

Package leaflet: Information for the user
Trazodone hydrochloride 50 mg and 100 mg Capsules, Hard
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 Capsule is and what it is used for
2. What you need to know before you take Trazodone Capsule
3. How to take Trazodone Capsule
4. Possible side effects
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1. What Trazodone Capsule is and what it is used for

The name of this medicine is Trazodone hydrochloride 50 mg and 100 mg Capsules, Hard (referred to as Trazodone Capsule throughout this leaflet). Trazodone Capsules contain a medicine called trazodone hydrochloride. Trazodone belongs to a group of medicines called antidepressants.

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

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

Do not take Trazodone Capsule 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 Capsule.

Warnings and precautions

Talk to your doctor or pharmacist before taking Trazodone Capsule 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 capsules”).

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

Take special care with Trazodone Capsules.

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

Other medicines and Trazodone capsules

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 Capsule can affect the way

some other medicines work. Also some medicines can affect the way Trazodone Capsule work.

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
- 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)
- St. John's Wort (a herbal remedy)
- Digoxin (used to treat heart problems)
- Warfarin (used to stop your blood from clotting)
- Some medicines used to treat HIV such as ritonavir and indinavir
- 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 Capsules.

Trazodone Capsule with food and drink and alcohol

You should avoid drinking alcohol while taking Trazodone Capsule.

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

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

Trazodone Capsules contain lactose

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 Capsule

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

Taking this medicine

- Take this medicine by mouth.
- Swallow the capsules whole with a drink of water.
- Take with or after food. This can help lower the chances of side effects.
- If you have been told to take Trazodone Capsules 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 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.

If a starting dose of 75 mg or 150 mg is not achievable with this product, 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.

Children

Trazodone Capsules 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 Capsules 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 Capsules until your doctor tells you to stop. Do not stop taking Trazodone Capsules just because you feel better. When your doctor tells you to stop taking these capsules 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 Capsules 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 Capsules.
- 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 authorization 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 capsule

- This medicinal product does not require any special storage conditions.
- 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 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 Capsule contains

- The **active** substance is Trazodone (as the hydrochloride).
- The 50 mg capsule contains 50 mg of Trazodone hydrochloride.
- The 100 mg capsule contains 100 mg of Trazodone hydrochloride.
- The **other** ingredients are Lactose monohydrate, Silica colloidal anhydrous, Magnesium stearate. **Capsule body and shell:** Erythrosine (E127), Patent blue V (E131), Titanium dioxide (E171), Iron oxide yellow (E172), Gelatin and Edible ink (Shellac and black iron oxide (E172)). The 50 mg capsule shell additionally contains Indigotine (E132).

What Trazodone Capsule looks like and contents of the pack

- Trazodone 50 mg Capsules are purple/green hard gelatin capsules of size ‘3’ and imprinted with ‘BL’ and ‘50’ on cap/body, containing white to off white granular powder.
- Trazodone 100 mg Capsules are purple/yellow hard gelatin capsules of size ‘2’ and imprinted with ‘BL’ and ‘100’ on cap/body, containing white to off white granular powder.
- Trazodone Capsules are available in blister packs of 56, 84 and 100 capsules. Not all pack sizes may be marketed.

Marketing Authorisation Holder

<To be completed nationally>

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} >

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