

Package Leaflet: Information for the user
TRAZODONE HYDROCHLORIDE 50MG/5ML 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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Trazodone oral solution is and what it is used for
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1. What Trazodone oral solution is and what it is used for

The name of your medicine is Trazodone hydrochloride 50mg/5ml Oral solution (called Trazodone oral solution throughout this leaflet). Trazodone oral solution contains the active substance called trazodone hydrochloride which belongs to a group of medicines called antidepressants. Trazodone oral solution can be used to treat all types of depression including depression accompanied by anxiety.

2. What you need to know before you take Trazodone oral solution

Do not take Trazodone oral solution:

- 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, eyelids, face, throat or tongue, unexplained high temperature (fever) and feeling faint
- If you have recently had a heart attack
- If you are a heavy drinker or taking sleeping tablets
- If you are under 18 years of age.

Do not take Trazodone oral solution if the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking Trazodone oral solution.

Warnings and precautions

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.

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 oral solution or if you have some other diseases.

Talk to your doctor, pharmacist or nurse before taking Trazodone oral solution if you:

- Have or have ever had fits or seizures
- 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

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

Children and adolescents

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

Other medicines and Trazodone oral solution

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 Oral Solution works.

Some medicines and trazodone may interfere with each other. Tell your doctor if you are taking any of the following medicines:

- MAOI (Mono Amine Oxidase Inhibitors) medicines such as tranylcypromine, 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**
- Other antidepressants (such as amitriptyline or fluoxetine)
- Sedatives (Such as tranquilizers or sleeping pills)
- Medicines used to treat epilepsy (e.g. carbamazepine or phenytoin)
- Medicines used to treat high blood pressure (e.g. clonidine) or heart disease (e.g. digoxin)
- Medicines used to treat fungal infections such as ketoconazole and itraconazole

- Some medicines used to treat HIV such as ritonavir and indinavir
- Erythromycin (a type of 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)
- Phenothiazines: chlorpromazine, fluphenazine, levomepromazine, perphenazine
- Antihistamines (used to treat allergies)
- Oral contraceptives
- Cimetidine (used to treat ulcers)

Anaesthetics

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

Trazodone oral solution with food, drink and alcohol

You should avoid drinking alcohol while taking Trazodone oral solution. This is because trazodone can change the way alcohol affects you.

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

Trazodone oral solution should not be taken during the first three months of pregnancy. Taking Trazodone in the late stages of pregnancy may lead to your baby experiencing withdrawal symptoms when they are born.

Breast-feeding

Trazodone can pass into breast-milk and should only be used if the benefit to the mother outweighs the risk to the child.

Driving and using machines

Trazodone oral solution is a drug which acts on the central nervous system and may make you feel sleepy or dizzy. Do not drive, operate machinery or do anything that requires you to be alert until you know how your medicine affects you.

Trazodone oral solution contains sorbitol, propylene glycol, benzoic acid, glycerol and sodium.

- Trazodone oral solution contains 2g of sorbitol in each 5ml. Sorbitol is a source of fructose. If your doctor has told you that you 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 take this medicine. Sorbitol may cause gastrointestinal discomfort and mild laxative effect.
- This medicine contains 15.5-16.75 mg propylene glycol in each 5ml
- This medicine contains 5 mg benzoic acid in each 5ml.
- This medicine contains glycerol which may cause headache, stomach upset and diarrhea.
- This medicine contains less than 1 mmol sodium (23 mg) per 5ml, that is to say essentially 'sodium-free'.

3. How to take Trazodone 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.

The dose of trazodone will depend on your needs and the illness being treated.

Taking this medicine

- Take this medicine by mouth
- Take with or after food. This can help lower the chances of side effects
- If you have been told to take Trazodone oral solution 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 too strong, do not change the dose yourself, but ask your doctor.

DEPRESSION:

The recommended dose is -

Adults:

- Adults usually start by taking 150mg (15ml) each day
- Your doctor may increase the dose to 300mg (30ml) each day depending on your condition
- For adults in hospital the dose may be as high as 600mg (60ml) each day.

Elderly:

- Older people or those who are frail will usually be given a starting dose of 100mg (10ml) each day
- Your doctor may increase the dose to 300mg (30ml) each day depending on your condition
- Doses of more than 300mg (30ml) will not normally be given.

ANXIETY:

The recommended dose is -

- Adults usually start by taking 75mg (7.5ml) each day
- Your doctor may increase the dose to 300mg (30ml) each day.

Use in children and adolescents

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

Note:

If necessary, Trazodone oral solution can be administered via a nasogastric, nasoduodenal or nasojejunal feeding tube that should be rinsed twice with 10ml of water immediately after administration.

If you take more Trazodone oral solution than you should

It is important to stick to the dose on the label of the medicine. If you take more Trazodone oral solution than you should, contact your doctor or nearest hospital emergency department immediately. Always take any medicine left over with you along with the box, as this will allow easier identification of the medicine.

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 oral solution

If you forget to take a dose, take it as soon as you remember. If it is almost time for your next dose do not take a double dose to make up for a forgotten dose, just carry on as before.

If you stop taking Trazodone oral solution

- Keep taking Trazodone oral solution until your doctor tells you to stop. Do not stop taking Trazodone oral solution just because you feel better
- When your doctor tells you to stop taking this medicine he/she will help you stop taking them gradually
- Stopping your medicine too quickly could cause sleep problems, leave you feeling more irritable than usual and cause you to sweat more than usual.

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

4. Possible side effects

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

Stop taking Trazodone oral solution and tell your doctor immediately if you experience:

- 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 oral solution
- Painful erection of the penis, unrelated to sexual activity, that will not go away (priapism)
- Yellowing of the eyes or skin which could be a liver problem (such as jaundice) or other abnormalities of liver function
- 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)
- You have severe abdominal pain and bloating, are 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.

The following side effects have also been reported (Not known: frequency cannot be estimated from the 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 of 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 leucopenia
- 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 potential 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme Website: 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 oral solution

- 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 the month
- Store in the original package (bottle) in order to protect from light. This medicinal product does not require any special temperature storage conditions
- 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 oral solution contains

The name of this medicine is Trazodone hydrochloride 50mg/5ml oral solution.

- The active substance is trazodone hydrochloride. Each 5ml spoonful contains 50mg of the trazodone hydrochloride
- The other ingredients are benzoic acid, glycerol, sorbitol liquid, orange flavour (containing propylene glycol), sodium saccharin, sodium hydroxide and purified water.

What Trazodone oral solution looks like and contents of the pack

Trazodone oral solution is a clear, colourless to pale yellow coloured solution, with orange colour, free from foreign particles. Each bottle contains 120ml of solution.

Marketing Authorisation Holder and Manufacturer

Mercury Pharmaceuticals Ltd.,

Dashwood House, 69 Old Broad Street, London, EC2M 1QS, United Kingdom

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