

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.

The name of your medicine is "Trazodone hydrochloride 50mg/5ml Sugar Free Oral Solution" but it will be referred to as "Trazodone" throughout this leaflet.

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
6. Contents of the pack and other information

1. What Trazodone is and what it is used for

This medicinal product contains trazodone hydrochloride. This belongs to a group of medicines called antidepressants.

Trazodone can be used to treat anxiety and depression.

2. What you need to know before you take Trazodone

Do not take Trazodone if:

- ▶ you are allergic (hypersensitive) to trazodone hydrochloride or any of the other ingredients of Trazodone (listed in Section 6). Signs of an allergic reaction can include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue
- ▶ you have recently had a heart attack
- ▶ you are 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.

Warnings and precautions

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 likely to think like this if:

- ▶ you have previously had thoughts about killing or harming yourself
- ▶ 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.

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

Other medicines and Trazodone

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines you buy without or with 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**
- ▶ 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.

Trazodone with food, drink and alcohol

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.

Trazodone contains:

Sorbitol (E420): This medicine contains 997.5mg sorbitol in each 5ml dose. 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 or receive this medicine. Sorbitol may cause gastrointestinal discomfort and mild laxative effect.

Glycerol (E422): May cause headache, stomach upset and diarrhoea.

Methyl parahydroxybenzoate (E218) and Propyl parahydroxybenzoate (E216), which may cause allergic reactions (possibly delayed).

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 using dosing device
- ▶ 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:

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 depending on your condition.

TURN OVER



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.

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

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
- ▶ painful erection of the penis, unrelated to sexual activity, that will not go away (priapism)
- ▶ yellowing of the eyes or skin. This could be a liver problem (such as jaundice)
- ▶ 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 ilius).

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 (parasthesia)
- ▶ 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 can not control, mainly 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 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 Yellow Card Scheme Website at: 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

- ▶ Keep out of the sight and reach of children.
- ▶ Do not use after the expiry date, which is clearly marked on the carton and bottle label 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.
- ▶ Discard 30 days after first opening.
- ▶ Do not use this medicine if you notice that the solution becomes discoloured or shows any signs of deterioration. Seek the advice of your pharmacist.
- ▶ 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 contains

Each 5ml of Trazodone contains 50mg of trazodone hydrochloride.

Other ingredients include methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216), glycerol (E422), liquid sorbitol (non-crystallising) (E420), saccharin sodium (E954), orange flavour [contains propylene glycol (E1520)], sodium hydroxide (for pH-adjustment) and purified water.

What Trazodone looks like and contents of the pack

Trazodone is a clear colourless to yellow colour oral solution with an orange odour and taste supplied in amber glass bottles with tamper-evident child-resistant polypropylene plastic screw cap and a 30ml measuring cup having 5ml graduation with intermediate graduation at 2.5ml and 7.5ml only.

Trazodone is supplied in bottles containing 120ml oral solution.

Marketing Authorisation Holder

SyriMed
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Manufacturer

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POM

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

UK and MT: Trazodone hydrochloride 50mg/5ml Sugar Free Oral Solution

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