

MEDICATION GUIDE

Trazodone hydrochloride tablets, USP

(traz' oh done hye'' droe klor' ide)

Read the Medication Guide that comes with trazodone hydrochloride tablets before you start taking it and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or treatment. Talk to your healthcare provider or pharmacist if there is something you do not understand or you want to learn about trazodone hydrochloride tablets.

What is the most important information I should know about trazodone hydrochloride tablets?

Antidepressant medicines, depression or other serious mental illnesses, and suicidal thoughts or actions: Talk to your healthcare provider about:

1. All risks and benefits of treatment with antidepressant medicines
2. All treatment choices for depression or other serious mental illnesses

1. Antidepressant medicines may increase suicidal thoughts or actions in some children, teenagers, and young adults within the first few months of treatment.

2. Depression and other serious mental illnesses are the most important causes of suicidal thoughts and actions. Some people may have a higher risk of having suicidal thoughts or actions. These include people who have or have a family history of bipolar illness (also called manic-depressive illness) or suicidal thoughts or actions.

3. How can I watch for and try to prevent suicidal thoughts and actions?

1. Pay close attention to any changes, especially sudden changes in mood, behaviors, thoughts, or feelings. This is very important when an antidepressant medicine is started or when the dose is changed.
2. Call your healthcare provider right away to report new or sudden changes in mood, behavior, thoughts or feelings.
3. Keep all follow-up visits with your healthcare provider as scheduled. Call your healthcare provider between visits as needed, especially if you are worried about symptoms.

Call a healthcare provider right away if you have any of the following symptoms, especially if they are new, worse, or worry you:

1. Thoughts about suicide or dying
2. Attempts to commit suicide
3. New or worse depression
4. New or worse anxiety
5. Feeling very agitated or restless
6. Panic attacks
7. Trouble sleeping (insomnia)
8. New or worse irritability
9. Acting aggressive, being angry or violent
10. Acting on dangerous impulses
11. An extreme increase in activity and talking (mania)
12. Other unusual changes in behavior or mood

4. Visual problems: eye pain, changes in vision, swelling or redness in or around the eye

1. eye pain
2. changes in vision
3. swelling or redness in or around the eye

Only some people are at risk for these problems. You may want to undergo an eye examination to see if you are at risk and receive preventative treatment if you are.

5. What else do I need to know about antidepressant medicines?

Never stop an antidepressant medicine without first talking to a healthcare provider. Stopping an antidepressant medicine suddenly can cause other symptoms.

Antidepressants are medicines used to treat depression and other illnesses. It is important to discuss all the risks of treating depression and also the risks of not treating it. You should discuss all treatment choices with your healthcare provider, not just the use of antidepressants.

Antidepressant medicines have other side effects. Talk to your healthcare provider about the side effects of your medicines.

Antidepressant medicines can interact with other medicines. Know all of the medicines that you take. Keep a list of all medicines to show your healthcare provider. Do not start new medicines without first checking with your healthcare provider.

4. Trazodone hydrochloride tablets **are not approved for use in children.** Talk to your healthcare provider for more information.

What are trazodone hydrochloride tablets?

Trazodone hydrochloride tablets are a prescription medicine used to treat major depressive disorder in adults.

What should I tell my healthcare provider before taking trazodone hydrochloride tablets?

Before you take trazodone hydrochloride tablets tell your healthcare provider if you:

1. have heart problems, including QT prolongation or a family history of it
2. have ever had a heart attack
3. have bipolar disorder
4. have liver or kidney problems
5. have other serious medical conditions
6. are pregnant or plan to become pregnant. Trazodone hydrochloride tablets may harm your unborn baby. Talk to your healthcare provider if you are pregnant or plan to become pregnant.
7. are breastfeeding or plan to breastfeed. It is not known if trazodone hydrochloride tablets enter your breast milk. You and your healthcare provider should decide if you will take trazodone hydrochloride or breastfeed.
8. have taken a Monoamine Oxidase Inhibitor (MAOI) or if you have stopped taking an MAOI in the last 2 weeks.

Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements.

Using trazodone hydrochloride tablets with certain other medicines can affect each other causing serious side effects.

Know the medicines you take. Keep a list of them and show it to your healthcare provider and pharmacist when you get a new medicine.

How should I take trazodone hydrochloride tablets?

1. Take trazodone hydrochloride tablets exactly as your healthcare provider tells you.
2. Trazodone hydrochloride tablets should be taken shortly after a meal or light snack.
3. If you feel drowsy after taking trazodone hydrochloride tablets, talk to your healthcare provider. Your healthcare provider may change your dose or the time of day you take your trazodone hydrochloride tablets.
4. Do not stop taking trazodone hydrochloride tablets without talking to your healthcare provider.
5. Trazodone hydrochloride tablets should be swallowed whole or broken in half along the score line. Do not chew or crush trazodone hydrochloride tablets. Tell your healthcare provider if you cannot swallow trazodone either whole or as a half tablet.
6. If you take too much trazodone hydrochloride, call your doctor or go to the nearest emergency room right away.

What should I avoid while taking trazodone hydrochloride tablets?

1. Do not drive, operate heavy machinery, or do other dangerous activities until you know how trazodone hydrochloride tablets affect you. Trazodone hydrochloride tablets can slow your thinking and motor skills.
2. Do not drink alcohol or take other medicines that make you sleepy or dizzy while taking trazodone hydrochloride tablets until you talk with your healthcare provider. Trazodone hydrochloride tablets may make your sleepiness or dizziness worse if you take it with alcohol or other medicines that cause sleepiness or dizziness.

What are the possible side effects of trazodone hydrochloride tablets?

Trazodone hydrochloride tablets can cause serious side effects or death. See “What is the most important information I should know about trazodone hydrochloride tablets?”

Serious side effects include:

1. Serotonin syndrome. Symptoms of serotonin syndrome include: agitation, hallucinations, problems with coordination, fast heartbeat, tight muscles, trouble walking, nausea, vomiting, diarrhea.
2. Feeling high or in a very good mood, then becoming irritable, or having too much energy, feeling like you have to keep talking or do not sleep (mania).
3. Irregular or fast heartbeat or faint (QT prolongation).
4. Low blood pressure. You feel dizzy or faint when you change positions (go from sitting to standing).
5. Unusual bruising or bleeding.
6. Erection lasting for more than 6 hours (priapism).
7. Low sodium in your blood (hyponatremia). Symptoms of hyponatremia include: headache, feeling weak, feeling confused, trouble concentrating, memory problems and feeling unsteady when you walk.
8. Withdrawal symptoms. Symptoms of withdrawal can include anxiety, agitation, and sleep problems. Do not stop taking trazodone hydrochloride tablets without talking to your healthcare provider.

Get medical help right away, if you have any of the symptoms listed above.

The most common side effects of trazodone hydrochloride tablets include:

1. Sleepiness
2. Dizziness
3. Constipation
4. Blurry vision

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of trazodone hydrochloride tablets. For more information, ask your

healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 .

How should I store trazodone hydrochloride tablets?

1. Store trazodone hydrochloride tablets between 20° to 25°C (68° to 77°F).
2. Keep in tight container
3. Keep out of the light
4. Safely throw away medicine that is out of date or no longer needed.

Keep trazodone hydrochloride tablets and all medicines out of the reach of children.

General information about the safe and effective use of trazodone hydrochloride tablets.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use trazodone hydrochloride tablets for a condition for which it was not prescribed. Do not give trazodone hydrochloride tablets to other people, even if they have the same symptoms that you have. It may harm them.

This Medication Guide summarizes the most important information about trazodone hydrochloride tablets. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about trazodone hydrochloride tablets that is written for health professionals.

For more information contact Apotex Corp., Drug Safety at 1-800-706-5575 .

What are the ingredients in trazodone hydrochloride tablets?

Active ingredient: trazodone hydrochloride, USP

Inactive ingredients: colloidal silicon dioxide, magnesium stearate, microcrystalline cellulose, pregelatinized starch, sodium lauryl sulfate, and sodium starch glycolate.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

APOTEX INC.

TRAZODONE HYDROCHLORIDE TABLETS, USP

50 mg, 100 mg, 150 mg and 300 mg

Manufactured by:

Apotex Inc.
Toronto, Ontario
Canada M9L 1T9

Manufactured For:

Apotex Corp.
Weston Florida 33326

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