ml) each day, depending on your condition.

For adults in hospital, the dose may be as high as 600 mg (60 ml) each day.

To treat anxiety

Adults: the starting dose is 75 mg (7.5 ml) each day. Your doctor may increase the dose to 300mg (30ml) each day.

Use in children

Children and adolescents under 18 years should not take Trazodone.

Use in elderly

Older people or those who are frail will usually be given a starting dose of 100 mg (10 ml) each day. Doses of more than 300 mg (30 ml) will not normally be given.

If you take more trazodone than you should

If you take more trazodone than you should, tell a doctor or go to the hospital 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, confusion, breathing or heart problems.

If you forget to take Trazodone

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 Trazodone

Keep taking trazodone until your doctor tells you to stop. Do not stop taking this medicine just because you feel better. When your doctor tells you to stop taking this medicine he/she will help you to stop taking it gradually.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4 Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop taking Trazodone and see a doctor or go to a hospital straight away if you experience:

- Swelling of the hands, feet, ankles, face, lips or throat which may cause difficulty swallowing or breathing, itching of the skin and nettle rash. This may mean you are having an allergic reaction to Trazodone.
- Painful erection of the penis, unrelated to sexual activity, that will not go away (priapism).

- Yellowing of the eyes or skin. This could be a liver problem (such as jaundice).
- 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, being sick (vomiting) and have constipation. These may be signs that your intestine is not working properly (paralytic ileus).

Talk to your doctor straight away if you notice the following side-effects:

- You have thoughts of harming or killing yourself.
- Feeling tired, faint, dizzy, having pale skin. These could be signs of anaemia.
- Convulsions/fits.
- Unusual skin sensations such as numbness, tingling, pricking, burning or creeping on the skin (paraesthesia).
- 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.
- 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 38°C). This could be a rare condition known as Neuroleptic Malignant Syndrome.
- Rapid, slow or irregular heartbeat.

Below is a list of other side effects that have been reported:

Frequency unknown (cannot be estimated from available data)

- Feeling drowsy or sleepy, tiredness.
- Feeling less alert than usual.
- Feeling sick (nausea) or being sick (vomiting), indigestion.
- Constipation, diarrhoea.
- Dry mouth, altered taste, increased amounts of saliva, blocked nose.
- Sweating more than usual.
- Dizziness, headache, confusion, weakness, tremor (shaking).
- Blurred vision.
- Loss of appetite and weight loss.
- Feeling dizzy or light-headed on standing or sitting up quickly (postural hypotension), fainting (syncope).
- Feeling restless and having difficulty sleeping.
- Water retention which may cause swollen arms or legs.
- Skin rash, itching.
- Chest pain.
- Pain in limbs, back pain, pain in your muscles, pain in your joints.
- Jerking movements that you cannot control, mainly in the arms and legs, uncontrolled muscle movements or twitches.
- Frequent infections with high temperature, severe chills, sore throat or mouth ulcers. These could be signs of a blood problem called leukopenia.
- 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.
- Feeling dizzy, possibly with a “spinning” feeling (vertigo).
- High blood pressure.
- High temperature.
- Flu type symptoms.
- Difficulty with speaking.
- Higher than normal number of white blood cells (seen by a blood test).
- High levels of liver enzymes in your blood (shown by a blood test).
- Severe liver disorders such as hepatitis.

- Liver failure with potentially fatal outcome.
- Feeling tired, weak and confused, having muscles 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.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store trazodone

Keep this medicine out of the sight and reach of children.

This medicine should be consumed within 30 days after its first opening.

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

Store below 25°C. Store in the original bottle to protect from light.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6 Contents of the pack and other information

What trazodone contains

The active substance is trazodone hydrochloride. Each 5 ml of Trazodone contains 50 mg of trazodone hydrochloride.

The other ingredients are: glycerol (E 422), sorbitol solution 70% non-crystallising (E 420), benzoic acid (E 210), saccharin sodium, orange flavour 501071, sodium hydroxide (for pH adjustment) and purified water.

What Trazodone looks like and contents of the pack

Trazodone is a clear, colourless to pale yellow liquid with an orange odour.

Pack: 125 ml Type III amber coloured glass bottle, sealed with a child resistant closure and cap with a tamper evident ring, containing 120 ml of solution.

Marketing Authorisation Holder & Manufacturer

Strides Pharma UK Ltd.
Unit 4, The Metro Centre,
Dwight Road, Watford,
WD18 9SS,
United Kingdom

This leaflet was last revised in 09/2024