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Package leaflet: Information for the user



Trazodone Hydrochloride 150 mg Film-Coated Tablets

trazodone

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

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1. What Trazodone Hydrochloride 150 mg Film-Coated Tablets are and what they are used for

The name of your medicine is Trazodone Hydrochloride 150 mg Film-Coated Tablets (referred to as Trazodone Tablets in this leaflet). Trazodone Tablets contain a medicine called trazodone hydrochloride, which belongs to a group of medicines called antidepressants. Trazodone Tablets can be used to treat anxiety and depression.

2. What you need to know before you take Trazodone Hydrochloride 150 mg Film-Coated Tablets

Do not take Trazodone Tablets:

- if you are allergic (hypersensitive) to trazodone hydrochloride or any of the other ingredients of Trazodone Tablets (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
- if you have recently had a heart attack
- if you are a heavy drinker or are taking sleeping tablets
- if 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 Tablets.

Warnings and precautions

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

- if you have or have ever had fits or seizures (epilepsy)
- 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 need to pass water (urine) frequently
- if you have narrow angle glaucoma (an eye disorder)
- if you have schizophrenia or other type of mental disorder
- if you are elderly, as you may be more prone to side effects

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

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 hospital straight away.**

You may find it helpful to talk to 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.

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

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 Tablets or if you have some other diseases.

Children and adolescents

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

Other medicines and Trazodone Tablets

Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines. This includes medicines you buy without a prescription, including herbal medicines. This is because Trazodone Tablets can affect the way some other medicines work. Also, some medicines can affect the way Trazodone Tablets work.

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

- MAOI (Mono Amine Oxidase Inhibitors) medicines such as tranylcypromine, phenelzine and dicarboxamide (for depression) or selegiline (for Parkinson's disease), or **have taken them in the last 2 weeks**
- Other antidepressants, (such as amitriptyline or fluoxetine)
- 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 use 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)

Anaesthetics

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

Trazodone Tablets with food, drink and alcohol

You should avoid drinking alcohol while taking this medicine. Take with or after food. This can help lower the chances of side effects.

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.

Taking this medicine 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 Trazodone Tablets.

Driving and using machines

Trazodone Tablets may make you feel sleepy or dizzy. If this happens do not drive or use any tools or machines.

Trazodone Tablets contain lactose and sodium

Trazodone Tablets contain lactose monohydrate. If you have been told that you cannot digest or tolerate some sugars, talk to your doctor before taking this medicine.

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

3. How to take Trazodone Hydrochloride 150 mg Film-Coated Tablets

Always take this medicine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. Your doctor will decide on the most appropriate dose depending on your illness.

When taking this medicine:

- Take this medicine by mouth
- Swallow the tablet whole with a drink of water
- It is recommended to take this medicine either as divided doses with or after food with the major portion of a divided dose taken at bedtime or taken as a single dose at bedtime. This can help lower the chances of side effects
- If you have been told to take Trazodone Tablets only once a 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.

Recommended dose

Adults:

Depression

- Adults usually start by taking 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

- Adults usually start by taking 75 mg each day. The tablet can be divided into equal doses. Each half tablet contains 75 mg of trazodone hydrochloride
- Your doctor may increase the dose to 300 mg each day.

Elderly:

- Older people or those who are frail will usually be given a starting dose of 100 mg each day.
- For lower doses the product is also available as 50 mg and 100 mg capsules and tablets.

Children and adolescents

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

If you take more Trazodone Tablets than you should

If you take more 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 Tablets

If you forget to take a dose, take your dose as soon as you remember. However, if it almost time for the next dose, skip the missed dose and take the next one when it is due. Do not take a double dose to make up for a forgotten dose.

If you stop taking Trazodone Tablets

Keep taking this medicine until your doctor tells you to stop. Do not stop taking Trazodone 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.

Serious side effects

Stop taking Trazodone Tablets 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 Tablets.
- You get a painful erection of the penis, unrelated to sexual activity, that will not go away (priapism).
- You have yellowing of the eyes or skin. This could be a liver problem (such as jaundice).
- You are getting infections more easily than usual. This could be because of a blood disorder (agranulocytosis).
- You are 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 of your intestine is not working properly (paralytic ileus).

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, bumping or creeping of the skin (paraesthesia)
- Feeling confused, restless, sweating, shaking, shivering, hallucinations (strange vision 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.

Other side effects

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

- 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 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, 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 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 150 mg Film-Coated Tablets

Keep this medicine out of the sight and reach of children.

This medicinal product does not require any special storage conditions.

Do not use Trazodone Tablets after the expiry date, which is stated on the blister and carton. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste.

Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Trazodone Tablets contain

Each tablet contains 150 mg of the active ingredient, trazodone hydrochloride. The other ingredients are lactose monohydrate, maize starch, povidone, calcium hydrogen phosphate, microcrystalline cellulose, sodium starch glycolate, magnesium stearate and Opadry II pink (polyvinyl alcohol, polyethylene glycol, talc, red iron oxide (E172) and titanium dioxide (E171)).

What Trazodone Tablets look like and contents of the pack

Trazodone Tablets are light pink, 11.0mm round, film-coated tablets with a break line on one side and plain on the other side.

Trazodone Tablets are available in blister packs of 28 and 30 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Sovereign Medical
Sovereign House, Miles Gray Road,
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Manufacturer

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