

MEDICATION GUIDE

Tranxene* (TRAN-zeen) T-TAB[®] (clorazepate dipotassium) tablets



Read this Medication Guide before you start taking TRANXENE 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.

What is the most important information I should know about TRANXENE?

Do not stop taking TRANXENE without first talking to your healthcare provider.

Stopping TRANXENE suddenly can cause serious problems.

TRANXENE can cause serious side effects, including:

1. TRANXENE can make you sleepy or dizzy and can slow your thinking and motor skills

- Do not drive, operate heavy machinery, or do other dangerous activities until you know how TRANXENE affects you.
- Do not drink alcohol or take other drugs that may make you sleepy or dizzy while taking TRANXENE without first talking to your healthcare provider. When taken with alcohol or drugs that cause sleepiness or dizziness, TRANXENE may make your sleepiness or dizziness much worse.

2. TRANXENE can cause abuse and dependence.

- Do not stop taking TRANXENE all of a sudden. Stopping TRANXENE suddenly can cause seizures that do not stop, hearing or seeing things that are not there (hallucinations), shaking, and stomach and muscle cramps.
 - Talk to your doctor about slowly stopping TRANXENE to avoid getting sick with withdrawal symptoms.
 - Physical dependence is not the same as drug addiction. Your healthcare provider can tell you more about the differences between physical dependence and drug addiction.

TRANXENE is a federally controlled substance (C-IV) because it can be abused or lead to dependence. Keep TRANXENE in a safe place to prevent misuse and abuse. Selling or giving away TRANXENE may harm others, and is against the law. Tell your healthcare provider if you have ever abused or been dependent on alcohol, prescription medicines or street drugs.

3. TRANXENE may harm your unborn or developing baby.

Medicines like TRANXENE can cause birth defects. Talk with your healthcare provider if you are pregnant or plan to become pregnant. Tell your healthcare provider right away if you become

pregnant while taking TRANXENE. You and your healthcare provider should decide if you will take TRANXENE while you are pregnant. Birth defects may occur even in children born to women who are not taking any medicines and do not have other risk factors.

- If you become pregnant while taking TRANXENE, talk to your healthcare provider about registering with the North American Antiepileptic Drug Pregnancy Registry. You can register by calling 1-888-233-2334. The purpose of this registry is to collect information about the safety of antiepileptic drugs during pregnancy.
- Tranxene can pass into breast milk. Talk to your healthcare provider about the best way to feed your baby if you take TRANXENE. You and your healthcare provider should decide if you will take TRANXENE or breast feed. You should not do both.

4. Like other antiepileptic drugs, TRANXENE may cause suicidal thoughts or actions in a very small number of people, about 1 in 500.

Call your healthcare provider right away if you have any of these 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 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

How can I watch for early symptoms of suicidal thoughts and actions?

- Pay attention to any changes, especially sudden changes, in mood, behaviors, 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.

Do not stop TRANXENE without first talking to a healthcare provider.

Stopping TRANXENE suddenly can cause serious problems.

Stopping a seizure medicine suddenly in a patient who has epilepsy can cause seizures that will not stop (status epilepticus).

Suicidal thoughts or actions can be caused by things other than medicines. If you have suicidal thoughts or actions, your healthcare provider may check for other causes.

What is TRANXENE?

TRANXENE is a prescription medicine used:

- to treat anxiety disorders
- with other medicines to treat partial seizures
- to treat the symptoms of sudden alcohol withdrawal

Who should not take TRANXENE?

Do not take TRANXENE if you:

- are allergic to clorazepate dipotassium or any of the ingredients in TRANXENE. See the end of this Medication Guide for a complete list of ingredients in TRANXENE.
- have an eye disease called acute narrow angle glaucoma.

What should I tell my healthcare provider before taking TRANXENE?

Before you take TRANXENE, tell your healthcare provider if you:

- have liver or kidney problems
- have or have had depression, mood problems, or suicidal thoughts or behavior
- have a history of abnormal thinking and behavior (psychotic reactions)
- have any other medical conditions

Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Taking TRANXENE with certain other medicines can cause side effects or affect how well they work. Do not start or stop other medicines without talking to your healthcare provider.

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 TRANXENE?

- Take TRANXENE exactly as prescribed. Your healthcare provider will tell you how much TRANXENE to take.
- Your healthcare provider may change your dose. Do not change your dose of TRANXENE without talking to your healthcare provider.
- Do not stop taking TRANXENE without first talking to your healthcare provider. Stopping TRANXENE suddenly can cause serious problems.

If you take too much TRANXENE, call your healthcare provider or local Poison Control Center right away.

What are the possible side effects of TRANXENE?

See “**What is the most important information I should know about TRANXENE?**”.

The most common side effects of TRANXENE include:

- drowsiness
- dizziness
- upset stomach
- blurred vision
- dry mouth
- confusion

These are not all the possible side effects of TRANXENE. For more information ask your healthcare provider or pharmacist.

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

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 TRANXENE?

- Store TRANXENE between 68⁰F to 77⁰F (20⁰C to 25⁰C).
- Keep TRANXENE in a tightly closed container.
- Keep TRANXENE out of the light.
- Keep TRANXENE tablets dry.

Keep TRANXENE and all medicines away from children.

General Information about TRANXENE

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use TRANXENE for a condition for which it was not prescribed. Do not give TRANXENE 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 TRANXENE. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about TRANXENE that is written for health professionals.

For more information about TRANXENE, go to www.lundbeckinc.com or call Lundbeck Inc. at 1-888-514-5204.

What are the ingredients in TRANXENE?

Active ingredient: clorazepate dipotassium

Inactive ingredients: colloidal silicon dioxide, magnesium oxide, magnesium stearate, microcrystalline cellulose, potassium carbonate, potassium chloride and talc.

In addition:

- the 3.75 mg tablets contain FD&C Blue No. 2
- the 7.5 mg tablets contain FD&C Yellow No. 6
- the 15 mg tablets contain FD&C Red No. 3

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

Manufactured by: Abbott Pharmaceuticals PR Ltd.

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Revised: May 2010

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