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Signs and Symptoms

The first signs and symptoms appear after 1 to 3 hours. Neuromuscular disturbances are the most prominent. Cardiovascular disorders are generally milder, and severe cardiac complications occur only when very high doses (greater than 60 g) have been ingested.

Respiration: Irregular breathing, respiratory depression.

Cardiovascular System: Tachycardia, hypotension or hypertension, shock, conduction disorders.

Nervous System and Muscles: Impairment of consciousness ranging in severity to deep coma. Convulsions, especially in small children. Motor restlessness, muscular twitching, tremor, athetoid movements, opisthotonos, ataxia, drowsiness, dizziness, mydriasis, nystagmus, adiadochokinesia, ballism, psychomotor disturbances, dysmetria. Initial hyperreflexia, followed by hyporeflexia.

Gastrointestinal Tract: Nausea, vomiting.

Kidneys and Bladder: Anuria or oliguria, urinary retention.

Laboratory Findings: Isolated instances of overdosage have included leukocytosis, reduced leukocyte count, glycosuria, and acetonuria. EEG may show dysrhythmias.

Combined Poisoning: When alcohol, tricyclic antidepressants, barbiturates, or hydantoin are taken at the same time, the signs and symptoms of acute poisoning with carbamazepine may be aggravated or modified.

Treatment

The prognosis in cases of severe poisoning is critically dependent upon prompt elimination of the drug, which may be achieved by inducing vomiting, irrigating the stomach, and by taking appropriate steps to diminish absorption. If these measures cannot be implemented without risk on the spot, the patient should be transferred at once to a hospital, while ensuring that vital functions are safeguarded. There is no specific antidote.

Elimination of the Drug: Induction of vomiting.

Gastric lavage. Even when more than 4 hours have elapsed following ingestion of the drug, the stomach should be repeatedly irrigated, especially if the patient has also consumed alcohol.

Measures to Reduce Absorption: Activated charcoal, laxatives.

Measures to Accelerate Elimination: Forced diuresis.

Dialysis is indicated only in severe poisoning associated with renal failure. Replacement transfusion is indicated in severe poisoning in small children.

Respiratory Depression: Keep the airways free; resort, if necessary, to endotracheal intubation, artificial respiration, and administration of oxygen.

Hypotension, Shock: Keep the patient's legs raised and administer a plasma expander. If blood pressure fails to rise despite measures taken to increase plasma volume, use of vasoactive substances should be considered.

Convulsions: Diazepam or barbiturates.

Warning: Diazepam or barbiturates may aggravate respiratory depression (especially in children), hypotension, and coma. However, barbiturates should not be used if drugs that inhibit monoamine oxidase have also been taken by the patient either in overdosage or in recent therapy (within 1 week).

Surveillance: Respiration, cardiac function (ECG monitoring), blood pressure, body temperature, pupillary reflexes, and kidney and bladder function should be monitored for several days.

Treatment of Blood Count Abnormalities: If evidence of significant bone marrow depression develops, the following recommendations are suggested: (1) stop the drug, (2) perform daily CBC, platelet, and reticulocyte counts, (3) do a bone marrow aspiration and trephine biopsy immediately and repeat with sufficient frequency to monitor recovery.

Special periodic studies might be helpful as follows: (1) white cell and platelet antibodies, (2) ⁵⁹Fe-ferrokinetic studies, (3) peripheral blood cell typing, (4) cytogenetic studies on marrow and peripheral blood, (5) bone marrow culture studies for colony-forming units, (6) hemoglobin electrophoresis for A₂ and F hemoglobin, and (7) serum folic acid and B₁₂ levels.

A fully developed aplastic anemia will require appropriate, intensive monitoring and therapy, for which specialized consultation should be sought.

DOSEAGE AND ADMINISTRATION (SEE TABLE BELOW)

Monitoring of blood levels has increased the efficacy and safety of anticonvulsants (see PRECAUTIONS, Laboratory Tests). Dosage should be adjusted to the needs of the individual patient. A low initial daily dosage with a gradual increase is advised. As soon as adequate control is achieved, the dosage may be reduced very gradually to the minimum effective level. Medication should be taken with meals.

Conversion of patients from oral carbamazepine tablets to Tegretol suspension: Patients should be converted by administering the same number of mg per day in smaller, more frequent doses (i.e., twice a day tablets to three times a day suspension).

Epilepsy (SEE INDICATIONS AND USAGE)

Adults and children over 12 years of age-Initial: 200 mg twice a day. Increase at weekly intervals by adding up to 200 mg/day using a three times a day or four times a day regimen until the optimal response is obtained. Dosage generally should not exceed 1000 mg daily in children 12 to 15 years of age, and 1200 mg daily in patients above 15 years of age. Doses up to 1600 mg daily have been used in adults in rare instances. **Maintenance:** Adjust dosage to the minimum effective level, usually 800 to 1200 mg daily.

Children 6 to 12 years of age-Initial: 100 mg twice a day. Increase at weekly intervals by adding up to 100 mg/day using a three times a day or four times a day regimen until the optimal response is obtained. Dosage generally should not exceed 1000 mg daily. **Maintenance:** Adjust dosage to the minimum effective level, usually 400 to 800 mg daily.

Children under 6 years of age-Initial: 10 to 20 mg/kg/day twice a day or three times a day. Increase weekly to achieve optimal clinical response administered three times a day or four times a day. **Maintenance:** Ordinarily, optimal clinical response is achieved at daily doses below 35 mg/kg. If satisfactory clinical response has not been achieved, plasma levels should be measured to determine whether or not they are in the therapeutic range. No recommendation regarding the safety of carbamazepine for use at doses above 35 mg/kg/24 hours can be made.

Combination Therapy: Carbamazepine may be used alone or with other anticonvulsants. When added to existing anticonvulsant therapy, the drug should be added gradually while the other anticonvulsants are maintained or gradually decreased, except phenytoin, which may have to be increased (see PRECAUTIONS, Drug Interactions, and Pregnancy).

Trigeminal Neuralgia (SEE INDICATIONS AND USAGE)

Initial: On the first day, 100 mg twice a day for a total daily dose of 200 mg. This daily dose may be increased by up to 200 mg/day using increments of 100 mg every 12 hours only as needed to achieve freedom from pain. Do not exceed 1200 mg daily. **Maintenance:** Control of pain can be maintained in most patients with 400 to 800 mg daily. However, some patients may be maintained on as little as 200 mg daily, while others may require as much as 1200 mg daily. At least once every 3 months throughout the treatment period, attempts should be made to reduce the dose to the minimum effective level or even to discontinue the drug.

Dosage Information			
	Initial Dose	Subsequent Dose	Maximum Daily Dose
Indication	Tablet*	Tablet*	Tablet*
Epilepsy Under 6 yr	10 to 20 mg/kg/day twice a day or 3 times a day	Increase weekly to achieve optimal clinical response, 3 times a day or 4 times a day	35 mg/kg/24 hr (See Dosage and Administration section above)
6 to 12 yr	100 mg twice a day (200 mg/day)	Add up to 100 mg/day at weekly intervals, 3 times a day or 4 times a day	1000 mg/24 hr
Over 12 yr	200 mg twice a day (400 mg/day)	Add up to 200 mg/day at weekly intervals, 3 times a day or 4 times a day	1000 mg/24 hr (12 to 15 yr) 1200 mg/24 hr (>15 yr) 1600 mg/24 hr (adults, in rare instances)
Trigeminal Neuralgia	100 mg twice a day (200 mg/day)	Add up to 200 mg/day in increments of 100 mg every 12 hr	1200 mg/24 hr

* Tablet = Chewable or conventional tablets.

HOW SUPPLIED

Carbamazepine Tablets, USP (chewable), 100 mg are available in the following form: pink colored, circular, strawberry/vanilla flavored, flat beveled, uncoated tablets with "271" debossed on one side and scoreline on the other.

Bottle of 100	NDC 13668-271-01
Bottle of 500	NDC 13668-271-05
Bottle of 750	NDC 13668-271-49
Bottle of 1000	NDC 13668-271-10

Carbamazepine Tablets, USP, 200 mg are available in the following form: pink colored, capsule shaped, biconvex tablets with "268" debossed on one side and scored on the other side.

Bottle of 30	NDC 13668-268-30
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Bottle of 100	NDC 13668-268-01
Bottle of 500	NDC 13668-268-05
Bottle of 1000	NDC 13668-268-10
Bottle of 2500	NDC 13668-268-31

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Protect from light and moisture. Dispense in a tight, light-resistant container as defined in the USP.

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MEDICATION GUIDE

Carbamazepine (kar ba MAZ e peen) Tablets, USP, 200 mg and Carbamazepine (kar ba MAZ e peen) Tablets, USP (Chewable), 100 mg Rx Only

Read this Medication Guide before you start taking carbamazepine tablets or chewable 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 carbamazepine tablets or chewable tablets?

Do not stop taking carbamazepine tablets or chewable tablets without first talking to your healthcare provider.

Stopping carbamazepine tablets or chewable tablets suddenly can cause serious problems.

Carbamazepine tablets or chewable tablets can cause serious side effects, including:

- Carbamazepine tablets or chewable tablets may cause rare but serious skin rashes that may lead to death. These serious skin reactions are more likely to happen when you begin taking carbamazepine tablets or chewable tablets within the first four months of treatment but may occur at later times. These reactions can happen in anyone, but are more likely in people of Asian descent. If you are of Asian descent, you may need a genetic blood test before you take carbamazepine tablets or chewable tablets to see if you are at a higher risk for serious skin reactions with this medicine. Symptoms may include:**
 - skin rash
 - hives
 - sores in your mouth
 - blistering or peeling of the skin

- Carbamazepine tablets or chewable tablets may cause rare but serious blood problems. Symptoms may include:**
 - fever, sore throat, or other infections that come and go or do not go away
 - easy bruising
 - red or purple spots on your body
 - bleeding gums or nose bleeds
 - severe fatigue or weakness

- Carbamazepine tablets or chewable tablets may cause allergic reactions or serious problems, which may affect organs and other parts of your body like the liver or blood cells. You may or may not have a rash with these types of reactions.** Call your healthcare provider right away if you have any of the following:
 - swelling of your face, eyes, lips, or tongue
 - a skin rash
 - painful sores in the mouth or around your eyes
 - unusual bruising or bleeding
 - frequent infections or infections that do not go away
 - fever, swollen glands, or sore throat that do not go away or come and go
 - trouble swallowing or breathing
 - hives
 - yellowing of your skin or eyes
 - severe fatigue or weakness
 - severe muscle pain

Call your healthcare provider right away if you have any of the following:

- swelling of your face, eyes, lips, or tongue
- a skin rash
- painful sores in the mouth or around your eyes
- unusual bruising or bleeding
- frequent infections or infections that do not go away
- fever, swollen glands, or sore throat that do not go away or come and go
- trouble swallowing or breathing
- hives
- yellowing of your skin or eyes
- severe fatigue or weakness
- severe muscle pain

- Like other antiepileptic drugs, carbamazepine tablets or chewable tablets 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 carbamazepine tablets or chewable tablets without first talking to a healthcare provider.

Stopping carbamazepine tablets or chewable tablets suddenly can cause serious problems. You should talk to your healthcare provider before stopping.

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 are carbamazepine tablets or chewable tablets?

Carbamazepine tablets or chewable tablets are a prescription medicine used to treat:

- certain types of seizures (partial, tonic-clonic, mixed)
- certain types of nerve pain (trigeminal and glossopharyngeal neuralgia)

Carbamazepine tablets or chewable tablets are not a regular pain medicine and should not be used for aches or pains.

Who should not take carbamazepine tablets or chewable tablets?

Do not take carbamazepine tablets or chewable tablets if you:

- have a history of bone marrow depression.
- are allergic to carbamazepine or any of the ingredients in carbamazepine tablets or chewable tablets. See the end of this Medication Guide for a complete list of ingredients in carbamazepine tablets or chewable tablets.
- take nefazodone.
- are allergic to medicines called tricyclic antidepressants (TCAs). Ask your healthcare provider or pharmacist for a list of these medicines if you are not sure.
- have taken a medicine called a Monoamine Oxidase Inhibitor (MAOI) in the last 14 days. Ask your healthcare provider or pharmacist for a list of these medicines if you are not sure.

What should I tell my healthcare provider before taking carbamazepine tablets or chewable tablets?

Before you take carbamazepine tablets or chewable tablets, tell your healthcare provider if you:

- have or have had suicidal thoughts or actions, depression, or mood problems
- have or ever had heart problems
- have or ever had blood problems
- have or ever had liver problems
- have or ever had kidney problems
- have or ever had allergic reactions to medicines
- have or ever had increased pressure in your eye
- have any other medical conditions
- drink grapefruit juice or eat grapefruit
- use birth control. Carbamazepine tablets or chewable tablets may make your birth control less effective. Tell your healthcare provider if your menstrual bleeding changes while you take birth control and carbamazepine tablets or chewable tablets.

- are pregnant or plan to become pregnant. Carbamazepine tablets or chewable tablets may harm your unborn baby. Tell your healthcare provider right away if you become pregnant while taking carbamazepine tablets or chewable tablets. You and your healthcare provider should decide if you should take carbamazepine tablets or chewable tablets while you are pregnant.
- If you become pregnant while taking carbamazepine tablets or chewable tablets, talk to your healthcare provider about registering with the North American Antiepileptic Drug (NAAED) Pregnancy Registry. The purpose of this registry is to collect information about the safety of antiepileptic medicine during pregnancy. You can enroll in this registry by calling 1-888-233-2334.
- are breastfeeding or plan to breastfeed. Carbamazepine passes into breast milk. You and your healthcare provider should discuss whether you

should take carbamazepine tablets or chewable tablets or breastfeed; you should not do both.

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

Taking carbamazepine tablets or chewable tablets with certain other medicines may 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 carbamazepine tablets or chewable tablets?

- Do not stop taking carbamazepine tablets or chewable tablets without first talking to your healthcare provider. Stopping carbamazepine tablets or chewable tablets suddenly can cause serious problems. Stopping seizure medicine suddenly in a patient who has epilepsy may cause seizures that will not stop (status epilepticus).
- Take carbamazepine tablets or chewable tablets exactly as prescribed. Your healthcare provider will tell you how many carbamazepine tablets or chewable tablets to take.
- Your healthcare provider may change your dose. Do not change your dose of carbamazepine tablets or chewable tablets without talking to your healthcare provider.
- Take carbamazepine tablets or chewable tablets with food.
- If you take too many carbamazepine tablets or chewable tablets, call your healthcare provider or local Poison Control Center right away.

What should I avoid while taking carbamazepine tablets or chewable tablets?

- Do not drink alcohol or take other drugs that make you sleepy or dizzy while taking carbamazepine tablets or chewable tablets until you talk to your healthcare provider. Carbamazepine tablets or chewable tablets taken with alcohol or drugs that cause sleepiness or dizziness may make your sleepiness or dizziness worse.
- Do not drive, operate heavy machinery, or do other dangerous activities until you know how carbamazepine tablets or chewable tablets affect you. Carbamazepine tablets or chewable tablets may slow your thinking and motor skills.

What are the possible side effects of carbamazepine tablets or chewable tablets?

See **“What is the most important information I should know about carbamazepine tablets or chewable tablets?”**

Carbamazepine tablets or chewable tablets may cause other serious side effects. These include:

- Irregular heartbeat - symptoms include:
 - Fast, slow, or pounding heartbeat
 - Shortness of breath
 - Feeling lightheaded
 - Fainting
- Liver problems - symptoms include:
 - yellowing of your skin or the whites of your eyes
 - dark urine
 - pain on the right side of your stomach area (abdominal pain)
 - easy bruising
 - loss of appetite
 - nausea or vomiting

Get medical help right away if you have any of the symptoms listed above or listed in “What is the most important information I should know about carbamazepine tablets or chewable tablets?”

The most common side effects of carbamazepine tablets or chewable tablets include:

- dizziness
- drowsiness
- problems with walking and coordination (unsteadiness)
- nausea
- vomiting

These are not all the possible side effects of carbamazepine tablets or chewable 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 carbamazepine tablets or chewable tablets?

- Store carbamazepine tablets or chewable tablets at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Protect from light and moisture. Dispense in a tight, light-resistant container as defined in the USP.

Keep carbamazepine tablets or chewable tablets and all medicines out of the reach of children.

General Information about carbamazepine tablets or chewable tablets

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

For more information, go to www.torrentpharma.com or call 1-800-912-9561.

What are the ingredients in carbamazepine tablets or chewable tablets?

Active ingredient: carbamazepine, USP

Inactive ingredients:

Carbamazepine tablets: colloidal silicon dioxide, FD&C Red #40 aluminum lake, hypromellose, magnesium stearate, pregelatinized maize starch, corn starch, and sodium starch glycolate.

Carbamazepine tablets (Chewable): artificial flavors, colloidal silicon dioxide, compressible sugar, corn starch, FD&C Red #40 aluminum lake, hydroxypropyl methyl cellulose, magnesium stearate, and sodium starch glycolate.

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

Dispense with Medication Guide available at:

<https://torrentpharma.com/pi/usa/products/>

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