

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
4. Possible side effects
5. How to store Trazodone
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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).

It contains a medicine called trazodone hydrochloride. This belongs to a group of medicines called antidepressants.

Trazodone can be used to treat all types of depression including depression accompanied by anxiety.

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). The signs of an allergic reaction 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 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 or pharmacist before taking Trazodone if:

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

when taking other medicines at the same time as trazodone or if you have some other diseases.

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

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.

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 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.

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

- **MAOI (MonoAmine Oxidase Inhibitors) medicine** such as tranylcypromine, phenelzine and isocarboxazid (for depression) or selegiline (for Parkinson's disease), or have taken them in the last 2 weeks.
 - **Wait 14 days** after stopping an MAOI before you take Trazodone.
 - **Wait 7 days** after stopping Trazodone before starting an MAOI.
- 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);
- Oral contraceptives;
- Cimetidine (for heartburn and stomach ulcers);
- 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.

Tell your doctor or pharmacist if you are taking, or have recently taken, any other medicines; including ones you have bought yourself.

Trazodone with food, drink and alcohol

- Trazodone can be taken with or after food.
- You should avoid drinking alcohol whilst taking Trazodone.

Pregnancy, breast-feeding and fertility

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.

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

If you are breast-feeding or planning to breast-feed, talk to your doctor or pharmacist before taking any medicine.

Driving and using machines

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

Trazodone contains sorbitol, glycerol and benzoic acid

- This medicine contains 1.4 g **sorbitol** in each 5 ml dose. 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.
- This medicine contains **glycerol** which may cause a headache, stomach upset and diarrhoea.
- This medicine contains 5 mg **benzoic acid** in each 5 ml. Benzoic acid may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).
- This medicine contains less than 1 mmol sodium (23 mg) per 5 ml dose, that is to say essentially 'sodium-free'.

3. How to take Trazodone

Always take Trazodone exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Taking this medicine

- Take this medicine by mouth.
- Use the measuring cup provided.
- Take with or after food. This can help lower the chances of 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 dose is:

Use in adults:

Depression

- Adults usually start by taking 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.

Anxiety

- Adults usually start by taking 75 mg (7.5 ml) each day.

- Your doctor may increase the dose to 300 mg (30 ml) each day.

Use in the elderly:

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

| Dose (mg) | ml equivalent | Cup equivalent |
|-----------|---------------|--|
| 75 | 7.5 | 1x 7.5 ml once a day |
| 100 | 10 | 1x 10 ml once a day OR 1x 5 ml twice a day |
| 150 | 15 | 1x 15 ml once a day OR 1x 7.5 ml twice a day |
| 300 | 30 | 2x 15 ml once a day OR 1x 15 ml twice a day |
| 600 | 60 | 4x 15 ml once a day OR 2x 15 ml twice a day |

Use in children and adolescents:

Children and adolescents under 18 years should not take Trazodone.

If you take more Trazodone than you should

If you take more Trazodone 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 Trazodone

If you forget to take a dose, take it as soon as you remember. 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 Trazodone 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 tell your doctor or go to a hospital straight away if:

- You get 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.
- Yellowing of the eyes or skin. This could be a liver problem.

- Getting infections more easily than usual. This could be because of a blood disorder.
- Bruising more easily than usual. This could be because of a blood disorder.
- You have severe abdominal pain and bloating, are being sick and have constipation. These may be signs that your intestine is not working properly.

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.
- Feeling confused, restless, sweating, shaking, shivering, hallucinations, sudden jerks of the muscles or a fast heartbeat, you may have something called Serotonin Syndrome.
- Feeling very unwell, possibly with shortness of breath, 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.

The following side effects have also been reported:

- Drowsiness or sleepiness, tiredness.
- Headache, dizziness, confusion, feeling less alert, agitation, anxiety.
- Overactive behaviour or thoughts, believing things that are not true, memory disturbance, difficulty speaking.
- Sweating, unexplained fever or shivering, flu like symptoms.
- Feeling sick or vomiting, indigestion.
- Constipation or diarrhoea.
- Dizziness while standing up from sitting or lying, fainting.
- Chest pain, high blood pressure.
- Dry mouth, altered taste, increased amounts of saliva, blocked nose and blurred vision.
- Weakness, pain in your limbs, back, muscles and joints.
- Weight loss, altered appetite.
- Slow or racing pulse, irregular heartbeat.
- Frequent infections with high temperature, severe chills, sore throat or mouth ulcers. These could be signs of blood problems.
- Higher than normal number of white blood cells (seen by a blood test).
- Water retention which may cause swollen arms or legs
- Restlessness or difficulty sleeping, nightmares.
- Decreased sex drive.
- Feeling dizzy, possibly with a “spinning” feeling.
- Difficulty in urination.
- Skin rashes, itching.
- Any uncontrolled body movements, including tremor, twitching, spasms, muscle rigidity and an inability to sit still.
- Altered liver function, abnormal liver enzymes in your blood (shown by a blood test).
- Severe liver disorder such as hepatitis.
- Liver failure with potential fatal outcome.
- 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.

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 national reporting system](#):

United Kingdom: Yellow Card Scheme. Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

Ireland: HPRA Pharmacovigilance. Website: www.hpra.ie

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.

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. Keep the bottle in the outer carton in order to protect from light.
Once opened use within 1 month.

Do not use this medicine if you notice any visible signs of deterioration.

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 Hydrochloride Oral Solution 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, sodium hydroxide solution (for pH-adjustment) and purified water.

What Trazodone looks like and contents of the pack

Trazodone is a clear, colourless solution with pungent taste and orange flavour. It is supplied in an amber glass bottle with a polypropylene child resistant cap containing 120 ml of solution. The pack also contains a clear polypropylene measuring cup with 2.5, 5, 7.5, 10 and 15 ml graduations.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Alissa Healthcare Research Limited

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This medicinal product is authorised in the Member States of the EEA under the following names:

United Kingdom: Trazodone Hydrochloride 50 mg/5 ml Oral Solution

Ireland: Trazodone Hydrochloride 50 mg/5 ml Oral Solution

This leaflet was last revised in 08/2020