

Package leaflet: Information for the user

Trazodone hydrochloride 50 mg tablets Trazodone hydrochloride 100 mg tablets Trazodone hydrochloride 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 hydrochloride tablet is and what it is used for
2. What you need to know before you take Trazodone hydrochloride tablets
3. How to take Trazodone hydrochloride tablets
4. Possible side effects
5. How to store Trazodone hydrochloride tablets
6. Contents of the pack and other information

1. What Trazodone hydrochloride tablet is and what it is used for

The name of your medicine is Trazodone hydrochloride tablets. Trazodone hydrochloride tablets contain a medicine called trazodone hydrochloride. This belongs to a group of medicines called antidepressants. Trazodone hydrochloride tablets can be used to treat symptoms of depression (major depressive episodes).

2. What you need to know before you take Trazodone hydrochloride tablets

Do not take this medicine and tell your doctor 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.
- You have recently had a heart attack.
- You have an alcohol intoxication or an intoxication with sleeping tablet

Do not take this medicine if this applies to you. If you are not sure, talk to your doctor or pharmacist before taking Trazodone hydrochloride tablets.

Warnings and precautions

Take special care with Trazodone hydrochloride tablets

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 hydrochloride 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)

Children

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

Elderly

Elderly patients when taking Trazodone hydrochloride 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 you suffer from other ailments and are taking medications to treat these, along with taking Trazodone hydrochloride tablets.

Talk to your doctor or pharmacist before taking Trazodone hydrochloride tablets if you:

- Have or have ever had fits or seizures (epilepsy)
- Have severe liver kidney disease
- 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 enlarged prostate
- Have low blood pressure (hypotension)
- 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, naloxone (strong pain killer). The use of buprenorphine and naloxone with trazodone can lead to serotonin syndrome, a potentially life-threatening condition (see “Other medicines and Trazodone hydrochloride).
- Are pregnant, trying to become pregnant or are breast-feeding

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 hydrochloride tablets.

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

Stop taking Trazodone hydrochloride tablets 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 hydrochloride tablets a depressive phase can change from a manic-depressive psychosis into a manic phase. In that case Trazodone hydrochloride tablets must be stopped.

If your throat hurts, you have fever or influenza like symptoms, while taking Trazodone hydrochloride tablets, 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 hydrochloride tablets” and Section 4. “Possible side effects”).

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

Children and adolescents

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

Other medicines and Trazodone hydrochloride 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 hydrochloride tablets can affect the way some other medicines work. Also some medicines can affect the way Trazodone hydrochloride 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**
- Other antidepressants
- Phenthiazines – antipsychotic medicines used in the treatment of schizophrenia and other mental disorders
- Buprenorphine and naloxone - used to treat pain. These medicines may interact with Trazodone hydrochloride tablets 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
- Sedatives (such as tranquilizers or sleeping pills)
- Medicines used to treat epilepsy such as carbamazepine and phenytoin
- 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)
- Tryptophan
- Triptans (medicines used to treat migraine)

- 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)

Anaesthetics

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

Trazodone hydrochloride tablets with alcohol

You should avoid drinking alcohol while taking Trazodone hydrochloride tablets

Pregnancy and breast-feeding

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

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

Taking Trazodone hydrochloride 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.

Driving and using machines

Trazodone hydrochloride tablets 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.

Trazodone hydrochloride tablets contain sodium

This medicine contains less than 1mmol sodium (23 mg) per tablet, that is to say essentially ‘sodium-free’

3. How to take Trazodone hydrochloride 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.

How much to take

Adults:

- Adults usually start by taking 150 mg each day in a single or divided doses.
- Your doctor may increase the dose every 3-4 days by steps of 50 mg 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

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

Use in children and adolescents

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

Taking this medicine

- Take this medicine by mouth.
- Swallow the tablet 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 hydrochloride 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.

For 50 mg: The score line is not intended for breaking the tablet.

For 100 mg: The tablet can be divided into equal doses. Each half tablet contains 50 mg of trazodone hydrochloride.

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 keep 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 hydrochloride tablets than you should

If you take more Trazodone hydrochloride 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 hydrochloride tablets

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 hydrochloride tablets

Keep taking Trazodone hydrochloride tablets until your doctor tells you to stop. Do not stop taking Trazodone hydrochloride tablets just because you feel better. When your doctor tells you to stop taking these tablets he/she will help you to stop taking them gradually.

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.

Cases of suicidal ideas and suicidal behaviour have been reported during trazodone treatment or early after treatment discontinuation (see section 2. “What you need to know before you take Trazodone hydrochloride tablets”)

You should stop taking the medicine and immediately contact your doctor if you get any of these effects:

- Allergic reaction, itching, lumpy irritable skin, skin rash, swelling of hands, face, or throat (oedema), chest tightness, or trouble breathing
- Prolonged, painful erection of the penis (priapism)
- Skin rash
- Unexplained fever or sore throat, or flu like symptoms
- Yellow colour of eyes (jaundice), or skin, passing very dark urine, pain in the back.

You should talk to your doctor or pharmacist if any of the following effects occur, especially if they are prolonged or get worse:

Very common: may affect more than 1 in 10 people

- nervousness, dizziness, sleepiness**
- dry mouth

Common: may affect up to 1 in 10 people

- expressive disorder of central nervous system that affects the ability to use and understand words (expressive aphasia).
- disorientation, confusion, agitation (very occasionally worsening to delirium), mental disorder characterized by great bursts of violent excitement (mania), aggressive outbursts and the experience of seeming to see something that is not really there (hallucinations).
- allergic reactions
- weight gain, anorexia and increased hunger
- changes to your vision, such as blurring, difficulty focusing, sometimes high pressure in the eye (glaucoma).
- palpitation, irregular or fast heart beat (bradycardia or tachycardia)
- dizziness when standing up suddenly (orthostatic hypotension), fainting (syncope), high blood pressure
- taste changes, wind (flatulence), indigestion (digestive upsets) with symptoms such as a full feeling in the upper stomach, belching, feeling or being sick and acid indigestion (dyspepsia), inflammation of the stomach or small intestine (gastro-enteritis), constipation or diarrhoea, pain in the stomach
- lumps or spots of the skin and itching
- feeling weak (asthenia), chest pain, back or limb pain
- sweating, hot flushes, swelling (oedema), influenza-like symptoms
- itchy, sore eyes (ocular pruritus)
- tinnitus (ringing in the ears), headache, tremor
- blocked, stuffy, sore nose (nasal/sinus congestion)

Uncommon: may affect up to 1 in 100 people

- weight loss
- shortness of breath (dyspnoea)
- decreased sex drive
- serotonin syndrome like condition, characterised by (extreme) restlessness, confusion, excitability, seeing things that are not there (hallucinations), cold shivers, sweating, increased reflexes and sudden muscle contractions, high fever, stiffness and convulsions – especially if you are taking other antidepressant medicines

Rare: may affect up to 1 in 1,000 people

- very serious blood disorders (shortage of white blood cells) accompanied by sudden high fever, severe sore throat and ulcers in the mouth (agranulocytosis), increased amount of specific white blood cells in the blood (eosinophilia), blood disorder (shortage of white blood cells) accompanied by increased sensitivity for infections (leucopenia), blood disorder (shortage of platelets) accompanied by blue spots and bleeding tendency (thrombocytopenia) and anaemia. Your Doctor will know to check for these.
- sudden contraction of the muscles (myoclonus)
- obstruction of bile flow, that may cause jaundice, disturbance of the liver function, elevated liver enzymes

Very rare: may affect up to 1 in 10,000 people

- prolonged, painful erection of your penis (priapism).
- a group of side effects due to the use of neuroleptic medicines like trazodone (neuroleptic malignant syndrome), such as: increased sweating and fever, changes in your body function (fast

heartbeat, changes in blood pressure, increased/decreased salivation), lowered levels of consciousness, skin paleness, skin rashes/flaking over the entire body, dumbness(mute), immobility of the body (stupor), may occur during treatment with trazodone

Not known: frequency cannot be estimated from the available data

- worsening delusions, feeling of fear or embarrassment that stops you from behaving naturally, inhibition, anxiety, suicidal ideas and suicidal behaviour*
- sleep disturbances (nightmares, inability to sleep)
- excessive release of antidiuretic hormone
- if you feel tired, weak or confused and have aching, stiff or uncoordinated muscles this may be because your blood is low in sodium. Contact your doctor if you get these symptoms (hyponatraemia).
- vertigo, restlessness, decreased alertness, memory disturbance, tingling or numbness (paraesthesia), abnormal and uncontrolled body movement (dystonia)
- fast, irregular heartbeat, fainting which could be symptoms of a life-threatening condition known as Torsades de Pointes
- alteration of the heart rhythm (called “prolongation of QT interval”, seen on ECG, electrical activity of the heart)
- muscle pain, joint stiffness or pain
- intestinal perforation, obstruction of the intestine caused by paralysis of the intestinal muscles (paralytic ileus), gastrointestinal cramps and the stomach passing through the abdominal muscles and making a lump in the skin (hiatus hernia), increased salivation
- weakness, fatigue, fever
- difficulty, or interruption in passing urine
- excessive sweating

*cases of suicidal ideas and suicidal behaviour have been reported during trazodone treatment or early after treatment discontinuation (see section 2. “What you need to know before you take Trazodone hydrochloride tablets”).

**sleepiness. This usually happens when starting treatment. It usually disappears when you continue taking your medicine.

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 HPRAs Pharmacovigilance Website: www.hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Trazodone hydrochloride tablets

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.

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 hydrochloride tablets contains

- The active substance is trazodone hydrochloride.
- Trazodone hydrochloride 50 mg tablets: Each tablet contains 50 mg trazodone hydrochloride
- Trazodone hydrochloride 100 mg tablets: Each tablet contains 100 mg trazodone hydrochloride
- Trazodone hydrochloride 150 mg tablets: Each tablet contains 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 hydrochloride tablets looks like and contents of the pack

Trazodone hydrochloride 50 mg tablets are white to off white, round, biconvex, uncoated tablets 7.14 mm in diameter, engraved 'IT' bisect 'I' on one side and plain on the other side.

Trazodone hydrochloride 100 mg tablets are white to off white, round, biconvex, uncoated tablets 9.52 mm in diameter, engraved 'IT' bisect 'II' on one side and plain on the other side.

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

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

Pack sizes:

50 mg: 30 or 84 tablets in blister. Also available in 84 x 1 perforated unit dose blister.

100 mg: 20, 30, 50, 56, 60 or 100 tablets in blister. Also available in 56 x 1 perforated unit dose blister.

150 mg: 28 tablets in blister. Also available in 28 x 1 perforated unit dose blister.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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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
Germany	Trazodon Accord 100 mg Tabletten
Ireland	Trazodone hydrochloride 50/100/150 mg tablets
Italy	Trazodone Accord
Netherland	Trazodone hydrochloride Accord 50/100/150 mg, tabletten
United Kingdom	Trazodone hydrochloride 50/100/150 mg tablets
Spain	Trazodona Stada 100 mg comprimidos EFG

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