12325

Package leaflet: Information for the user

Trazodone hydrochloride 50 mg capsule, hard
Trazodone hydrochloride 100 mg capsule, hard

trazodone hydrochloride

Warning – Thoughts of self- harm and suicidal behaviour – see section 2

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 is and what it is used for
2. What you need to know before you take trazodone
3. How to take trazodone
4. Possible side effects
5. How to store trazodone
6. Contents of the pack and other information

1. What trazodone is and what it is used for

The name of your medicine is Trazodone hydrochloride 50 mg or 100 mg capsule, hard (called trazodone in this leaflet).
This belongs to a group of medicines called antidepressants.
Trazodone can be used to treat anxiety and depression.

2. What you need to know before you take trazodone

Do not take trazodone:
– if you are allergic to trazodone or any of the other ingredients of this medicine (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.

Warnings and precautions

Talk to your doctor or pharmacist before taking trazodone if you have:
The use of Buprenorphine together with trazodone can lead to serotonin syndrome, a potentially life-threatening condition (see "Other medicines and trazodone").

Thoughts of suicide and worsening of your depression or anxiety disorder

This medicine may be associated with thoughts of self-harm and suicidal behaviour in some people.
Tell someone you trust, who can help you in an emergency, that you are taking this medicine and ask that they read this leaflet
Talk to your trusted person, prescriber or go to a hospital straight away, if after starting this medicine, you have new or worse:
• Feelings of anxiety or irritability
• Feelings of restlessness and agitation
• Extreme increases in activity and difficulty sleeping
• Thoughts of acting on dangerous impulses to harm yourself
• Thoughts about suicide or dying
• Changes in behaviour or mood you, or someone you trust, notices and is worried about

In some people, thoughts of self-harm and suicidal behaviour may be increased when first starting antidepressants.
Antidepressants take time to work; and sometimes side effects occur before you or others notice improvements in your mood.
Never stop taking an antidepressant suddenly without first talking to a healthcare professional. Stopping an antidepressant medicine suddenly can cause other symptoms related to withdrawal to occur.
Information from clinical trials has shown the highest risk of thoughts of self harm and suicidal behaviour, is in adults aged less than 25 years who were treated with an antidepressant but the risk applies to people of all ages treated with these medicines.
Call NHS 111 who can offer you support, until you can be with someone who can help you in person.
Trazodone 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 or 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 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.

Children and adolescents

Trazodone should not be used in children and adolescents under 18 years of age. Patients under 18 have increased risk of side effects such as suicide attempt, suicidal thoughts and hostility (predominantly aggression, oppositional behaviour and anger) when they take antidepressant medicines. Moreover, there are no data available on the long-term safety on children and adolescents regarding growth, maturation and cognitive and behavioural development.

Other medicines and trazodone

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 can affect the way some other medicines work. Also some medicines can affect the way trazodone works.
Some medicines may increase the side effects of trazodone and may sometimes cause very serious reactions. Do not take any other medicines whilst taking trazodone without first talking to your doctor, especially:

• **buprenorphine/opioids -** These medicines may interact with trazodone 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.

In particular, 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 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.

Trazodone hydrochloride with alcohol

You should avoid drinking alcohol while taking trazodone.

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.

Pregnancy

Avoid taking trazodone during the first trimester of your pregnancy. Taking this medicine in the late stages of pregnancy may lead to your baby experiencing withdrawal symptoms when they are born.

Breast-feeding

Talk to your doctor if you are breast-feeding or intend to breast-feed. Your doctor will explain to you, whether you should continue/discontinue breast-feeding or continue/ discontinue taking trazodone.

Driving and using machines

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

Trazodone contains lactose and carmoisine

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine. The colouring agent carmoisine may cause allergic reactions.

Information on sodium content

This medicine contains less than 1 mmol sodium (23 mg) per Capsule, i.e. is essentially 'sodium-free'.

3. How to take trazodone

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

12325

Dimension - 180 x 310 mm

Front Side

Font size: Times New Roman 9 pt.

Non-Printing Colour

MFG. LOCATION: KRSG

ARTWORK DETAIL LABEL

Product	**Trazodone hydrochloride capsules**				
Buyer/Country	SPUK	Component	Pack Insert		
Dimension	180 x 310 mm			Pack	----
New Item Code	**1055890**	Old Item Code	1047115		
Colour Shades	BLACK			No. of Colours	1

Change Control No.	PC-ODF/2026/850 - Record Number: 511036	Artwork Version	4.0
Design/Style	Front & Back side printing, to be supplied in the Unfolded size.		
Substrate	60 GSM Paper.		
Special Instructions	PRINTING CLARITY TO BE CLEAR AND SHARP.		
Autocartonator Requirements	**Pack insert supply should be as per auto-cartonator. Refer auto-cartonator drawing for instructions.**		

Caution to the printer: Before processing, please ensure that the ARTWORK received for printing is exactly in line with APPROVED ARTWORK provided to you. In case of any FONTS/DESIGN are Mis-matching with the APPROVED ARTWORK, please inform PDC for further action. **DO NOT MAKE ANY CHANGE TO THE ARTWORK WITHOUT WRITTEN INSTRUCTIONS FROM PDC.**

Taking this medicine
- Take this medicine by mouth.
- Swallow the capsules whole with a drink of water.
- Take the capsules with or after food. This can help lower the chances of getting side effects.
- If you have been told to take trazodone 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.

The recommended doses are:
To treat depression (including depression accompanied by anxiety)
Adults: the starting dose is 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.
To treat anxiety
Adults: the starting dose is 75 mg each day. Your doctor may increase the dose to 300 mg each day.
Use in elderly
Older people or those who are frail will usually be given a starting dose of 100 mg each day.
If you take more trazodone than you should
If you take more trazodone than you should, tell a doctor or go to the hospital 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, confusion, breathing or heart problems.
If you forget to take Trazodone
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
Keep taking trazodone until your doctor tells you to stop. Do not stop taking this medicine 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.
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 and see a doctor or go to a hospital straight away if you experience:
- 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.
- 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).
- Severe abdominal pain and bloating, 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 (paresthesia).
- 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:
Frequency unknown (cannot be estimated from available data)
- 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 couldbe 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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via 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
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 carton and blister after EXP. The expiry date refers to the last day of that month.
This medicinal product does not require any special storage conditions.
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 contains
- The active substance is trazodone hydrochloride. Each 50 mg capsule, hard contains 50 mg of trazodone hydrochloride. Each 100 mg capsule, hard contains 100 mg of trazodone hydrochloride.
- The other ingredients are:
  Capsule content: lactose monohydrate, magnesium stearate.
  Capsule shell:
  Trazodone hydrochloride 50 mg capsule, hard gelatin, titanium dioxide (E171), carmoisine (E122), patent blue V (E131), iron oxide yellow (E172).
  Trazodone hydrochloride 100 mg capsule, hard gelatin, titanium dioxide (E171), carmoisine (E122), patent blue V (E131), iron oxide yellow (E172), iron oxide red (E172).
  Printing ink: shellac (E904), propylene glycol (E1520), black iron oxide (E172), potassium hydroxide (E525).

What trazodone capsules looks like and contents of the pack
The 50 mg capsules are white to off white granular powder filled in size "3" hard gelatin capsule with violet colour cap and green colour body printed 'TZ' on cap and '50' on body in black.
Blister pack sizes of 20, 28, 30, 56, 84, 90, 100, 112, 120, 168 and 180 capsules.
The 100 mg capsules are white to off white granular powder filled in size '2" hard gelatin capsule with violet colour cap and fawn colour body printed 'TZ' on cap and '100' on body in black.
Blister pack sizes of 20, 28, 30, 56, 84, 90, 100, 112, 120, 168 and 180 capsules.
Not all pack sizes may be marketed.

Marketing Authorisation Holder & Manufacturer
Strides Pharma UK Ltd.
Unit 4, The Metro Centre
Dwight Road, Watford
WD18 9SS
United Kingdom

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