

Package leaflet: Information for the user
TRAZODONE 50MG & 100MG CAPSULES
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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

The name of your medicine is either Trazodone 50mg or 100mg capsules. It will be referred to as Trazodone Capsules for ease hereafter.

What is in this leaflet

1. What Trazodone Capsules are and what they are used for
2. What you need to know before you take Trazodone Capsules
3. How to take Trazodone Capsules
4. Possible side effects
5. How to store Trazodone Capsules
6. Contents of the pack and other information

1. What Trazodone Capsules are and what they are used for

Trazodone Capsules belongs to a group of medicines called antidepressants and can be used to treat all types of depression including depression accompanied by anxiety.

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

Do not take Trazodone Capsules:

- if you are allergic to trazodone hydrochloride or any of the other ingredients of this medicine (listed in Section 6). The signs of an allergic reaction include a 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 if you are taking sleeping capsules.

Do not take Trazodone Capsules if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist prior to taking this medicine.

Warnings and precautions

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 Capsules or if you have some other diseases.

Talk to your doctor, pharmacist or nurse before taking Trazodone Capsules:

- if you suffer from Epilepsy (fits or seizures)
- if you have severe liver, kidney or heart problems
- if you are pregnant, trying to become pregnant or are breast-feeding
- if you have an overactive thyroid gland (hyperthyroidism)
- if you have problems passing water or needing to pass water (urine) more frequently
- if you have narrow angle glaucoma (an eye disease)
- if you suffer from schizophrenia or other type of mental disorder.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before 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 some medicines and trazodone may interfere with each other.

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

MAOI (Mono Amine Oxidase Inhibitors) medicines such as tranylcypromine, phenelzine and isocarboxazid (for depression) or selegiline (for Parkinson's disease).

Tell your doctor or pharmacist if you are taking them now or have taken them in the last 2 weeks

- Muscle relaxants and inhaled anaesthetics
- Other antidepressants such as amitriptyline or fluoxetine
- Sedatives such as tranquilizers and sleeping pills
- Medicines used to treat epilepsy (e.g. carbamazepine or phenytoin)
- Medicines used to treat high blood pressure (e.g. clonidine) or heart disease (e.g. digoxin)
- Medicines used to treat fungal infections such as ketoconazole and itraconazole
- Some medicines used to treat HIV such as ritonavir and indinavir
- Erythromycin (a type of antibiotic used to treat infections)
- Levodopa (used for Parkinson's disease)

- St. John's Wort (a herbal medicine)
- Warfarin (a drug used to stop blood from clotting)
- Phenothiazines: chlorpromazine, fluphenazine, levomepromazine, perphenazine
- Antihistamines (used to treat allergies)
- Oral contraceptives
- Cimetidine (used to treat ulcers).

Anaesthetics

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

Trazodone Capsules with food, drink and alcohol

You should avoid drinking alcohol while taking Trazodone Capsules. This is because trazodone can change the way alcohol affects you.

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.

Pregnancy

Trazodone Capsules should not be taken during the first three months of pregnancy. Taking Trazodone in the late stages of pregnancy may lead to your baby experiencing withdrawal symptoms when they are born.

Breast-feeding

Trazodone can pass into breast-milk and should only be used if the benefit to the mother outweighs the risk to the child.

Driving and using machines

Trazodone is a drug which acts on the central nervous system and may make you feel sleepy or less alert. Do not drive, operate machinery or do anything that requires you to be alert until you know how this medicine affects you.

Trazodone contains lactose

Trazodone Capsules contain lactose. If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Trazodone Capsules

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. The dose of trazodone will depend on your needs and the illness being treated. The capsules should always be taken with plenty of water. Taking trazodone with, or soon after, food will lower the risk of side effects. If you are to take your dose as a single dose it should be taken just before going to bed. If you feel the effect of your medicine is too weak or too strong, do not change the dose yourself, but ask your doctor

DEPRESSION AND DEPRESSION ACCOMPANIED BY ANXIETY:

The recommended dose is.

Adults:

The recommended starting dose is 150mg each day in divided doses after food or as a single dose at bedtime.

This may be increased up to 300mg each day in single or divided doses. The major portion of a divided dose is to be taken at bedtime. If you are in hospital the dose may be further increased to 600mg each day in divided doses.

Elderly:

Dosage in elderly or frail patients should be started at 100mg each day in divided doses or as a single dose at bedtime. This may be increased by your doctor depending on how you react to this medicine. Dosages above 300mg each day are unlikely to be required.

Use in children and adolescents

Trazodone is not recommended for use in children and adolescents under 18 years of age.

ANXIETY:

The recommended starting dose is 75mg each day and this may be increased to 300mg each day as necessary.

If you take more Trazodone Capsules than you should

It is important to stick to the dose on the label of the medicine. Do not adjust your dose without consulting with your doctor.

If you or someone else swallows several of these capsules all together, contact your doctor or nearest hospital emergency department immediately. Always take any capsules left over with you along with the box, as this will allow easier identification of the capsules.

The following effects may occur: nausea, sickness, drowsiness, dizziness, fainting, fits (seizures), confusion and problems with your heart or breathing.

If you forget to take Trazodone Capsules

If you forget to take a dose, take it as soon as you remember. If it is almost time for your next dose do not take a double dose to make up for a forgotten dose, just carry on as before.

If you stop taking Trazodone Capsules

- 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 capsules he/she will help you stop taking them gradually
- Stopping your medicine too quickly could cause sleep problems, leave you feeling more irritable than usual and cause you to sweat more than usual.

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

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 experience:

- A long lasting and painful erection, unrelated to sexual activity that will not go away (priapism)

- You get swelling of your face, lips, tongue, throat, hands, feet or ankles, swallowing or breathing difficulties or itching of the skin and nettle rash. This is an allergic reaction to trazodone
- Yellowing of the eyes or skin which could be a liver problem (such as jaundice) or other abnormalities of liver function
- You have severe abdominal pain and bloating, which may be accompanied by vomiting or constipation. These may be signs that your intestine is not working properly (paralytic ileus)
- Bruising more easily than usual. This could be because of a blood disorder (thrombocytopenia)
- Getting more infections than usual (sore throat, skin infections) which may indicate a blood disorder (agranulocytosis).

Talk to your doctor straight away if you notice the following side-effects:

- Thoughts of harming or killing yourself
- Feeling tired, faint, dizzy, having pale skin. These could be signs of anaemia
- Convulsions, fits (seizures)
- 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 with the following frequency:
Not known (frequency cannot be estimated from available data)**

- 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 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the 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 Capsules

- Keep this medicine out of the sight and reach of children
- Do not store above 25°C. Store in the original packaging
- Do not use this medicine after the expiry date which is stated on the blister and carton. 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 to protect the environment.

6. Contents of the pack and other information

What Trazodone Capsules contain

- The active ingredient is trazodone hydrochloride.

Each Trazodone 50mg Capsule contains 50mg of trazodone hydrochloride.

Each Trazodone 100mg Capsule contains 100mg of trazodone hydrochloride.

- The other ingredients are lactose monohydrate, colloidal silica anhydrous, magnesium stearate, gelatin, titanium dioxide (E171), yellow iron oxide (E172), erythrosin (E127) and patent blue V (E131). In addition to these Trazodone 50mg Capsules also contain indigo carmine (E132).

What Trazodone Capsules look like and contents of the pack

Trazodone 50mg Capsules are green-violet capsules.

Trazodone 100mg Capsules are yellow-violet capsules.

Trazodone 50mg Capsules are supplied in blister packs of 84 capsules and Trazodone 100mg Capsules are supplied in blister packs of 56 capsules.

Marketing Authorisation Holder

Focus Pharmaceuticals Limited, Dashwood House, 69 Old Broad Street, London, EC2M 1QS, United Kingdom

Manufacturer

Mercury Pharmaceuticals Limited, Capital House, 85 King William Street, London EC4N 7BL, UK

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