

# Carbamazepina Comprimidos BP 200 mg

**Composition:** Each uncoated tablet contains:

Carbamazepine BP 200 mg

Excipients q.s.

**Mechanism of Action:** Carbamazepine belongs to a class of medications known as anticonvulsants. It works by reducing abnormal electrical activity in the brain. It stabilizes the inactivated state of sodium channels, rendering neurons less excitable; it may also reduce activity in the ventral nucleus of the thalamus, or decrease synaptic transmission or the summation of temporal stimulation leading to neuronal discharge.

**Indications and Usage:** Carbamazepine is used alone or in combination with other medications to control certain types of seizures in patients with epilepsy. It is also used to treat trigeminal neuralgia (a condition that causes pain in the facial nerve). Carbamazepine is also sometimes used to treat mental illnesses, depression, post-traumatic stress disorder (PTSD), drug and alcohol withdrawal, restless legs syndrome, diabetes insipidus, certain pain syndromes, and a condition in children known as chorea. Discuss the potential risks of using this medication for your specific condition with your doctor.

**Contraindications:** Carbamazepine should not be used in patients with a history of prior bone marrow depression, hypersensitivity to the drug, or known sensitivity to any tricyclic compounds—such as amitriptyline, desipramine, imipramine, protriptyline, nortriptyline, etc. Similarly, for theoretical reasons, its use in conjunction with monoamine oxidase (MAO) inhibitors is not recommended. Prior to the administration of carbamazepine, MAO inhibitors must be discontinued for a minimum period of 14 days, or longer if the clinical situation permits. Co-administration of carbamazepine and nefazodone may result in plasma concentrations of nefazodone—and its active metabolite—that are insufficient to achieve a therapeutic effect. Therefore, the co-administration of carbamazepine with nefazodone is contraindicated.

**Side Effects:** Seek emergency medical help if you experience any of these signs of an allergic reaction: hives; difficulty breathing; swelling of the face, lips, tongue, or throat. Report any new or worsening symptoms to your doctor, such as: sudden changes in mood or behavior, depression, anxiety, insomnia, or if you feel agitated, hostile, restless, or irritable, or have thoughts of suicide or self-harm.

#### **Drug Interactions:**

1. Birth control pills or hormone replacement therapy;
2. An antibiotic, or medications to treat tuberculosis;
3. Antifungal medications such as fluconazole or ketoconazole;
4. Cancer medications;
5. Blood pressure or heart medications;
6. Medications for HIV or AIDS;
7. Steroid medications.

**Warnings and Precautions:** Severe Dermatological Reactions: Severe and sometimes fatal dermatological reactions, including toxic epidermal necrolysis (TEN) and Stevens-Johnson syndrome (SJS), have been reported with carbamazepine treatment.

**Hypersensitivity:** Hypersensitivity reactions to carbamazepine have been reported in patients who have previously experienced such reactions to anticonvulsants, including phenytoin, primidone, and phenobarbital.

**Precautions:** General: Before initiating therapy, a detailed medical history and physical examination should be performed. Carbamazepine should be used with caution in patients with mixed seizure disorders that include atypical absence seizures, as in these patients, carbamazepine has been associated with an increased frequency of generalized seizures. Therapy should be prescribed only after a critical assessment of the benefit-risk balance in patients with a history of cardiac conduction disorders, including second- and third-degree AV heart block; cardiac, hepatic, or renal impairment; hematological or hypersensitivity adverse reactions to other drugs (including reactions to other anticonvulsants); or interrupted courses of carbamazepine therapy. AV heart block, including second- and third-degree block, has been reported following carbamazepine treatment. This has occurred generally—though not exclusively—in patients with underlying ECG abnormalities or risk factors for conduction disorders.

**Pregnancy, Breastfeeding, and Fertility:** Carbamazepine may cause fetal harm when administered to a pregnant woman.

Due to the potential for serious adverse reactions in nursing infants exposed to carbamazepine, a decision should be made regarding whether to discontinue the drug or discontinue breastfeeding, taking into account the importance of the medication to the mother.

**Symptoms of Overdosage and Antidote:** Respiration: Irregular breathing, respiratory depression.

**Cardiovascular System:** Tachycardia, hypotension or hypertension, shock, conduction disturbances. **Nervous System and Gastrointestinal Tract:** Nausea, vomiting. **Kidneys and Bladder:** Anuria and oliguria, urinary retention.

**Laboratory Results:** Isolated cases of overdose have included leukocytosis, reduced leukocyte count, glycosuria, and ketonuria. ECG may show dysrhythmias.

**Combined Poisoning:** When alcohol, tricyclic antidepressants, barbiturates, or hydantoin are taken concurrently, the signs and symptoms of acute carbamazepine intoxication may be exacerbated or altered.

#### **Treatment for Overdose:**

**Drug Elimination:** Induction of vomiting. Gastric lavage. Even if more than 4 hours have elapsed since ingestion of the medication, the stomach should be repeatedly irrigated, especially if the patient has also consumed alcohol.

**Measures to Accelerate Elimination:** Forced diuresis. Dialysis is indicated only in cases of severe intoxication associated with renal failure. Exchange transfusion is indicated in cases of severe intoxication in young children.

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

**Dosage and Administration:** Oral: As directed by the physician.

**STORAGE INSTRUCTIONS:** Store below 30°C in a cool, dry place. Protect from light.

Keep medications out of the reach of children.

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