

# ZEPRAN<sup>®</sup>

Clorazepate dipotassium Tablets

TAJ PHARMACEUTICALS LIMITED., INDIA

ANTI ANXIETY

P R O D U C T S

Anxiety disorders



## MEDICATION GUIDE

ZEPRAN<sup>®</sup>\* Tablets  
(clorazepate dipotassium)  
tablets  
C-IV/DEA Schedule IV

Read this Medication Guide before you start taking ZEPRAN<sup>®</sup> 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 ZEPRAN<sup>®</sup>

Do not stop taking ZEPRAN<sup>®</sup> without first talking to your healthcare provider.

Stopping ZEPRAN<sup>®</sup> suddenly can cause serious problems.

ZEPRAN<sup>®</sup> can cause serious side effects, including:

### 1. ZEPRAN<sup>®</sup> 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 ZEPRAN<sup>®</sup> affects you.

Do not drink alcohol or take other drugs that may make you sleepy or dizzy while taking ZEPRAN<sup>®</sup> without first talking to your healthcare provider. When taken with alcohol or drugs that cause sleepiness or dizziness, ZEPRAN<sup>®</sup> may make your sleepiness or dizziness much worse.

### 2. ZEPRAN<sup>®</sup> can cause abuse and dependence.

Do not stop taking ZEPRAN<sup>®</sup> all of a sudden. Stopping ZEPRAN<sup>®</sup> 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 ZEPRAN<sup>®</sup> 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.

ZEPRAN<sup>®</sup> is a federally controlled substance (C-IV) because it can be abused or lead to dependence. Keep ZEPRAN<sup>®</sup> in a safe place to prevent misuse and abuse. Selling or giving away ZEPRAN<sup>®</sup> 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. ZEPRAN<sup>®</sup> may harm your unborn or developing baby.

Medicines like ZEPRAN<sup>®</sup> 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 ZEPRAN<sup>®</sup>. You and your healthcare provider should decide if you will take ZEPRAN<sup>®</sup> 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 ZEPRAN<sup>®</sup>, 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.

~~ZEPRAN<sup>®</sup> can pass into breast milk. Talk to your healthcare provider about the best way to feed your baby if you take ZEPRAN<sup>®</sup>. You and your healthcare provider should decide if you will take ZEPRAN<sup>®</sup> or breast feed. You should not do both.~~

**4. Like other antiepileptic drugs, ZEPRAN<sup>®</sup> 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 ZEPRAN<sup>®</sup> without first talking to a healthcare provider.

Stopping ZEPRAN<sup>®</sup> 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 ZEPRAN<sup>®</sup>?**

ZEPRAN<sup>®</sup> 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 ZEPRAN<sup>®</sup>?**

Do not take ZEPRAN<sup>®</sup> if you:

are allergic to clorazepate dipotassium or any of the ingredients in ZEPRAN<sup>®</sup>. See the end of this Medication Guide for a complete list of ingredients in ZEPRAN<sup>®</sup>.

have an eye disease called acute narrow angle glaucoma.

**Note :** This product information is intended only for residents of the India. Taj Pharmaceuticals Limited, medicines help to treat and prevent a range of conditions—from the most common to the most challenging—for people around the world.

Information for Health Care Professionals

\*\*\* Please consult local Prescribing Information for any product before use. This DOCUMENT is an international information resource for healthcare professionals with an interest in disease management. This DOCUMENT is not intended to replace the advice of a qualified healthcare professional. Above brand is a trademark of the Taj group of companies (Taj Pharmaceuticals Limited)

**FOLLOW THE PRESCRIBED DOSES  
PRESCRIPTION ONLY MEDICINE**

**What should I tell my healthcare provider before taking ZEPRAN<sup>®</sup>?**

Before you take ZEPRAN<sup>®</sup>, 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 ZEPRAN<sup>®</sup> 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 ZEPRAN<sup>®</sup>?**

Take ZEPRAN<sup>®</sup> exactly as prescribed. Your healthcare provider will tell you how much ZEPRAN<sup>®</sup> to take.

Your healthcare provider may change your dose. Do not change your dose of ZEPRAN<sup>®</sup> without talking to your healthcare provider.

Do not stop taking ZEPRAN<sup>®</sup> without first talking to your healthcare provider. Stopping ZEPRAN<sup>®</sup> suddenly can cause serious problems.

If you take too much ZEPRAN<sup>®</sup>, call your healthcare provider or local Poison Control Center right away.

**What are the possible side effects of ZEPRAN<sup>®</sup>?**

See "What is the most important information I should know about ZEPRAN<sup>®</sup>?"

The most common side effects of ZEPRAN<sup>®</sup> include:

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



**FOLLOW THE PRESCRIBED DOSES  
PRESCRIPTION ONLY MEDICINE**

These are not all the possible side effects of ZEPRAN<sup>®</sup>. 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 ZEPRAN<sup>®</sup>?

Store ZEPRAN<sup>®</sup> between 68°F to 77°F (20°C to 25°C).

Keep ZEPRAN<sup>®</sup> in a tightly closed container.

Keep ZEPRAN<sup>®</sup> out of the light.

Keep ZEPRAN<sup>®</sup> tablets dry.

Keep ZEPRAN<sup>®</sup> and all medicines away from children.

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**General Information about ZEPRAN<sup>®</sup>**

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

For more information about ZEPRAN<sup>®</sup>, go to [www.tajpharma.com](http://www.tajpharma.com) or call Taj Pharma. at 1-888-523-5504.

What are the ingredients in ZEPRAN<sup>®</sup>?

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: Taj Pharma India

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Revised: May 2010



Manufactured in India By:  
Taj Pharmaceuticals Limited

TAJ PHARMACEUTICALS LIMITED., INDIA

ANTI ANXIETY

P R O D U C T S

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN.



**FOLLOW THE PRESCRIBED DOSES  
PRESCRIPTION ONLY MEDICINE**

TAJ PHARMA INDIA



**ZEPRAN<sup>®</sup> (Clorazepate dipotassium) for anxiety disorders.**

TAJ PHARMACEUTICALS LIMITED., INDIA

ANTI ANXIETY

P R O D U C T S

**ZEPRAN<sup>®</sup>**

Clorazepate dipotassium Tablets  
(Anti Anxiety)

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ZEPRAN<sup>®</sup> (Clorazepate dipotassium)

## Treatment of anxiety disorders and for short-term relief of the symptoms of anxiety

Updated on: May 2013

Source: Taj Pharmaceuticals Research and Development

**Taj Pharmaceuticals Limited** is a pharmaceutical company founded and based in India. The company manufactures pharmaceutical formulations and API for India and other countries of world. The company was established in 1995 as an enterprise and in 2004 became a public limited company. As per Mumbai pharmaxil and Chemixil association the company manufactures and exports to countries like Albania, Argentina, Austria, Chile and Iraq. In 1995 pharmaceuticals wing only has a schedule M certification for pharmaceuticals products manufacturing in India. Taj Pharmaceuticals established its manufacturing unit in Gujarat because of government policies in 1999 with WHO / GMP licence. The company in 2003 revived all the old manufacturing units and approached the **FDA Gujarat for 4000 new pharmaceuticals drug permissions** for the first time in India.

According to the Indian Trade Mark the company owns about **450 brands and 4600 generic** manufacturing permissions in India. According to the export data analysis the company was the largest exporter of generic medicines to the Europe and Middle East countries.

MANUFACTURED IN INDIA BY:

Taj Pharmaceuticals Limited (INDIA)



**Taj Pharmaceuticals Limited**  
Working For Healthier World<sup>™</sup> INDIA