Trazodone hydrochloride
50mg/5ml Oral Solution

Read all of this leaflet carefully before you start taking this medicine

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:
1. What trazodone hydrochloride oral solution is and what it is used for
2. Before you take trazodone hydrochloride oral solution
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4. Possible side effects
5. How to store trazodone hydrochloride oral solution
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1. What trazodone hydrochloride oral solution is and what it is used for

The name of your medicine is Trazodone hydrochloride 50mg/5ml 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 anxiety and depression.

2. Before you take trazodone hydrochloride oral solution

- Do not take this medicine and tell your doctor if:
  - You are allergic (hypersensitive) to trazodone hydrochloride or any of the other ingredients of trazodone (listed in Section 6 Further Information).
  - You have recently had a heart attack
  - You have recently had a heart attack
  - You have a heavy drinker or are taking sleeping tablets
  - 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.

- Take special care with 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 like 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.

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

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 if 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
- 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

Do not take this medicine and tell your doctor if any of the above applies to you. Talk to your doctor or pharmacist before taking trazodone.

3. How to take trazodone hydrochloride oral solution

Trazodone can be used to treat anxiety and depression.

50mg/5ml Oral Solution (called trazodone in this leaflet).

The name of your medicine is Trazodone hydrochloride

4. Possible side effects

You may have some or all of the following side effects:

- Changes in behaviour in adults aged less than 25 years with psychiatric conditions who were treated with an antidepressant.
- Other antidepressants (such as amitriptyline or fluoxetine)

5. How to store trazodone hydrochloride oral solution

6. Further information

- 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
- 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 food and drink
You should avoid drinking alcohol while taking trazodone.

Pregnancy and breast-feeding
Talk to your doctor before taking this medicine if you are pregnant, might become pregnant, or think you may be pregnant.

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.

Important information about some of the ingredients of trazodone
• Trazodone contains sorbitol. If you have been told that you cannot digest or tolerate some sugars, talk to your doctor before taking trazodone.
• Trazodone contains glycerol which may cause a headache, an upset stomach and diarrhoea.

3. How to take trazodone hydrochloride oral solution

How much to take

Adults:
• Depression
  • 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
• Anxiety
  • Adults usually start by taking 75mg (7.5ml) each day
  • Your doctor may increase the dose to 300mg (30ml) each day
• Elderly
  • Older people or those who are frail will usually be given a starting dose of 100mg (10ml) each day
  • Doses of more than 300mg (30ml) will not normally be given
• Children
  • 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 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 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.

4. Possible side effects

Like all medicines, trazodone 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 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
• Jerking movements that you cannot control, mainly in your joints.
• Pain in limbs, back pain, pain in your muscles, chest pain.
• Skin rash, itching.
• Water retention which may cause swollen arms or legs.
• Feeling restless and having difficulty sleeping.
• Feeling dizzy or light-headed on standing or sitting up.
• Loss of appetite and weight loss.
• Blurred vision.

Dizziness, headache, confusion, weakness, tremor (shaking).

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

• You have thoughts of harming or killing yourself.
• Feeling tired, weak and confused, having muscle that aches, are stiff or do not work well. There may also 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.
• 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 muscle that ache, are still 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 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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store trazodone hydrochloride oral solution

Keep this medicine in a safe place where children cannot see or reach it.

Do not use trazodone 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 and protect from light.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

What trazodone contains

• Each 5ml of trazodone contains:
• 50mg of the active substance, trazodone hydrochloride.
• Other ingredients include glycerol, sorbitol, benzoic acid, saccharin sodium, orange flavour FC 901775, sodium hydroxide solution 1N, purified water and nitrogen.

What Trazodone Liquid looks like and contents of the pack

Trazodone is a clear colourless solution that smells and tastes of orange. It is supplied in an amber glass bottle containing 120ml of solution.
Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Zentiva, One Onslow Street, Guildford, Surrey, GU1 4YS, UK.

Manufacturer
Unither Liquid Manufacturing
1-3 Allee de la Neste
Z.I. d'en Sigal
31770 Colomiers,
France

This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

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