MEDICATION GUIDE

Trazodone hydrochloride tablets, USP, for oral use

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

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:

- All risks and benefits of treatment with antidepressant medicines
- 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?**

- 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.
- Call your healthcare provider right away to report new or sudden changes in mood, behavior, thoughts or feelings.
- 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:

- Thoughts about suicide or dying
- Attempts to commit suicide
- New or worse depression
- New or worse anxiety
- Feeling very agitated or restless
- Panic attacks
- Trouble sleeping (insomnia)
- New or worse irritability
- Acting aggressive, being angry or violent
- Acting on dangerous impulses
- An extreme increase in activity and talking (mania)
- Other unusual changes in behavior or mood

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.

It is not known if trazodone is safe and effective in children.

What are trazodone hydrochloride tablets?

Trazodone hydrochloride tablets are a prescription medicine used in adults to treat major depressive disorder (MDD). Trazodone belongs to a class of medicines known as SSRIs (or selective serotonin reuptake inhibitors).

Do not take trazodone hydrochloride tablets:

- If you take a monoamine oxidase inhibitor (MAOI). Ask your healthcare provider or pharmacist if you are not sure if you take an MAOI, including the antibiotic linezolid, and intravenous methylene blue.
- Do not take an MAOI within 2 weeks of stopping trazodone hydrochloride tablets unless directed to do so by your healthcare provider.
- Do not start trazodone hydrochloride tablets if you stopped taking an MAOI in the last 2 weeks unless directed to do so by your healthcare provider.

Before you take trazodone hydrochloride tablets tell your healthcare provider about all of your medical conditions, including if you:

- have heart problems, including QT prolongation or a family history of it
- have ever had a heart attack
- have bipolar disorder
- have liver or kidney problems
- have other serious medical conditions
- 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.
- are breastfeeding or plan to breastfeed. It is not known if trazodone hydrochloride passes into your breast milk. You and your healthcare provider should decide if you will take trazodone hydrochloride or breastfeed.
- 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 over-the-counter medicines, vitamins, and herbal supplements. Using trazodone hydrochloride tablets with certain other medicines can affect each other causing serious side effects.

Especially tell your healthcare provider if you take:

- triptans used to treat migraine headache
- medicines used to treat mood, anxiety, psychotic or thought disorders, including tricyclics, lithium, SSRIs, SNRIs, buspirone, or antipsychotics
- tramadol
- over-the-counter supplements such as tryptophan or St. John’s Wort
- nonsteroidal anti-inflammatory drugs (NSAIDS)
- aspirin
- warfarin (Coumadin, Jantoven)
- phenytoin (Mesantoin)
- diuretics

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?

- Take trazodone hydrochloride tablets exactly as your healthcare provider tells you.
- Trazodone hydrochloride tablets should be taken shortly after a meal or light snack.
- 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.
- Do not stop taking trazodone hydrochloride tablets without talking to your healthcare provider.
- 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.
- If you take too much trazodone hydrochloride, call your healthcare provider, your Poison Control Center at 1-800-222-1222, or go to the nearest emergency room right away.

What should I avoid while taking trazodone hydrochloride tablets?

- 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.
- 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, including:

- **See "What is the most important information I should know about trazodone hydrochloride tablets?"**

- **Serotonin syndrome.** Symptoms of serotonin syndrome include: agitation, hallucinations, problems with coordination, fast heartbeat, tight muscles, trouble walking, sweating, fever, nausea, vomiting, and diarrhea.
- **Irregular or fast heartbeat or faint (QT prolongation)**
- **Low blood pressure.** You feel dizzy or faint when you change positions (go from sitting to standing)
- **Unusual bruising or bleeding**
- **Erection lasting for more than 6 hours (priapism)**
- **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).**
- **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.
- **Visual problems.**
  - eye pain
  - changes in vision
  - 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.

- **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.

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

The most common side effects of trazodone hydrochloride tablets include:

- swelling
- blurred vision

- dizziness
- sleepiness
- tiredness
- diarrhea
- stuffy nose
- weight loss

These are not all the possible side effects of trazodone hydrochloride tablets. 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?

- Store trazodone hydrochloride tablets between 20°C to 25°C (68°F to 77°F).
- Keep in tight container
- Keep out of the light
- 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. 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	Manufactured For
Apotex Inc.	Apotex Corp.
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