

PACKAGE LEAFLET

Package leaflet: Information for the patient

Trazodone Hydrochloride 50 mg Capsules Trazodone Hydrochloride 100 mg Capsules

Read all 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 hydrochloride is and what it is used for
2. What you need to know before you take Trazodone hydrochloride
3. How to take Trazodone hydrochloride
4. Possible side effects
5. How to store Trazodone hydrochloride
6. Content of the pack and other information

1. What Trazodone is and what it is used for

Trazodone Hydrochloride belongs to a class of medicines known as antidepressants. It is used to make you feel less depressed and less anxious.

Trazodone Hydrochloride helps to treat your depression, if you follow the treatment it will:

- Improve your general feeling of well-being or mood.
- Help to restore your interest in everyday activities.

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

Do not take this medicine and tell your doctor if you:

- are allergic to trazodone or any of the other ingredients of this medicine (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.
- are a heavy drinker or are taking sleeping tablets
- have suffered from a heart attack
- 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 this medicine.

Warnings and precautions

Talk to your doctor or pharmacist before taking Trazodone hydrochloride, particularly if any of the following applies to you.

Depression or other conditions that are treated with antidepressants

The use of these medicines together with Trazodone can lead to serotonin syndrome, a potentially life-threatening condition (see “Other medicines and 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.
- 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.

You must tell your doctor before taking your medicine if you:

- are pregnant or think you may be or could become pregnant
- are breast feeding your baby
- have or had fits or seizures
- have heart disease
- have hypotension
- have kidney or liver disease
- have narrow angle glaucoma (an eye disorder)
- have problems in passing water or need to pass water urine frequently, prostate enlargement
- are elderly, as you may be more prone to side effects
- have an overactive thyroid gland (hyperthyroidism)
- have schizophrenia or other type of mental disorders
- are taking buprenorphine (a strong pain killer). The use of buprenorphine with this medicine can lead to serotonin syndrome, a potentially life-threatening condition (see "Other medicines and Trazodone").

While being treated with Trazodone Hydrochloride, if you experience loss of appetite, unusual weakness, stomach pain, nausea, vomiting and yellowing of the skin and/or eyes; these may be signs of life-threatening liver disease. Contact your doctor immediately, he/she should carry out some liver function tests and may decide to stop your treatment with this medicine.

Older people more often experience dizziness on standing up, especially when getting up from a sitting or lying position (orthostatic hypotension), sleepiness and drowsiness (somnolence) particularly concomitant administration of other medicines used to treat certain mental conditions or medicines used to help lower blood pressure or in the presence of risk factor such as comorbid disease. It is recommended to the older patients/carer to exercise caution for such effects during initiation of therapy.

Children and adolescents

This medicine **should not** be given to children and adolescents **under 18 years old.**

Other medicines and Trazodone

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Some medicines may increase the side effects of Trazodone and may sometimes cause very serious reactions. Do not take any other medicines whilst taking Trazodone without first talking to your doctor, especially:

- MAOIs (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 two weeks

- anti-depressants such as moclobemide, tranylcypromine, citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline, duloxetine, venlafaxine, amitriptyline, doxepine, or trimipramine. These medicines 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.- medicines used to produce calmness or to help you sleep (such as tranquilizers or sleeping pills)
- medicines to treat epilepsy, eg. phenytoin, carbamazepine
- antihistaminic drugs
- oral contraceptives
- medicines to treat high blood pressure and heart disease, including clonidine, digoxin and guanethidine
- ritonavir and indinavir (used to control HIV infection), itraconazole and ketoconazole (used to treat fungal infections)
- cimetidine (used to treat ulcers)
- erythromycin (antibiotic used to treat infections)
- levodopa (used to treat Parkinson's disease)
- chlorpromazine, fluphenazine, levomepromazine, perphenazine (all used to block the effect of chemicals in the brain)
- St John's wort (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.

Heart problems

Caution should be taken when using this kind of medicine, if you were born with or have family history of prolonged QT interval (seen on ECG, electrical recording of the heart).

Trazodone hydrochloride 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.

This medicine should only be taken during pregnancy if your doctor tells you that treatment with Trazodone is essential for you and tells you to take this medicine.

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 this medicine.

Driving and using machines

Trazodone may make you feel sleepy, dizzy or you can be affected by blurred vision. If this happens do not drive or use any tools or machines.

Trazodone hydrochloride contains lactose and sodium

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

This medicine contains less than 1mmol sodium (23 mg) per capsule, that is to say essentially 'sodium free'.

This product also contains sunset yellow (E110), an azo dye which may cause allergic reactions.

3. How to take Trazodone Hydrochloride

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

Adult:

Depression

- The recommended dose is 150 mg each day.
- Your doctor may increase the dose to 300 mg each day depending on your condition. For adults in hospital the dose may be as high as 600 mg each day.

Anxiety

- the recommended dose is 75 mg each day
- your doctor may increase the dose to 300 mg each day.

Older people:

The recommended dose is 100 mg each day.

Use in children and adolescents

Trazodone Hydrochloride Capsules **should not** be given to children below 18 years old.

Method of administration

When taking Trazodone hydrochloride:

- swallow the capsules with water
- always take with or after a meal. This can help lower the chances of side effects
- if you 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 too strong, do not change the dose yourself, but ask your doctor.

If you take more Trazodone hydrochloride than you should

If you accidentally take too many capsules, contact your doctor or nearest hospital emergency department immediately for advice.

The following effects may happen: feeling sick or being sick, sleepy, dizzy or faint, fits (seizures), confusion, breathing problems, low blood pressure or heart problems.

If you forget to take Trazodone hydrochloride

If you forget to take your Trazodone Hydrochloride Capsules, **do not take the missed dose at all and do not double the next dose**, just carry on as before. Do not take a double dose to make up for a forgotten tablet.

If you stop taking Trazodone hydrochloride

Keep taking Trazodone hydrochloride capsules until your doctor tells you to stop.

Do not stop taking Trazodone hydrochloride capsules just because you feel better. When your doctor tell you to stop taking these capsules he/she will help you to stop taking them gradually to minimise the risk of nausea, headache and malaise.

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 the 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 (allergic reaction). This may mean you are having an allergic reaction to trazodone
- 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, 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
- painful erection of the penis, unrelated to sexual activity, that will not go away
- yellowing of the eye or skin, feeling sick, being sick, loss of appetite, unusual weakness, stomach pain; these may be signs of severe liver disease which could lead to life-threatening liver failure.
- getting infections more easily than usual. This could be because of a blood disorder (decrease in number of white blood cells that fight infection)
- bruising more easily than usual. This could be because of a blood disorder (decrease in number of blood platelets that help your blood clot)
- 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.

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

- you have thoughts of harming or killing yourself (that can especially occur during the first weeks of treatment or following dose changes)
- feeling tired, faint, dizzy, having pale skin
- convulsions/fits
- unusual skin sensations such as numbness, tingling, pricking, burning or creeping on the skin
- this medicine may cause irregular heart beats in patients with heart disease, abnormal fast heart rhythm, life-threatening irregular heart rhythm, alteration of the heart rhythm (called 'prolongation of QT interval', seen on ECG, electrical activity of the heart).

Other side effects that can occur:

- drowsiness on starting treatment (this usually goes away)
- slow or racing pulse
- swelling of the ankles
- dizziness, headache, nausea, vomiting, weakness, decreased alertness, confusion, shaking
- weight loss, loss of appetite, indigestion
- dry mouth, altered taste, increased amount of saliva, blocked nose
- fainting on standing up, confusion
- difficulty passing water, constipation, diarrhoea
- blurred vision
- restlessness or difficulty sleeping and skin rash
- chest pain
- pain in limbs, back pain, pain in your muscles, pain in your joints
- jerking movements that you can not 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 (decrease in number of white blood cells that fight infection)
- feeling anxious or more nervous than usual, feeling agitated
- overactive behaviour or thoughts, believing things that are not true, memory disturbance

- nightmares
- decreased sex drive
- sweating more than usual, itching
- high blood pressure
- high temperature, flu type symptoms
- difficulty with speaking
- high levels of liver enzymes in your blood
- feeling tired, weak and confused, having muscles that ache, are stiff or do not work well.

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 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 Hydrochloride

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 label or carton after 'EXP'. The expiry date refers to the last day of that month.

There are no special storage requirements for this medicine.

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 Hydrochloride capsules contains

Each capsule contains either 50 mg or 100 mg of the active ingredient trazodone hydrochloride.

The other ingredients are lactose monohydrate, purified talc, sodium starch glycollate, magnesium stearate; capsule shells containing gelatin, sodium lauryl sulfate and the colouring agents sunset yellow (E110), erythrosine (E127), patent blue V (E131), titanium dioxide (E171) (the 50 mg capsules also contain quinoline yellow (E104)); printing ink containing shellac, propylene glycerol, ammonium hydroxide, potassium hydroxide and black iron oxide (E172).

What Trazodone Hydrochloride capsules look like and contents of the pack

The 50 mg are size 3 hard gelatin capsules with a dark purple opaque cap and light green opaque body. The capsules are printed with "TZ50" on the body and "G" on the cap with black ink.

The 100 mg are size 2 hard gelatin capsules with a dark purple opaque cap and a light orange opaque body. The capsules are printed "TZ 100" on the body and "G" on the cap in black ink.

Trazodone Hydrochloride is available in blister packs of 20, 28, 30, 56, 84, 90, 100, 112, 120, 168 & 180 capsules and HDPE or polypropylene bottle with polyethylene caps in packs of 5, 7, 10, 15, 20, 21, 25, 28, 30, 50, 56, 60, 84, 90, 100, 112, 120, 180, 200 and 500 capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Mylan, Potters Bar, Hertfordshire, EN6 1TL, United Kingdom.

Manufacturer

Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland.
Mylan Hungary Ltd., Mylan utca 1., Komárom, 2900, Hungary

This leaflet was last revised in 03/2022.