

Package leaflet: Information for the user

Trazodone Hydrochloride 50mg/5ml Oral Solution

Trazodone Hydrochloride

Seven important things you need to know about Trazodone Oral Solution.

You should read all of this leaflet carefully before taking your medicine. It includes a lot of additional important information.

- **Trazodone Oral Solution treats depression and depression accompanied by anxiety.** Like all medicines it can cause side effects. Before you start taking your medicine it is important that you and your doctor discuss the benefits of treatment against the possible side effects (see section 4, Possible side effects).
- **Trazodone Oral Solution should not be used by children and adolescents under 18 years old** (see section 3, How to take Trazodone Oral Solution).
- **Some people who are depressed or anxious think of harming or killing themselves.** If you start to feel worse, or think of harming or killing yourself, **see your doctor or go to a hospital straight away** (see section 4, Possible side effects).
- **Trazodone Oral Solution may not work straight away.** Some people taking antidepressants feel worse before feeling better. Your doctor should ask to see you again in a couple of weeks after you first start treatment. Tell your doctor if you haven't started feeling better (see section 3, How to take Trazodone Oral Solution).
- **Don't stop taking Trazodone Oral Solution without talking to your doctor** (see section 3, How to take Trazodone Oral Solution).
- **Taking some other medicines with Trazodone Oral Solution can cause problems.** You may need to talk to your doctor (see section 2, What you need to know before you take Trazodone Oral Solution).
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Read all of this leaflet carefully before you start using 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

2. What you need to know before you take Trazodone Oral Solution
3. How to take Trazodone Oral Solution
4. Possible side effects
5. How to store Trazodone Oral Solution
6. Contents of the pack and other information

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 Hydrochloride 50mg/5ml Oral Solution contains active substance Trazodone Hydrochloride.

What this medicine does

Your doctor has prescribed Trazodone Oral Solution to treat depression, including depression accompanied by feelings of anxiety.

Trazodone hydrochloride belongs to a group of medicines called antidepressants. Everyone has natural substances called serotonin and noradrenaline in their brain which help to lighten your mood. People who are depressed or anxious have lower levels of serotonin and noradrenaline than others. Trazodone hydrochloride works by helping to prolong the mood lightening effect of serotonin and noradrenaline which has been released in the brain.

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)
- If you are a heavy drinker or are taking sleeping tablets
- If you have recently had a heart attack.

Symptoms of an allergic reaction may include a red and lumpy skin rash, difficulty breathing or swallowing, swelling of eyelids, face, lips, mouth or tongue, unexplained high temperature (fever) and feeling faint. **If the swelling affects your throat and makes breathing and swallowing difficult, go to hospital straight away.**

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 disease.

Talk to your doctor, pharmacist or nurse before taking Trazodone Oral Solution.

- If you have severe liver, kidney or heart problems
- If you have epilepsy (fits) or seizures. Your doctor will monitor your dosage carefully
- If you are pregnant, trying to become pregnant or are breast-feeding
- If you have an overactive thyroid gland (hyperthyroidism)
- If you have difficulty passing water (urine), or need to pass water more frequently
- If you suffer from increased pressure or pain in the eye (narrow angle glaucoma)
- If you suffer from schizophrenia or any other type of mental disorder.
- **If you start to have a manic period whilst taking this medicine, tell your doctor immediately**

Children and adolescents

- Trazodone oral solution should **not** be used in children and adolescents under 18 years old

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.

- **Erythromycin** (an antibiotic, used to treat infections); if taken with trazodone, you may have more serious side effects and your doctor may decide to change your dose of Trazodone Oral Solution
- **Ketoconazole** or **Itraconazole** (used to treat fungal infections); if taken with trazodone, you may have more serious side effects and your doctor may decide to change your dose of Trazodone Oral Solution
- **Ritonavir** or **Indinavir** (for HIV infections); if taken with trazodone, your doctor may need to change your dose of Trazodone Oral Solution and you may experience increased side effects

- **Carbamazepine** (used to control epilepsy and also to treat serious mood disorders e.g. manic depression); if taken with trazodone, your doctor will need to monitor you carefully and may need to change your dose of Trazodone Oral Solution
- **Muscle relaxants** such as diazepam (used to relieve muscle spasms); if taken with trazodone, your doctor may need to change your dose of muscle relaxant
- **Other sedative and antidepressant drugs** e.g. diazepam (a sedative, used to help you relax) and citalopram, nefazodone or fluoxetine (used for treating depression); if taken with trazodone, you may have more serious side effects and your doctor may decide to change your dose of Trazodone Oral Solution
- **Antidepressant medicines known as tricyclics** e.g. amitriptyline; your doctor may decide not to give you trazodone at the same time due to the possibility of increased side effects
- **Monoamine Oxidase Inhibitors (MAOIs)** such as phenelzine, isocarboxazid, tranylcypromine and moclobemide, used to treat depression and selegiline, used to treat Parkinson's disease
 - **Wait 14 days** after stopping an MAOI before you take Trazodone Oral Solution
 - **Wait 7 days** after stopping Trazodone Oral Solution before starting an MAOI
- **Clonidine** (used to treat high blood pressure, migraine and menopausal flushing); if taken with trazodone, this medicine may not be as effective
- **Other drugs used to treat high blood pressure**; if taken with trazodone, the effects of these medicines may be enhanced
- **Digoxin** (used to treat heart failure and other heart problems); if taken with trazodone, your doctor will need to monitor you carefully
- **Phenytoin** (used to control epilepsy); if taken with trazodone, your doctor will need to monitor you carefully
- **Oral contraceptives**; if taken with trazodone, your doctor may need to change your dose of Trazodone Oral Solution
- **Barbiturates** (medicines to help you sleep); if taken with trazodone, your doctor may need to change your dose of Trazodone Oral Solution
- **Cimetidine** (for heartburn and stomach ulcers); if taken at the same time as trazodone, you may experience increased side effects
- **Levodopa** (used to treat Parkinson's disease); if taken with trazodone, this medicine may not be as effective
- **Medicines for treating mental illnesses (phenothiazines)** e.g. chlorpromazine, fluphenazine, levomepromazine or perphenazine; if taken with trazodone, you may experience increased side effects
- **St. John's Wort** (a herbal remedy for depression); if taken with trazodone, you may experience increased side effects
- **Warfarin** (used to thin the blood); if taken with trazodone, the time it takes your blood to clot could be affected.

Anaesthetics

If you are going to have an anaesthetic (for an operation), tell your doctor or dentist that you are taking trazodone oral solution as it may affect drugs you are given during the procedure.

Trazodone Oral Solution with food, drink and alcohol

- Trazodone Oral Solution can be taken with, or without food (see section 3, **How to take Trazodone Oral Solution**). Taking Trazodone Oral Solution with food can help to lower the chances of side effects such as feeling or being sick
- You should avoid drinking alcohol whilst taking Trazodone Oral Solution.

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. If you have been taking Trazodone Oral Solution during the late stages of pregnancy, your baby may experience 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 may make you feel drowsy, therefore care should be taken when driving or operating machinery.

Do not drive or use machines if you feel dizzy, sleepy, or your coordination is affected.

Trazodone Oral Solution contains:

- This medicine contains less than 1 mmol sodium (23 mg) per 5ml, that is to say essentially 'sodium-free'
- This medicine contains 500mg 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 5 mg benzoic acid in each 5ml.
- This medicine contains maximum of 9.86mg of propylene glycol in each 5ml.
- This medicine contains 0.1-0.2mg of benzyl alcohol in each 5ml. Benzyl alcohol may cause allergic reactions. Ask your doctor or pharmacist for advice if you are pregnant or breast-feeding, if you have a liver or kidney disease. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called "metabolic acidosis")
- This medicine contains 0.079mg of alcohol (ethanol) in each 5ml, which is equivalent to 0.0158mg/ml. The amount in 5 ml of this medicine is equivalent to less than 0.002 ml beer or 0.001 ml wine. The small amount of alcohol in this medicine will not have any noticeable effects.

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.

- Your doctor may tell you to take your medicine either in divided doses, after food, or as a single dose before you go to bed
- This medicine must not be mixed with other medicines.

The recommended dose is.

Adults

- The usual starting dose is 15ml (150mg trazodone hydrochloride) daily
- This may be increased to 30ml (300mg trazodone hydrochloride) daily
- If you are in hospital you may be given a higher dose, of up to 60ml (600mg trazodone hydrochloride) daily.

Use in children and adolescents

- Trazodone Oral Solution should **not** be given to children and adolescents under 18 years of age.

Elderly

- The usual starting dose is 10ml (100mg trazodone hydrochloride) daily
- This may be increased gradually to a maximum of 30ml (300mg trazodone hydrochloride) daily.

It may take 1 to 2 weeks of treatment before you begin to feel better. This is normal for this type of medicine. Your doctor should ask to see you 3 to 4 weeks after you start taking your medicine. If you do not feel any better, tell your doctor.

You must continue to take your medicine for as long as the doctor tells you to even if you feel better; this may be for several months after you start to feel better.

Do not stop taking Trazodone Oral Solution suddenly. Your doctor will tell you how to reduce your dose gradually to help lower the chance of you getting withdrawal symptoms.

Stopping Trazodone Oral Solution suddenly can lead to **withdrawal symptoms** such as feeling sick, headaches and feeling generally unwell.

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

- If you take more Trazodone Oral Solution than your doctor has told you to, contact your nearest hospital or casualty department immediately and take your Trazodone Oral Solution with you. This is so the doctor knows what you have taken.
- Symptoms of overdose may include feeling sick, or being sick, drowsiness, dizziness or feeling faint, seizures (fits), confusion, breathing difficulties, fast, slow

or uneven heartbeat, coma or hyponatraemia (abnormally low levels of sodium in your blood).

If you forget to take Trazodone Oral Solution

- If you forget to take a dose, do not worry. Take the next dose when it is due
- Do not take a double dose to make up for a forgotten dose.

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 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 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).
- You have thoughts of harming or killing yourself.

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

- 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:

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
- Becoming aggressive
- Difficulty or not being able to pass urine
- 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 [national reporting system]. 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 carton and bottle label after Exp:. The expiry date refers to the last day of that month.

Do not store above 25°C.

Keep the bottle in the outer carton in order to protect from light.

Once opened, use within one month.

Do not use this medicine if you notice any visible signs of damage to the bottle or deterioration in your medicine. Return it to your pharmacist.

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 active substance is trazodone hydrochloride. Each 5ml of Trazodone Oral Solution contains 50mg of trazodone hydrochloride
- The other ingredients are benzoic acid, sodium saccharin, hypromellose, sorbitol (E420), glycerol, orange flavour (contains propylene glycol, benzyl alcohol and ethanol), citric acid monohydrate, sodium citrate and purified water (see section 2, **What you need to know before you take Trazodone Oral Solution**).

What Trazodone Oral Solution looks like and contents of the pack

Trazodone Oral Solution is a colourless to yellowish clear to slightly opalescent solution with a characteristic odour of orange. It is available in an amber glass bottle containing 120ml of medicine.

Marketing Authorisation Holder

For IE- Amdipharm Limited, Temple Chambers, 3 Burlington Road, Dublin 4, Ireland.

For UK- Focus Pharmaceuticals Limited, Capital House, 85 King William Street, London EC4N 7BL, UK.

Manufacturer

HELP S.A., Pedini Ioannina, 45500 Ioannina, Greece.

For any information about this medicinal product, please contact the Marketing Authorisation Holder, details provided above.

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