

Package leaflet: Information for the patient

Trazodone 150 mg 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 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
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1. What Trazodone is and what it is used for

Trazodone contains the active substance trazodone hydrochloride. This belongs to a group of medicines called antidepressants. Trazodone is used to treat symptoms of depression (major depressive episodes) in adults.

2. What you need to know before you take Trazodone

Do not take Trazodone:

- 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 include a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- If you have recently had a heart attack (acute myocardial infarction)
- If you are drunk or under the influence of sleeping tablets (alcohol intoxication or intoxication with hypnotics)

Warnings and precautions

Thoughts of suicide and worsening of your depression

If you are depressed 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, 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. 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 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 medicines to treat these, along with taking Trazodone.

Talk to your doctor or pharmacist before taking this medicine if you:

- Have or have ever had fits or seizures
- Have liver or kidney problems, particularly if severe
- Have heart disease (such as cardiovascular insufficiency, angina pectoris, conduction disorders or AV blocks of different degree, arrhythmias, recent myocardial infarction, congenital long QT syndrome or bradycardia)
- Have low levels of potassium in your blood (hypokalaemia) that can cause muscle weakness, twitching, abnormal heart rhythm
- Have low levels of magnesium in your blood (hypomagnesemia)
- Have an overactive thyroid gland (hyperthyroidism)
- Have problems passing water or need to pass water (urine) frequently
- Have an enlarged prostate
- Have narrow angle glaucoma (an eye disorder)
- Have low blood pressure (hypotension)
- Have schizophrenia or other type of mental disorder
- Are elderly, as you may be more prone to side effects such as lowered blood pressure when standing up quickly from a sitting or lying position (orthostatic hypotension), sometimes accompanied by dizziness, and inability to stay still, mental arousal state, seeing things that are not really there (hallucinations) or hyponatraemia (low levels of sodium in your blood, that can make you feel tired, weak or confused and have aching, stiff or uncoordinated muscles)

If you have liver disease, kidney disease, heart disease, suffer from epilepsy, have raised eye pressure (glaucoma), problems with urination or your prostate gland your doctor will probably want to check you periodically while taking Trazodone.

Severe hepatic disorders with potential fatal outcome have been reported with trazodone use.

Stop taking Trazodone and talk to your doctor immediately if you experience yellowing of your skin, or the whites of your eyes (icterus) or signs such as asthenia, anorexia, nausea, vomiting, abdominal pain (see Section 4. "Possible side effects").

If you have schizophrenia or other psychotic disorders administration of antidepressants may result in a possible worsening of psychotic symptoms. Paranoid thoughts may be intensified. During therapy with Trazodone a depressive phase can change from a manic-depressive psychosis into a manic phase. In that case Trazodone must be stopped.

If your throat hurts, you have fever or influenza like symptoms, while taking Trazodone, you must talk to your doctor immediately. In these cases it is recommended to check your blood since agranulocytosis, a blood disorder, may clinically reveal itself with these symptoms.

Caution is advised when trazodone is used together with other medicines known to prolong QT interval or known to increase the risk of serotonin syndrome/malignant neuroleptic syndrome (see “Other medicines and Trazodone” and Section 4. “Possible side effects”).

Use in Children *and adolescents*

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

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

Other medicines and Trazodone

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 can affect the way some other medicines work. Also some medicines can affect the way Trazodone 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**
- Other antidepressants (such as amitriptyline, nefazodone or fluoxetine)
- Tryptophan (amino acid used for biosynthesis of proteins)
- Triptans (medicines used to treat migraine)
- Sedatives (such as tranquilizers or sleeping pills)
- Medicines used to treat epilepsy such as carbamazepine and phenytoin
- Medicines known to prolong QT interval on ECG such as class IA and III antiarrhythmics (a group of medicines that are used to suppress abnormal rhythms of the heart)
- Medicine used to treat allergies such as antihistamines
- The birth control pill (oral contraceptives)
- Muscle relaxants (group of medicines that have the ability to relax or reduce tension in muscle)
- Some antipsychotics (such as phenothiazines e.g. chlorpromazine, fluphenazine, levomepromazine and perphenazine)
- 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)
- Buprenorphine. 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.

Trazodone with food, drink and alcohol

You should avoid drinking alcohol while taking Trazodone.

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.

Taking Trazodone in the late stages of pregnancy may lead to your baby experiencing withdrawal symptoms when it is born.

Driving and using machines

Trazodone may make you feel sleepy or dizzy. It may also cause blurred vision and confusion. If this happens do not drive or use any tools or machines.

3. How to take Trazodone

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

How much to take Trazodone**Adults:**

- Adults usually start by taking 150 mg each day in a single or divided doses.
- Your doctor may increase the dose gradually, e.g. by steps of 50 mg every 3-4 days, up to a maximum of 300 mg each day depending on your condition.
- For adults in hospital the dose may be as high as 600 mg each day.

Elderly

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

Use in children and adolescents

Children and adolescents under 18 years should not take Trazodone.

Taking this medicine

- Trazodone is for oral use. Swallow the tablet with a drink of water.
- Take after food. This can help lower the chances of side effects.

For 150 mg: The tablet can be divided into equal doses. Each half tablet contains 75 mg of trazodone hydrochloride.

Duration of treatment

It usually will take two to four weeks before you start to feel better.

When the right dose is found, you should be kept on this for at least four weeks.

Your doctor will periodically reassess your dose depending on your condition and determine the continued need for maintenance treatment.

In general, treatment with an antidepressant should be continued until you have felt well for four to six months.

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 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 these tablets he/she will help you stop taking them gradually in order to avoid the risk of withdrawal symptoms, such as agitation, sleep disturbances, feeling sick, headache, and feeling ill.

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

4. Possible side effects

Like all medicines, this medicine 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)
- 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 ileus)

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.

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

- Feeling drowsy or sleepy (somnolence)
- Feeling less alert than usual
- Feeling sick (nausea) or being sick (vomiting)

- Constipation, diarrhoea
- Dry mouth, altered taste, increased amounts of saliva, blocked nose
- Sweating more than usual
- Dizziness, headache, confusion, weakness, tremor (shaking)
- Blurred vision
- Weight loss
- Rapid or slow heartbeat
- Feeling dizzy or light-headed on standing or sitting up quickly (postural hypotension)
- 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 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 potentially 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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly Yellow Card Scheme Website: 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 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 after “EXP”. The expiry date refers to the last day of that month.

This medicine does not require any special temperature storage conditions. Store in the original package in order to protect from light.

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 contains

- The active substance is trazodone hydrochloride.
- Trazodone 150 mg tablets: Each tablet contains trazodone as 150 mg trazodone hydrochloride

The other ingredients of the tablets are cellulose microcrystalline, sodium starch glycolate (Type A), starch pregelatinised (maize), silica colloidal anhydrous and magnesium stearate.

What Trazodone looks like and contents of the pack

Trazodone 150 mg tablets are white to off white, 16.90 mm in length, 8.40 mm in width, oval, flat faced bevelled edge, uncoated tablets with score line engraved “IT” and “III” on one side and plain on the other side.

The tablet can be divided into equal doses.

Tablets are available in Aluminium-Aluminium, PVC/PVdC-Aluminium and PVC-Aluminium blisters.

Pack sizes:

150 mg: 14, 20, 28, 30, 50, 60 or 100 tablets in blister. Also available in 28 x 1 perforated unit dose blister.

Not all pack sizes may be marketed.

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