

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE
PATIENT MEDICATION INFORMATION

PrTRAZODONE-50
PrTRAZODONE-100
PrTRAZODONE-150 D

Trazodone Hydrochloride Tablets USP

Read this carefully before you start taking **TRAZODONE** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **TRAZODONE**.

What is TRAZODONE used for?

TRAZODONE has been prescribed for you by your healthcare professional to relieve your symptoms of depression which may include:

- feeling sad;
- loss of interest in usual activities;
- significant change in weight or appetite;
- change in sleeping habits;
- having a hard time concentrating;
- feeling tired;
- having suicidal thoughts.

How does TRAZODONE work?

TRAZODONE is an antidepressant medication. It is thought to work by increasing the activity of serotonin in your brain. Serotonin is a brain chemical that helps to improve mood. It works at two different receptors in the brain.

What are the ingredients in TRAZODONE? Medicinal ingredients: trazodone hydrochloride

Non-medicinal ingredients: colloidal silicon dioxide, magnesium stearate, microcrystalline cellulose, sodium lauryl sulfate, sodium starch glycolate and starch. The 50 and 150 mg tablets also contain FD&C yellow #6.

TRAZODONE comes in the following dosage forms:

Tablets: 50 mg, 100 mg and 150 mg

Do not use TRAZODONE if you:

- are allergic to any of the ingredients in TRAZODONE.
- take a Monoamine Oxidase Inhibitor (MAOI).
 - Ask your healthcare professional or pharmacist if you are not sure if you take a MAOI.
 - Examples of MAOIs include linezolid which is an antibiotic, methylene blue which is a dye used in certain surgeries.
 - If you stopped taking a MAOI within the last 14 days, only start TRAZODONE if your healthcare professional tells you to.
 - Do not take a MAOI within 14 days of stopping TRAZODONE unless directed to do so by your healthcare professional.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take TRAZODONE. Talk about any health conditions or problems you may have, including if you:

- are taking or have recently taken a monoamine oxidase inhibitor (MAOI).
- have a history or a family history of heart problems, including: heart disease, heart attack, QT prolongation, and irregular heartbeats.
- have high blood pressure that is not controlled by your medication or any heart problems.
- have a history of drug abuse.
- have a bleeding disorder.
- take certain medicines which may affect blood clotting and increase bleeding, such as oral anticoagulants (e.g., warfarin, dabigatran), acetylsalicylic acid and other non-steroidal anti-inflammatory drugs (e.g., ibuprofen).

- have or had seizures or convulsions.
- take other medications that may increase your chance of a seizure, including drugs for depression and some antibiotics.
- have glaucoma or increased pressure in your eyes.
- have suicidal thoughts.
- have a family history of mania or bipolar disorder.
- have or have had an eating disorder, for example binge eating (bulimia) or anorexia nervosa.
- have liver problems.
- have kidney problems.
- have previous detected breast cancer.
- are pregnant or plan to become pregnant. It is not known if TRAZODONE will harm your unborn baby. Talk to your healthcare professional about the benefits and risks of treating depression during pregnancy.
- are breastfeeding or plan to breastfeed. It is not known if TRAZODONE passes into breast milk. You and your healthcare professional should decide if you should take TRAZODONE while breastfeeding.
- have any other medical conditions.

TRAZODONE is not for use in children under 18 years of age.

Other warnings you should know about:

It is important to talk to your healthcare professional about the risks of treating depression and also the risk of not treating it. You should discuss all treatment options with your healthcare professional.

New or worsened emotional or behaviour problems:

Treatment with these types of medications is most safe and effective when you and your healthcare professional have good communication about how you are feeling. You may find it helpful to tell a relative or close friend that you are depressed. You might ask them to tell you if they think you are getting worse or if they are worried about changes in your behavior.

Some patients may feel worse instead of better when they first start taking drugs like TRAZODONE or when changing the dose. You may have:

- new or worsened feelings of nervousness, tension, anger, agitation, or aggression.
- thoughts about suicide, hurting yourself or other people. Thoughts and actions about suicide can occur especially if you have had thoughts of hurting yourself in the past. Suicidal thoughts and actions can occur in any age group but may be more likely in patients 18 to 24 years old. **If this happens, seek immediate medical help.** Do NOT stop taking TRAZODONE on your own.

Effects on pregnancy and newborns:

If you are pregnant or are planning to become pregnant while taking TRAZODONE, talk to your healthcare professional about the risks and benefits of various treatment options. It is very important that you keep taking TRAZODONE until your healthcare professional tells you to stop.

When pregnant women took drugs in the same group of medications as TRAZODONE, some newborn babies had complications at birth. This happened especially when the medication was taken in the last three months of pregnancy. Some newborns:

- Required breathing support, tube feeding and a longer stay in the hospital.
- Had difficulty feeding or breathing, seizures, tense or overly relaxed muscles and were jittery and cried constantly.
- Had a serious condition called persistent pulmonary hypertension. This made the babies breathe faster and appear blue in color.

These symptoms normally go away over time. However, if your baby experiences any of these symptoms, consult your healthcare professional as soon as possible.

Angle-closure Glaucoma

TRAZODONE can cause an acute attack of glaucoma. Get immediate medical help if you experience eye pain, changes in vision or swelling or redness in or around the eye.

Risk of breaking a bone

You should tell your healthcare professional if you:

- are elderly and had a recent bone fracture, or
- were told you have osteoporosis or risk factors for osteoporosis.

Taking TRAZODONE may increase your risk of breaking a bone if you are elderly or have osteoporosis or have other major risk factors for breaking a bone. This is especially true when you first start taking TRAZODONE and soon after you stop taking it. Take extra care to avoid falling, especially if you get dizzy or have low blood pressure.

Effect on the hormones

In women, medicines of this type may cause changes in the regularity of their monthly period or leakage of milk from the breast even if they are not pregnant. In some men, after prolonged treatment, there may be some diminished sexual function and breast enlargement may be experienced. Tell your healthcare professional if you experience any of these symptoms.

Discontinuation symptoms:

If your healthcare professional recommends that you stop taking TRAZODONE, they will gradually lower the dose of TRAZODONE you are taking. This may help manage any symptoms of discontinuation, such as:

- dizziness, headache, ringing in the ears, seizures;
- nausea, diarrhea, vomiting;
- tingling, burning, or prickling sensation of your skin, excessive sweating;
- feeling nervous, confused, irritated, restless, or having an unstable mood;
- fatigue, insomnia (inability to sleep), nightmares.

These symptoms will usually disappear without needing treatment. Tell your healthcare professional immediately if you have these or any other symptoms. Your healthcare professional may adjust the dosage of TRAZODONE to alleviate the symptoms.

Driving and Using Machines:

TRAZODONE can make you feel sleepy or may affect your ability to think clearly, make decisions or react quickly. Wait until you know how you feel after you have taken TRAZODONE before you drive or use heavy machines.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines, especially:

- other antidepressants;
- other drugs that affect serotonin such as lithium, linezolid, sibutramine, tryptophan, triptans, St.

John's Wort;

- drugs used to treat schizophrenia (e.g. olanzapine, risperidone);
- medicines used to treat anxiety, such as clonazepam, alprazolam, lorazepam, diazepam or phenobarbital;
- certain medicines which may affect blood clotting and increase bleeding, such as oral anticoagulants (e.g., warfarin, dabigatran), acetylsalicylic acid and other non-steroidal anti-inflammatory drugs (e.g., ibuprofen);
- certain medicines used to treat pain, such as fentanyl (used in anaesthesia or to treat chronic pain), tramadol, tapentadol, meperidine, methadone, pentazocine;
- certain medicines used to treat cough, such as dextromethorphan;
- when taking certain medicines such as antifungals (e.g. ketoconazole); antibiotics (e.g. erythromycin) or medicines used to treat seizures (carbamazepine). Your healthcare professional may adjust your dose of TRAZODONE when taking these medicines.
- mephenytoin;
- diuretics

You should avoid drinking alcohol while taking TRAZODONE.

How to take TRAZODONE:

It is important to take TRAZODONE exactly as your healthcare professional has told you. Your healthcare professional may need to change the dose until it is right for you.

- Take your TRAZODONE tablet at the same time each day. If you have any problems with your dosing routine, contact your doctor or pharmacist.

- TRAZODONE should be taken shortly after a meal or light snack.
- Take only the recommended dose prescribed by your healthcare professional. Never increase the dose of TRAZODONE you or those in your care are taking, unless your healthcare professional tells you to.
- The effects of your medication may not be noticeable in the first few days of treatment, and significant improvement may take several weeks. If you are concerned that your medicine is not working, discuss this with your healthcare professional.
- Even if you feel better, do not stop taking TRAZODONE without talking to your healthcare professional.

Usual dose:

- The usual adult starting dose is 150 to 200 mg daily, in two or three divided doses.
- Your healthcare professional may increase your dose gradually by 50 mg each time up to 300 mg a day, in divided doses.

Elderly (65 years of age or older):

- The dose in elderly patients will be less than half the usual adult dose.

Remember: The medicine has been prescribed only for you. Do not give it to anybody else, as they may experience undesirable effects, which may be serious.

Overdose:

If you think you have taken too much TRAZODONE, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed dose:

If you miss a dose of TRAZODONE, take the missed dose as soon as you remember. If it is almost time for the next dose, skip the missed dose and take your next dose at the regular time. Do not take two doses of TRAZODONE at the same time.

What are possible side effects from using TRAZODONE?

These are not all the possible side effects you may feel when taking TRAZODONE. If you experience any side effects not listed here, contact your healthcare professional.

Common side effects in people who take trazodone include:

- headache
- dry mouth
- nausea/vomiting
- dizziness
- drowsiness, fatigue, weakness
- blurred vision

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Get immediate medical help
	Only if severe	In all cases	
UNCOMMON Mania/Hypomania: elevated or irritated mood, decreased need for sleep, racing thoughts		✓	
Seizures: loss of consciousness with uncontrollable shaking			✓
RARE Serotonin syndrome: a combination of most or all of the following: confusion, restlessness, sweating, shaking, shivering, hallucinations, sudden jerking of the muscles, fast heartbeat			✓
Glaucoma: increased pressure in the eyes, eye pain and blurred vision		✓	
Low sodium level in blood: tiredness, weakness, confusion, combined with achy, stiff or uncoordinated muscles		✓	
Priapism: painful, longer than normal erection of the penis			✓
Bleeding in the gut: vomiting blood or passing blood in stool			✓
UNKNOWN Allergic reaction: red skin, hives, itching, swelling of the lips, face, tongue or throat, trouble breathing, wheezing, shortness of breath, skin rashes, blisters of the skin, sores or pain in the mouth or eyes			✓
Low platelets: bruising or unusual bleeding from the skin or other areas		✓	
New or worsened emotional or behavioural problems: feeling angry, aggressive, worried, agitated, hostile or impulsive. Feeling violent or suicidal. Thoughts of hurting yourself or other people. Feeling like you are not yourself or that you are less inhibited.			✓

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store TRAZODONE at controlled room temperature 15°C to 30°C. Protect from light.
Keep out of reach and sight of children.

If you want more information about TRAZODONE:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and include this Patient Medication Information by visiting the Health Canada website (<https://health-products.canada.ca/dpd-bdpp/index-eng.jsp>); the manufacturer's website (<http://www.prodoc.qc.ca>) or by calling at 1-800-361-8559.

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