The compound occurs as a fine, lightyellow, practically odorless powder. It is insoluble in water. The crystals melt at 186-187°C (367-365°F). The melting point is 189°C (372°F) in a sealed tube.

Chemically, clorazepate dipotassium USP is a benzodiazepine. Its empirical formula is C_{22}H_{22}ClNO_{2}. Its molecular weight is 382.83. It is a white, odorless powder with a bitter taste. It is freely soluble in water, but is insoluble in ether, chloroform, and alcohol.

## Pharmacokinetics

Clorazepate dipotassium tablets are rapidly absorbed after oral administration. The peak plasma concentrations are usually reached within 2 hours. The drug is extensively metabolized in the liver and excreted primarily in the urine. The elimination half-life of clorazepate dipotassium is approximately 6 hours.

### Overview

Clorazepate dipotassium is indicated for the management of anxiety disorders and for the treatment of sleep disorders. It is also used to treat convulsions in status epilepticus. It is effective in the management of anxiety disorders, including panic disorder, and for the treatment of insomnia. It is also used in the management of alcohol withdrawal syndrome.

### Adverse Reactions

The most common adverse reactions associated with clorazepate dipotassium include somnolence, dizziness, ataxia, drowsiness, and sedation. Other less common adverse reactions include nausea, vomiting, diarrhea, and rash. Clorazepate dipotassium may also cause drowsiness, dizziness, and sedation, which may increase with the duration of therapy.

### Contraindications

Clorazepate dipotassium is contraindicated in patients with a known hypersensitivity to the drug or any of its ingredients.

### Indications

Clorazepate dipotassium is indicated for the treatment of anxiety disorders, including panic disorder, and for the treatment of insomnia. It is also used in the management of alcohol withdrawal syndrome.

### Precautions

The use of clorazepate dipotassium in the elderly is generally recommended, but the elderly should be monitored closely for signs of sedation and dizziness. Patients with a history of sleep disorders, alcoholism, or drug abuse should be closely monitored for the potential of abuse or misuse.

### Dosage and Administration

Clorazepate dipotassium tablets are administered orally in divided doses. The usual daily dose is 20 mg, and the maximum daily dose is 120 mg. The dosage may be increased gradually by 5 mg every 2 days until a therapeutic response is obtained. The dosage should be adjusted according to the patient’s response and the clinical condition.

### Pregnancy

Clorazepate dipotassium is excreted in the urine and the feces, with approximately 1% of the dose excreted in the urine and 15% in the stool. The drug is metabolized in the liver and excreted primarily in the urine. The elimination half-life of clorazepate dipotassium is approximately 6 hours.

### References


**DESCRIPTION**

Clorazepate dipotassium tablets are indicated as adjunctive therapy in the management of partial seizures. Clorazepate dipotassium is indicated for the management of anxiety or tension associated with the stress of everyday life usually considered part of the normal stresses of life by the individual, and which do not require medical or psychiatric treatment. Clorazepate dipotassium tablets may be used, in conjunction with other treatments, to provide relief of the symptoms of depression. Clorazepate dipotassium is indicated for the management of anxiety associated with acute and chronic alcoholism.

**INDICATIONS AND USAGE**

Clorazepate dipotassium tablets are indicated for the management of anxiety disorders or for the short-term relief of the symptoms of anxiety. Anxiety or tension associated with the stress of everyday life is not regarded as pathologic and does not require treatment with a sedative-hypnotic.

**CONTRAINDICATIONS**

Clorazepate dipotassium tablets are contraindicated in patients with known hypersensitivity to the drug or its excipients.

**WARNINGS**

**ADVERSE REACTIONS**

The following adverse reactions have been reported with clorazepate dipotassium. These reactions were either life-threatening or caused discontinuation of therapy. Other reactions have been reported with clorazepate dipotassium but have not been classified.

**DRUG INTERACTIONS**

Clorazepate dipotassium is subjected to the same potential for drug interactions as other benzodiazepines. The concomitant use of clorazepate dipotassium and an antiestrogen may enhance the sedative properties of clorazepate dipotassium. No formal studies have been conducted with clorazepate dipotassium and antibiotics, calcium channel blockers, oral anticoagulants, or oral hypoglycemic agents. However, because of the mechanism of action of clorazepate dipotassium, the possibility of an interaction cannot be excluded.

**PRECAUTIONS**

**OVERDOSAGE**

**DRUG INTERACTIONS**

Clorazepate dipotassium is subjected to the same potential for drug interactions as other benzodiazepines. The concomitant use of clorazepate dipotassium and an antiestrogen may enhance the sedative properties of clorazepate dipotassium. No formal studies have been conducted with clorazepate dipotassium and antibiotics, calcium channel blockers, oral anticoagulants, or oral hypoglycemic agents. However, because of the mechanism of action of clorazepate dipotassium, the possibility of an interaction cannot be excluded.
**DESCRIPTION**

Clorazepate dipotassium tablets USP are a benzodiazepine. The empirical formula is C_{33}H_{39}ClN_{2}O_{7}P_{2}, with a molecular weight of 648.98. In the body, clorazepate is metabolized to nordiazepam. The primary metabolite, nordiazepam, undergoes further metabolism in the liver to oxazepam. In animals, clorazepate is found in the CNS at five times the concentration of nordiazepam.

**CONTRAINDICATIONS**

Clorazepate dipotassium is contraindicated in patients with allergy to any component of the tablets, including neomycin, sorbitol, or polysorbate 80. Clorazepate dipotassium is also contraindicated in patients with a known hypersensitivity to the drug and in those with acute narrow angle glaucoma.

**WARNINGS**

Hypersensitivity reactions to this product have occurred in some patients. In addition, anaphylactic reactions have been reported in some cases. These reactions may be life-threatening and require immediate medical attention.

**ADVERSE REACTIONS**

The most common adverse reactions associated with clorazepate dipotassium are drowsiness, dizziness, and fatigue. Other common reactions include somnolence, ataxia, sedation, and euphoria. Rare reactions include hallucinations, nightmares, convulsions, and paradoxical excitation. These reactions may be prevented or reduced by gradual dosage increases.

**DOSE AND ADMINISTRATION**

Clorazepate dipotassium tablets are available in strengths of 7.5 mg, 15 mg, and 30 mg. The usual daily dose is 7.5 to 30 mg, with a maximum daily dose of 90 mg. The dose should be increased gradually, not exceeding 7.5 mg every 2 days, and not exceeding 90 mg daily.

**OVERDOSAGE**

Clorazepate dipotassium is a benzodiazepine and may cause sedation, drowsiness, and impairment of motor function. Overdosage may result in drowsiness, confusion, and respiratory depression. In cases of overdose, supportive care, including airway management, is recommended. In severe cases, intubation and mechanical ventilation may be necessary.

**PREGNANCY**

Clorazepate dipotassium is classified as category C for use during pregnancy. Clorazepate dipotassium should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Clorazepate dipotassium is not recommended for use during the first trimester of pregnancy, as the risk of congenital malformations associated with the use of benzodiazepines is increased.

**NURSING MOTHERS**

Clorazepate dipotassium is excreted in human breast milk. The risk to the infant is unknown. Mothers should be advised to discontinue breastfeeding during treatment with clorazepate dipotassium.

**REPRODUCTIVE TOXICITY**

Clorazepate dipotassium is known to have teratogenic effects. Animal studies have shown that clorazepate dipotassium causes fetal abnormalities in rabbits. In humans, the risk of congenital malformations is increased with the use of benzodiazepines during pregnancy.

**LACTATION**

Clorazepate dipotassium is excreted in human breast milk. The risk to the infant is unknown. Mothers should be advised to discontinue breastfeeding during treatment with clorazepate dipotassium.

**DRUG INTERACTIONS**

Clorazepate dipotassium is a benzodiazepine and may interact with other CNS depressants, such as alcohol, barbiturates, and other sedatives. The combined use of clorazepate dipotassium and other CNS depressants may be associated with an increased risk of adverse effects, including respiratory depression, sedation, and coma.
MEDICATION GUIDE
CLORAZEPATE DIPOTASSIUM TABLETS, USP

Read this Medication Guide before you start taking clorazepate dipotassium tablets 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 clorazepate dipotassium tablets?

Do not stop taking clorazepate dipotassium tablets without first talking to your healthcare provider. Stopping clorazepate dipotassium tablets suddenly can cause serious problems.

Clorazepate dipotassium tablets can cause serious side effects, including:

1. Clorazepate dipotassium tablets 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 clorazepate dipotassium tablets affect you.
   - Do not drink alcohol or take other drugs that may make you sleepy or dizzy while taking clorazepate dipotassium tablets without first talking to your healthcare provider. When taken with alcohol or drugs that cause sleepiness or dizziness, clorazepate dipotassium tablets may make your sleepiness or dizziness much worse.

2. Clorazepate dipotassium tablets can cause abuse and dependence.
   - Do not stop taking clorazepate dipotassium tablets all of a sudden. Stopping clorazepate dipotassium tablets suddenly can cause seizures that do not stop, hearing or seeing things that are not there (hallucinations), shakiness, and stomach and muscle cramps.
   - Talk to your doctor about slowly stopping clorazepate dipotassium tablets to avoid getting sick with withdrawal symptoms.

What should I tell my healthcare provider before taking clorazepate dipotassium tablets?

Tell your healthcare provider about all the medicines you take. This may include prescription, non-prescription medicines, vitamins, dietary supplements, clorazepate dipotassium tablets, and herbal products. This list may not include all medicines that could affect clorazepate dipotassium tablets. Tell your healthcare provider if you:

- are allergic to clorazepate dipotassium or any of the ingredients in clorazepate dipotassium tablets
- have ever abused or been dependent on clorazepate dipotassium tablets
- are pregnant or plan to become pregnant
- breastfeed
- have a history of drug or alcohol abuse
- have liver or kidney problems
- have or had depression, mood problems, or other mental health problems
- have a history of alcohol or drug problems
- have any other medical conditions

Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal products. Taking clorazepate dipotassium tablets 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.

Call your healthcare provider if you have any of these symptoms, especially if they are new, worse, or worry you:

- thoughts about suicide or dying
- new or worse depression
- new or worse anxiety
- feeling agitated or restless
- panic attacks
- double sleeping (insomnia)
- new or worse irritability
- acting aggressive, being angry, or violent
- acting on dangerous impulses
- an extreme increase in activity and talking (mania)
- unusual changes in behavior or mood
- other unusual changes in behavior

How can I watch for early symptoms of Stopping clorazepate dipotassium tablets

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.

Keep your healthcare provider between visits as needed, especially if you are worried about your symptoms.

Do not stop taking clorazepate dipotassium tablets without first talking to a healthcare provider.

What are the possible side effects of clorazepate dipotassium tablets?

The most common side effects of clorazepate dipotassium tablets include:

- drowsiness
- dizziness
- upset stomach

Other possible side effects of clorazepate dipotassium tablets include:

- dry mouth
- confusion

These are not all the possible side effects of clorazepate dipotassium tablets. 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 clorazepate dipotassium tablets?

Store clorazepate dipotassium tablets between 20° to 25°C (68° to 77°F).

Keep clorazepate dipotassium tablets in a tightly closed container.

Keep clorazepate dipotassium tablets out of the reach of children.

General Information about clorazepate dipotassium tablets

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

What are the ingredients in clorazepate dipotassium tablets?

Active ingredient: clorazepate dipotassium, USP

Inactive ingredients: colloidal silicon dioxide, magnesium oxide heavy, magnesium stearate, microcrystalline cellulose, potassium carbonate anhydrous, potassium chloride, talc, and the following coloring agents:

- 3.75 mg - FD&C Blue No. 1 Lake and FD&C Red No. 40 Lake
- 7.5 mg - FD&C Red No. 40 Lake and D&C Yellow No. 10 Lake

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

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1. Serious side effects, including:

- Stopping clorazepate dipotassium tablets without first talking to your healthcare provider can cause seizures that will not stop (status epilepticus). Seizures that do not stop can cause serious problems.

Clorazepate dipotassium tablets are a federally controlled substance (C-II) because it can be abused or lead to dependence. Keep clorazepate dipotassium tablets in a safe place to prevent abuse and misuse. Call your doctor if you have any side effects that bother you or that do not go away.

2. Clorazepate dipotassium tablets may harm your unborn or developing baby.

- Clorazepate dipotassium tablets may cause physical dependence in your unborn baby. Your newborn baby may be at risk of withdrawal symptoms such as the following coloring agents:

- dizziness
- confusion

These are not all the possible side effects of clorazepate dipotassium tablets. For more information, ask your healthcare provider or pharmacist.

Tell your healthcare provider if you have any side effects that bother you or that do not go away.

3. Clorazepate dipotassium tablets may harm your unborn or developing baby.

- Clorazepate dipotassium tablets may cause suicidal thoughts or actions in a very small number of people, usually during the first few weeks of treatment or when the dose is changed. Contact your healthcare provider immediately if you have any suicidal thoughts or actions.

4. Clorazepate dipotassium tablets may cause suicidal thoughts or actions in a very small number of people, usually during the first few weeks of treatment or when the dose is changed. Contact your healthcare provider immediately if you have any suicidal thoughts or actions.

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