

Package leaflet: Information for the user

Trazodone hydrochloride 150 mg Film-coated Tablets

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 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 Tablets is and what it is used for
2. What you need to know before you take Trazodone Tablets
3. How to take Trazodone Tablets
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6. Contents of the pack and other information

1. What Trazodone Tablets is and what it is used for

The name of this medicine is Trazodone hydrochloride 150 mg film-coated tablets (referred to as Trazodone Tablets throughout this leaflet). Trazodone Tablets contain a medicine called trazodone hydrochloride. Trazodone belongs to a group of medicines called antidepressants.

Trazodone Tablets is used to treat depression and depression accompanied by anxiety.

2. What you need to know before you take Trazodone Tablets

Do not take Trazodone Tablets if

- You are allergic to active substance or any of the other ingredients of this medicine (listed in Section 6). The symptoms of an allergic reaction can include: a rash, swelling of your lips, face, throat or tongue, swallowing or breathing problems,

- You have recently had a heart attack
- You are taking sleeping tablets or a heavy drinker
- 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 Tablets.

Warnings and precautions

Talk to your doctor or pharmacist before taking Trazodone Tablets if any of the following points apply to you:

- Have or have ever had fits or seizures (epilepsy)
- 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
- are taking buprenorphine (a strong pain killer). The use of buprenorphine with Trazodone can lead to serotonin syndrome, a potentially life-threatening condition (see “Other medicines and Trazodone Tablet”).

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

Take special care with Trazodone Tablets.

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.

There have been reports of severe liver disorders with use of Trazodone Tablets. If you experience any of the following symptoms you must contact your doctor immediately:

- Weakness (asthenia)
- Loss of appetite (anorexia)
- Nausea, vomiting
- Stomach pain
- Yellowing of the skin and/or eyes (jaundice)

Elderly

Elderly patients when taking Trazodone Tablets may experience light headedness and dizziness upon standing or stretching. They may also feel more drowsy or sleepy than usual.

Increased caution is necessary especially if the patient suffers from other ailments and is taking medications to treat these, along with taking Trazodone.

Children and adolescents:

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

Other medicines and Trazodone Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines you buy without a prescription, including herbal medicines. This is because Trazodone Tablets can affect the way some other medicines work. Also some medicines can affect the way Trazodone Tablets work.

Tell your doctor if you are taking any of the following medicines:

- MAOI (Monoamine Oxidase Inhibitors) medicines such as tranylcypromine, phenelzine and isocarboxazid (for depression) or selegiline (for Parkinson's disease), or have taken them in the last 2 weeks
- Sedatives (such as tranquilizers or sleeping pills)
- Medicines used to treat epilepsy such as carbamazepine and phenytoin
- Other antidepressants (such as amitriptyline or fluoxetine)

- Phenothiazines - antipsychotic medicines used in the treatment of schizophrenia and other mental disorders
- Medicines used to treat fungal infections such as ketoconazole and itraconazole
- Medicines used to treat high blood pressure for example, clonidine
- Erythromycin, an antibiotic used to treat infections
- Medicines used to treat Parkinson's disease (such as Levodopa)
- Some medicines used to treat HIV such as ritonavir and indinavir
- St. John's Wort (a herbal remedy)
- Digoxin (used to treat heart problems)
- Warfarin (used to stop your blood from clotting)
- Buprenorphine- used to treat pain This- medicine may interact with trazodone and you may experience symptoms such as involuntary, rhythmic contractions of muscles, including the muscles that control movement of the eye, agitation, hallucinations, coma, excessive sweating, tremor, exaggeration of reflexes, increased muscle tension, body temperature above 38°C. Contact your doctor when experiencing such symptoms.

Anaesthetics

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

Trazodone with food and drink and alcohol

You should avoid drinking alcohol while taking Trazodone Tablet.

Pregnancy and breast-feeding and fertility

Pregnancy

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

Trazodone Tablets should only be taken during pregnancy if recommended by your doctor.

Taking Trazodone Tablets during pregnancy may lead to your baby experiencing withdrawal symptoms when they are born. In this case, monitoring of your newborn should be performed by your doctor. If you are breast-feeding or planning to breast-feed, talk to your doctor or pharmacist before taking any medicine.

Breast-feeding

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 Tablets may make you feel sleepy or dizzy. Do not drive or use hazardous machinery unless you are sure that you are not affected.

Trazodone Tablet contains lactose monohydrate

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product

3. How to take Trazodone Tablets

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Taking this medicine

- Take this medicine by mouth.
- Swallow the tablets whole with a drink of water. The tablets may begin disintegrating as soon as they are placed in the mouth.
- Take with or after food. This can help lower the chances of side effects
- If you have been told to take Trazodone Tablets 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 score line is only there to help you break the tablet if you have difficulty swallowing it whole.

How much to take

Adults:

Depression

- Adults usually start by taking 75 mg to 150 mg each day
- Your doctor may increase this to up to 300 mg per day depending on your condition
- For adults in hospital the dose may be as high as 600 mg per day

A starting dose of 75 mg is not achievable with this 150 mg tablet, therefore another formulation/strength should be used.

Elderly

Older people or those who are frail will usually be given a starting dose of 100 mg each day.

A dose of 100mg is not achievable with this 150mg tablet, therefore another formulation/strength should be used.

Children

Trazodone Tablet is not recommended for children and adolescents under the age of 18.

If you take more Trazodone than you should

If you take more Trazodone Tablets 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 Tablet until your doctor tells you to stop. Do not stop taking Trazodone Tablet just because you feel better. When your doctor tells you to stop taking these Tablet he/she will help you stop taking them gradually.

4. Possible side effects

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

Stop taking Trazodone Tablet 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 Tablet.
- Painful erection of the penis, unrelated to sexual activity, that will not go away (priapism)
- Loss of appetite, feeling sick or being sick, confusion, abdominal pain, fever, yellowing of the eyes or skin (jaundice). These could be symptoms of a serious liver problem (such as hepatitis)

- 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 (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(somnolence)
- Feeling less alert than usual
- Feeling weak
- 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

- Rapid or slow heartbeat
- Feeling dizzy or light-headed on standing or sitting up quickly (postural hypotension), fainting (syncope)
- Feeling agitated, restless, anxious or more nervous than normal
- Difficulty sleeping, nightmares
- Water retention which may cause swollen arms or legs
- Skin rash, itching
- Chest pain
- Pain in limbs muscles or joints, flu like symptoms
- 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
- 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 potentially 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 suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system listed in [Appendix V](#).

5. How to store Trazodone tablets

- Keep this medicine out of the sight and reach of children.
- This medicinal product does not require any special storage conditions.
- Do not use this medicine after the expiry date which is stated on the blister and carton after EXP. The expiry date refers to the last day of that month.
- 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 Tablets contain

- The **active** substance is Trazodone (as the hydrochloride).
- Each tablet contains 150 mg of Trazodone hydrochloride.
- The **other** ingredients are:
Core: Lactose monohydrate, Microcrystalline cellulose, Magnesium stearate
Coating: Hypromellose, Titanium dioxide (E171), Red Iron oxide (E172) and Yellow Iron Oxide (E172).

What Trazodone Tablets look like and contents of the pack

- Trazodone 150mg Tablets are salmon pink colour, round biconvex film coated tablets having lipped break line on one side and “BL 150” embossing on other side (11.00mm in diameter).
- Trazodone Tablets are available in blister packs of 28 and 100 Tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

<To be completed nationally>

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

< {Name of the Member State} > < {Name of the medicinal product} >
 < {Name of the Member State} > < {Name of the medicinal product} >

This leaflet was last revised in month MM/YYYY