

PATIENT INFORMATION LEAFLET

TRAZODONE 50mg and 100mg CAPSULES

Trazodone Hydrochloride

Read all of this leaflet carefully before you start taking this medicine.

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 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 contains the active substance trazodone hydrochloride which is an antidepressant with the ability to help reduce anxiety. In the first days of treatment Trazodone may have a sedative effect which may cause drowsiness.

Trazodone Capsules are used to treat symptoms in all types of depression, including when anxiety is also present.

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). Signs of an allergic reaction 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 Capsules.

Warning 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 behavior 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 behavior.

Trazodone 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 Capsules or if you have some other diseases.

Check with your doctor or pharmacist before taking this medicine:

- 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 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 any of these conditions apply to you, talk to your doctor before you take these Capsules. Your doctor will want to monitor your response to this medicine carefully, particularly if you are young or elderly.

Other medicines and Trazodone Capsules

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines or food supplements, including medicines obtained without a prescription. The effects of any of these medicines may change, particularly if you are taking:

- MAOI (Monoamine Oxidase Inhibitors) medicines such as tranylcypromine, phenelzine and isocarboxazid (for depression) or selegine (for Parkinson's disease), **or have taken them within the last two weeks**
- Other antidepressants (such as amitriptyline or fluoxetine)
- Sedatives (such as tranquilizers or sleeping pills)
- Medicines 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 Capsules.

Trazodone Capsules with food, drink and alcohol

You should not drink alcohol whilst you are taking this medicine as it may increase the effects of Trazodone Capsules.

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. **You must speak to your doctor** about the possible effects this medicine might have on your baby before you take this medicine. Taking Trazodone Capsules in the late stages of pregnancy may lead to your baby experiencing withdrawal symptoms when they are born.

You should NOT take this medicine if you are in the first three months of pregnancy or breast-feeding.

Driving and using machines

Trazodone Capsules may cause sleepiness, dizziness, drowsiness, blurred vision or reduced concentration. You should not drive or use machines when you first start to take this medicine until you are certain that you are not getting these side effects. If in any doubt, speak to your doctor before you drive or use machines.

Trazodone capsules contains lactose which is a sugar. If you have been told by your doctor that you have an intolerance to sugars, contact your doctor before taking this medicine.

3. HOW TO TAKE TRAZODONE CAPSULES

Always take this medicine exactly as your doctor has told you. It is important to take your medicine at the right time. You must take it as directed by your doctor. The label will tell you how much to take and how often. If it doesn't or you are not sure, check with your doctor or pharmacist.

Taking Trazodone Capsules

Do not chew but swallow the Capsules with a glass of water, with or after food to reduce the chances of side-effects.

The recommended dose is:**Adults:****Depression**

- Adults usually start by taking 150mg each day, either in divided doses throughout the day, or as a single dose just before bedtime.
- Your doctor will advise you if this needs to be increased.

Anxiety

- Adults usually start by taking 75mg each day.
- Your doctor will advise you if this needs to be increased.

Elderly:

- Older people may need a lower daily dose (100mg), taken either in divided doses throughout the day, or as a single dose at night time. Under supervision and depending on tolerance of effect, this dose may be increased, but it is unlikely that it will exceed 300mg each day.

Children:

- Children should not take Trazodone Capsules.

If you take more Trazodone Capsules than you should

If you take too many Trazodone Capsules, tell your doctor or go to the nearest hospital casualty department immediately. Take any remaining Capsules and this leaflet with you so that the medical staff know exactly what you have taken.

The following effect may happen: feeling sick or being sick, feeling sleepy, dizzy or faint, fits (seizure), confusion, breathing or heart problems.

Your medicine is very dangerous if taken by young children, and care should be taken to keep the medicine safely out of the reach of children.

If you forget to take your Trazodone Capsules

Take your dose as soon as you remember, then go on as before.

If it is almost time for the next dose, then do not take the missed dose at all. Do not take a double dose to make up for a forgotten dose.

If you stop taking Trazodone Capsules

Your doctor will advise you on how long you should take the Capsules. Do not stop taking the Capsules early.

Trazodone Capsules may take time to work, usually about two weeks but sometimes longer. If you feel your depression or anxiety is getting worse, contact your doctor.

If you feel the effect of your medicine is too strong or too weak, talk to your doctor or pharmacist.

If you have to go to another doctor or to hospital tell them you are taking Trazodone Capsules.

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 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 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 ilius)

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 (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:

- 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 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. These could be signs of a blood problem called leucopenia.
- Feeling anxious or more nervous than usual, feeling agitated
- Overactive behavior 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)
- 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.
- Severe liver disorders such as hepatitis
- Liver failure with potentially fatal outcome.

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

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 package in order to protect from light and moisture.

Do not use your medicine if the pack is damaged. Do not use this medicine after the expiry date which is stated on the carton and blisters.

If you have any of your medicine left after finishing your treatment, return it to your pharmacist. 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 Capsules contain

- The active substance is trazodone hydrochloride.
Trazodone Capsules are available in two strengths, containing either 50 mg or 100 mg trazodone hydrochloride.
- The other ingredients are lactose monohydrate, magnesium stearate, colloidal silica anhydrous. The capsule shell coating is made from titanium dioxide (E171), yellow iron oxide (E172), erythrosine (E127), patent blue V (E131) and gelatin.
50mg capsule also contains Indigo carmine (E132).

What Trazodone Capsules look like and contents of pack:

Each Trazodone 50mg Capsule is green-violet, marked FW301. Each Trazodone 100mg Capsule is yellow-violet, marked FW311. Trazodone Capsules are supplied in blister packs available in pack sizes of 28, 56, 84 or 112 Capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Rivopharm UK Ltd,
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