

## Package leaflet: Information for the user

### Trazodone Hydrochloride 50mg/5ml Oral Solution

Trazodone Hydrochloride

**You and your caregiver should 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 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 50mg/5ml Oral Solution (called Trazodone Oral Solution throughout this leaflet).

The active substance is trazodone hydrochloride. This belongs to a group of medicines called antidepressants.

Trazodone Oral Solution can be used to treat anxiety and depression.

#### 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).  
Signs of an allergic reaction can include: red and lumpy skin rash, swallowing or breathing problems, swelling of your eyelids, lips, 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 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 Oral Solution.

#### Warnings and precautions

##### Take special care with 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.

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 or pharmacist 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
- 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 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.

**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**
- 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 Oral Solution.

**Trazodone Oral Solution with food, drink and alcohol**

You should avoid drinking alcohol while taking Trazodone Oral Solution.

**Pregnancy, breast-feeding and fertility**

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

Taking Trazodone Oral Solution 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 Oral Solution 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 other ingredients in Trazodone Oral Solution**

Your medicine contains:

- **Sorbitol** - 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.
- **Glycerol** - may cause, headache, stomach upset and diarrhoea
- **Ethanol** – this medicinal product contains small amounts of ethanol (alcohol), less than 100mg per dose.
- **Sodium benzoate** - may increase jaundice (yellowing of the skin and eyes) in new-born babies (up to 4 weeks old).

**3. How to take Trazodone Oral Solution**

**Always take this medicine 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.
- 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 strong, do not change the dose yourself, but ask your doctor.

**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 and adolescents:**

Children and adolescents under 18 years should not take trazodone oral solution

Note:

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

**If you take more Trazodone Oral Solution than you should**

If you take more Trazodone Oral Solution 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 Oral Solution**

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 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 to stop taking it gradually.

**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.
- You have a painful erection of the penis, unrelated to sexual activity, that will not go away (priapism).
- You have yellowing of the eyes or skin. This could be a liver problem (such as jaundice).
- You are getting infections more easily than usual. This could be because of a blood disorder (agranulocytosis).
- You are 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.

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

- 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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL-Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: [www.hpra.ie](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie). 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 Trazodone Oral Solution 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.

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

After first opening, do not store above 25°C and use within 1 month.

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. 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 Sorbitol liquid (Non-crystallizing), Glycerol, Sodium benzoate, Saccharin sodium, Concentrated hydrochloric acid solution (for pH adjustment), Purified water and Orange flavour (14104/04) containing Ethanol, Propylene glycol and Triacetin.

### **What Trazodone Oral Solution looks like and contents of the pack**

Trazodone Oral Solution is a colourless to yellowish clear solution with an orange odour. It is available in an amber glass bottle with white child-resistant high-density polyethylene (HDPE) cap containing 120ml of medicine.

The pack also contains a 20 ml plastic measuring cup with intermediate graduations of 2.5 / 5 / 10 / 15 / 20 ml.

### **Marketing Authorisation Holder**

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### **Manufacturer**

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