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Trazodone Hydrochloride 150mg Film-coated Tablets (POM)

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PHARMA CODE XXXX

Pharmacode Reading Direction

PACKAGE LEAFLET: INFORMATION FOR THE USER
Trazodone Hydrochloride 150mg Film-coated Tablets

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 Tablets are and what they are 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 TABLETS ARE AND WHAT THEY ARE USED FOR

The name of your medicine is Trazodone Hydrochloride 150mg Film-coated Tablets (called Trazodone Hydrochloride Tablets in this leaflet). 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 anxiety and depression.

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 (hypersensitive) to trazodone hydrochloride or any of the other ingredients of Trazodone Hydrochloride 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.
- 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 Tablets.

Take special care with Trazodone Hydrochloride 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 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 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 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

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

Taking Trazodone Hydrochloride Tablets 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 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 (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 ketoconozole 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 Tablets.

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 Tablets with food and drink
You should avoid drinking alcohol while taking Trazodone Hydrochloride Tablets.

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 Tablets 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 Tablets 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 Tablets
Trazodone Hydrochloride Tablets 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.

3. HOW TO TAKE TRAZODONE HYDROCHLORIDE TABLETS

Always take Trazodone Hydrochloride Tablets 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 tablets 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

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 Tablets.

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, Trazodone Hydrochloride Tablets can cause side effects, although not everybody gets them.

Stop taking Trazodone Hydrochloride 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 Hydrochloride Tablets
- 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 (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
- 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 TABLETS

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

Do not use Trazodone Hydrochloride Tablets 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.

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 Tablets contains:
Each film-coated tablet contains 150mg of Trazodone hydrochloride.

Other ingredients include lactose monohydrate, microcrystalline cellulose, calcium hydrogen phosphate dihydrate, sodium starch glycolate Type A, povidone (PVP-K30), purified Water, colloidal anhydrous silica, magnesium stearate and instacoat sol IC-S-5585 Peach which contains hypromellose, polyethylene glycol, talc, titanium dioxide (E171), iron oxide red (E172) and iron oxide yellow (E172).

What Trazodone Hydrochloride Tablets looks like and contents of the pack

Trazodone Hydrochloride Tablets are pink, approx 10 mm round, biconvex film coated tablet debossed with "T" on upper side of breakline and plain on other side. The tablet can be divided into equal doses.

Trazodone Hydrochloride Tablets are available in blisters of Aluminium-PVC/PVDC White Opaque Film containing packs of 20's, 28's, 30's, 56's, 84's and 100's along with leaflet inside.
Not all pack sizes may be marketed.

Trazodone Hydrochloride Tablets are available in white opaque HDPE bottle with white polypropylene child resistant cap containing packs of 100, 250 and 500 tablets.
Not all pack sizes may be marketed.

Marketing Authorization Holder
Flamingo Pharma (UK) Ltd.
1st Floor, Kirkland House, 11-15 Peterborough Road, Harrow, Middlesex, HA1 2AX, United Kingdom.

Manufacturer
Flamingo Pharma (UK) Limited,
The Bloc, 38 Springfield Way,
Anlaby, Hull, HU10 6RJ,
United Kingdom

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