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PACKAGE LEAFLET: INFORMATION FOR THE USER

Trazodone Hydrochloride 50mg and 100mg Capsules

trazodone hydrochloride

PHARMA CODE

Pharmaco Reading Direction
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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 symptoms 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 Capsule is and what it is used for
2. What you need to know before you take Trazodone Hydrochloride Capsules
3. How to take Trazodone Hydrochloride Capsules
4. Possible side effects
5. How to store Trazodone Hydrochloride Capsules
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1. WHAT TRAZODONE HYDROCHLORIDE CAPSULE IS AND WHAT IT IS USED FOR

The name of your medicine is Trazodone Hydrochloride 50 mg and 100 mg Capsules (called Trazodone Hydrochloride Capsules in this leaflet). Trazodone Hydrochloride Capsule contain a medicine called trazodone hydrochloride. This belongs to a group of medicines called antidepressants.

Trazodone Hydrochloride Capsules can be used to treat anxiety and depression.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE TRAZODONE HYDROCHLORIDE CAPSULES

Do not take this medicine and tell your doctor if:

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

Take special care with Trazodone Hydrochloride 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.

Trazodone Hydrochloride Capsules 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 Hydrochloride or you have some other diseases.

Warnings and precautions

Check with your doctor or pharmacist before taking this medicine if 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 Hydrochloride Capsules can lead to serotonin syndrome, a potentially life-threatening condition (see "Taking Trazodone Hydrochloride Capsules with other medicines").

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

Taking Trazodone Hydrochloride Capsules with other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines you buy without a prescription, including herbal medicines. This is because Trazodone Hydrochloride Capsules can affect the way some other medicines work. Also some medicines can affect the way Trazodone Hydrochloride Capsules 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**
- Oral contraceptives
- Cimetidine (for heartburn and stomach ulcers)
- Other antidepressants (such as amitriptyline or fluoxetine)
- **Buprenorphine/opioids.** These medicines may interact with Trazodone Hydrochloride Capsules 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)

Anaesthetics

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

Tell your doctor or pharmacist if you are taking, or have recently taken, any other medicines; including ones you have bought yourself.

Taking Trazodone Hydrochloride Capsules with food and drink

You should avoid drinking alcohol while taking Trazodone Hydrochloride Capsules.

Pregnancy, breastfeeding and fertility

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

Taking Trazodone Hydrochloride Capsules 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 any medicine.

Driving and using machines

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

Important information about some of the ingredients of Trazodone Hydrochloride Capsules

Trazodone Hydrochloride 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.

Trazodone Hydrochloride Capsules contain sodium. This medicine contains less than 1 mmol sodium (23 mg) per unit dose, that is to say essentially 'sodium-free'.

3. HOW TO TAKE TRAZODONE HYDROCHLORIDE CAPSULE

Always take Trazodone Hydrochloride Capsules exactly as your doctor has told you. You should 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 Hydrochloride 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 150mg each day
- Your doctor may increase the dose to 300mg each day depending on your condition
- For adults in hospital the dose may be as high as 600mg each day

Anxiety

- Adults usually start by taking 75mg each day
- Your doctor may increase the dose to 300mg each day

Elderly

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

Children

Children and adolescents under 18 years should not take Trazodone Hydrochloride Capsules.

If you take more Trazodone Hydrochloride Capsules than you should

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.

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 Capsules

If you take more Trazodone Hydrochloride 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.

If you forget to take 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 tells you to stop taking these capsules he/she will help you to stop taking them gradually.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Trazodone Hydrochloride Capsules can cause side effects, although not everybody gets them.

Stop taking Trazodone Hydrochloride 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 Hydrochloride Capsules.
- Painful erection of the penis, unrelated to sexual activity, that will not go away (priapism)
- Yellowing of the eyes or skin. This could be a liver problem (such as jaundice)
- 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 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, burning or creeping on the skin (parasthesia)
- 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, 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

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- Chest pain
- Pain in limbs, back pain, pain in your muscles, pain in your joints
- Jerking movements that you can not 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 CAPSULES

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

Do not use Trazodone Hydrochloride Capsules after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month. The capsules should be discarded after 100 days of the first opening of the HDPE container.

This medicinal product does not require any special storage conditions.

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

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

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Trazodone Hydrochloride Capsules contains:

Each Trazodone Hydrochloride 50 mg Capsule contains 50mg of Trazodone as Trazodone hydrochloride.
Each Trazodone Hydrochloride 100 mg Capsule contains 100mg of Trazodone as Trazodone hydrochloride.

Other ingredients include lactose monohydrate, microcrystalline cellulose (PH 101), calcium hydrogen phosphate dihydrate, sodium starch glycolate Type A, povidone (PVP-K30), colloidal anhydrous silica and magnesium stearate. The capsule is made up of gelatin, water, sodium lauryl sulfate, allura red (E129), brilliant blue (E133), erythrosine (E127) and titanium dioxide (E171). The 50 mg capsule shell additionally contains carmoisine (E122), patent blue V (E131) and quinoline yellow (E104). The 100 mg capsule shell additionally contains iron oxide yellow (E172). The printing ink contains shellac (E904), dehydrated alcohol (E1510), isopropyl alcohol, butyl alcohol, propylene glycol (E1520), strong ammonium solution (E527), black iron oxide (E172) and potassium hydroxide (E525).

What Trazodone Hydrochloride Capsules looks like and contents of the pack

Trazodone Hydrochloride 50 mg Capsules are Violet/Green Size '4' Hard Gelatin Capsule imprinted with 'T' on cap and '50' on body in black ink and filled with white to off white granular powder.

Trazodone Hydrochloride 100 mg Capsules are Violet/Yellow Size '2' Hard Gelatin Capsule imprinted with 'T' on cap and '100' on body in black ink and filled with white to off white granular powder.

Trazodone Hydrochloride 50 mg and 100 mg Capsules are available in blisters of Aluminium-PVC/PVDC containing packs of 14's, 20's, 28's, 56's, 84's and 100's along with leaflet inside and in white opaque HDPE bottle with white polypropylene child resistant cap containing packs of 56, 84, 100, 250 and 500 capsules. Not all pack sizes may be marketed.

Marketing Authorization Holder

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