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Carbamazepine

pronounced as (kar ba maz' e peen)

IMPORTANT WARNING:

Carbamazepine may cause life-threatening allergic reactions called Stevens-Johnson syndrome (SJS) or toxic epidermal necrolysis (TEN). These allergic reactions may cause severe damage to the skin and internal organs. The risk of SJS or TEN is highest in people of Asian ancestry who have a genetic (inherited) risk factor. If you are Asian, your doctor will usually order a test to see if you have the genetic risk factor before prescribing carbamazepine. If you do not have this genetic risk factor, your doctor may prescribe carbamazepine, but there is still a slight risk that you will develop SJS or TEN. Call your doctor immediately if you develop a painful rash, hives, blistering or peeling of skin, easy bruising, mouth sores, or a fever during your treatment with carbamazepine. Stevens-Johnson syndrome or toxic epidermal necrolysis usually occurs during the first few months of treatment with carbamazepine.

Carbamazepine may decrease the number of blood cells produced by your body. In rare cases, the number of blood cells may decrease enough to cause serious or life-threatening health problems. Tell your doctor if you have ever had bone marrow depression (decreased number of blood cells) or any other blood disorders, especially if it was caused by another medication. If you experience any of the following symptoms, call your doctor immediately: sore throat, fever, chills, or other signs of infection that come and go or do not go away; shortness of breath; fatigue; unusual bleeding or bruising such as heavy menstrual bleeding, nose bleeds, or bleeding gums; tiny red or purple dots or spots on the skin; or mouth sores..

Keep all appointments with your doctor and the laboratory. Your doctor will order certain lab tests before and during your treatment to check your body's response to carbamazepine.

Your doctor or pharmacist will give you the manufacturer's patient information sheet (Medication Guide) when you begin treatment with carbamazepine and each time you refill your prescription. Read the information carefully and ask your doctor or pharmacist if you have any questions. You can also visit the Food and Drug Administration (FDA) website (<http://www.fda.gov/Drugs> [<http://www.fda.gov/Drugs>]) or the manufacturer's website to obtain the Medication Guide.

Why is this medication prescribed?

Carbamazepine is used alone or in combination with other medications to control certain types of seizures in people with epilepsy. It is also used to treat trigeminal neuralgia (a condition that causes facial nerve pain). Carbamazepine extended-release capsules (Equetro brand only) are also used to treat episodes of mania (frenzied, abnormally excited or irritated mood) or mixed episodes (symptoms of mania and depression that happen at the same time) in patients with bipolar I disorder (manic-depressive disorder; a disease that causes episodes of depression, episodes of mania, and other abnormal moods). Carbamazepine is in a class of medications called anticonvulsants. It works by reducing abnormal electrical activity in the brain.

How should this medicine be used?

Carbamazepine comes as a tablet, a chewable tablet, an extended-release (long-acting) tablet, an extended-release capsule, and as a suspension (liquid) to take by mouth. The regular tablet, chewable tablet, and suspension are usually taken two to four times a day with meals. The extended-release tablet (Tegretol XR) is usually taken twice a day with meals. The extended-release capsule (Carbatrol, Equetro) is usually taken twice a day with or without meals. To help you remember to take carbamazepine, take it at around the same times every day. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take carbamazepine exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.

Swallow the extended-release tablets whole; do not split, chew, or crush them. The extended-release capsules may be opened and the beads inside sprinkled over food, such as a teaspoon of applesauce or similar food. Do not crush or chew the extended-release capsules or the beads inside them.

Shake the suspension well before each use to mix the medication evenly.

Your doctor will start you on a low dose of carbamazepine and gradually increase your dose.

Carbamazepine may help control your condition but will not cure it. It may take a few weeks or longer before you feel the full benefit of carbamazepine. Continue to take carbamazepine even if you feel well. Do not stop taking carbamazepine without talking to your doctor, even if you experience side effects such as unusual changes in behavior or mood. If you have a seizure disorder and you suddenly stop taking carbamazepine, your seizures may become worse. Your doctor will probably decrease your dose gradually.

Other uses for this medicine

Carbamazepine is also sometimes used to treat mental illnesses, depression, posttraumatic stress disorder, drug and alcohol withdrawal, restless legs syndrome, diabetes insipidus, certain pain syndromes, and a disease in children called chorea. Talk to your doctor about the possible risks of using this medication for your condition.

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

What special precautions should I follow?

Before taking carbamazepine,

- tell your doctor and pharmacist if you are allergic (rash, wheezing, hives, difficulty swallowing or breathing, swelling of your face, eyes, eyelids, lips, or tongue) to carbamazepine, amitriptyline (Elavil), amoxapine, clomipramine (Anafranil), desipramine (Norpramin), doxepin (Silenor, Zonalon), imipramine (Tofranil), nortriptyline (Pamelor), oxcarbazepine (Trileptal), protriptyline (Vivactil), other medications for seizures such as phenobarbital, phenytoin (Dilantin, Phenytek), or primidone (Mysoline), any other medications, or any of the ingredients in carbamazepine preparations. Ask your pharmacist or check the Medication Guide for a list of the ingredients.
- tell your doctor if you are taking nefazadone or certain non-nucleoside reverse transcriptase inhibitors (NNRTIs) such as delavirdine (Rescriptor). Your doctor will probably tell you not take carbamazepine with these medications. Also, tell your doctor if you are taking a monoamine oxidase (MAO) inhibitor such as isocarboxazid (Marplan), linezolid (Zyvox), methylene blue, phenelzine (Nardil), selegiline (Eldepryl, Emsam, Zelapar), and tranylcypromine (Parnate), or if you have stopped taking an MAO inhibitor within the past 14 days. Your doctor will probably tell you not to take carbamazepine. If you stop taking carbamazepine, you should wait at least 14 days before you start to take an MAO inhibitor.
- tell your doctor and pharmacist what other prescription and nonprescription medications, vitamins, and nutritional supplements you are taking or plan to take. Be sure to mention any of the following: acetaminophen (Tylenol); acetazolamide (Diamox); albendazole (Albenza); alprazolam (Panax); aminophylline; anticoagulants ('blood thinners') such as apixaban (Eliquis), dabigatran (Pradaxa), edoxaban (Savaysa), rivaroxaban (Xarelto), and warfarin (Coumadin, Jantoven); antidepressants such as amitriptyline (Elavil), bupropion (Wellbutrin, Zyban), buspirone (BuSpar), citalopram (Celexa), clomipramine (Anafranil), desipramine (Norpramin), fluoxetine (Prozac, Sarafem), fluvoxamine (Luvox), mirtazapine (Remeron), nortriptyline (Pamelor); antifungals such as fluconazole (Diflucan), itraconazole (Onmel, Sporanox), ketoconazole, and voriconazole (Vfend); aprepitant (Emend); aripiprazole (Abilify); buprenorphine (Butrans, Sublocade); bupropion (Aplenzin, Wellbutrin, Zyban); cimetidine (Tagamet); ciprofloxacin; cisplatin (Platinol); corticosteroids such as dexamethasone and prednisolone (Prelone); clarithromycin (Biaxin, in Prevpac); clonazepam (Klonopin); clozapine (Clozaril); cyclophosphamide; cyclosporine (Gengraf, Neoral, Sandimmune); dalfopristin and quinupristin (Synercid); danazol (Danocrine); dantrolene (Dantrium); diltiazem (Cardizem, Diltzac, Tiazac, others); diuretics (water pills); doxorubicin (Adriamycin, Rubex); doxycycline (Vibramycin); erythromycin (E.E.S., E-Mycin, Erythrocin); eslicarbazepine (Aptiom); everolimus (Afinitor, Zortress); felodipine (Plendil); haloperidol (Haldol); HIV protease inhibitors including atazanavir (Reyataz), indinavir (Crixivan), lopinavir (in Kaletra), nelfinavir (Viracept), ritonavir (Norvir, in Kaletra), and saquinavir (Fortovase, Invirase); ibuprofen (Advil); imatinib (Gleevec); isoniazid (INH, Laniazid, in Rifater); levothyroxine (Levoxyl, Synthroid); lithium (Lithobid); loratadine (Claritin); lorazepam (Ativan); loxapine (Adasuve); certain medications to treat malaria such as chloroquine (Aralen) and mefloquine; medications for anxiety or mental illness; other medications for seizures such as ethosuximide (Zarontin), felbamate (Felbatol), fosphenytoin (Cerebyx); lamotrigine (Lamictal), methsuximide (Celontin), oxcarbazepine (Trileptal), phenobarbital, phensuximide (Milontin) (not available in the US), phenytoin (Dilantin, Phenytek), primidone (Mysoline), tiagabine (Gabitril), topiramate (Topamax), and valproic acid (Depakene, Depakote); lapatinib; methadone (Dolophine, Methadose); midazolam; niacinamide (nicotinamide, Vitamin B3); olanzapine; omeprazole; oxybutynin; propoxyphene (Darvon); praziquantel (Biltricide); quetiapine; quinine; rifampin (Rifadin, Rimactane); risperidone; sedatives; sertraline (Zoloft); sirolimus; sleeping pills; tacrolimus (Prograf); tadalafil (Adcirca, Cialis); temsirolimus (Torisel); terfenadine (Seldane) (not available in the US); theophylline (Theo-24, Theochron, others); ticlopidine; tramadol (Ultram); tranquilizers; trazodone; troleandomycin (TAO); verapamil (Calan, Verelan); zileuton (Zyflo); ziprasidone (Geodon), and zonisamide (Zonegran). Many other medications may also interact with

carbamazepine, so be sure to tell your doctor about all the medications you are taking, even those that do not appear on this list. Your doctor may need to change the doses of your medications or monitor you carefully for side effects.

- if you are taking any other liquid medications, do not take them at the same time as carbamazepine suspension.
- tell your doctor if you have or have ever had glaucoma (a condition in which increased pressure in the eye can lead to gradual loss of vision); or heart, kidney, thyroid, or liver disease.
- you should know that carbamazepine may decrease the effectiveness of hormonal contraceptives (birth control pills, patches, rings, injections, implants, or intrauterine devices). Use another form of birth control while taking carbamazepine. Tell your doctor if you have unexpected vaginal bleeding or think you may be pregnant while you are taking carbamazepine.
- tell your doctor if you are pregnant, plan to become pregnant, or are breastfeeding. Carbamazepine may harm the fetus. If you become pregnant while taking carbamazepine, call your doctor immediately.
- if you are having surgery, including dental surgery, tell the doctor or dentist that you are taking carbamazepine.
- you should know that carbamazepine may make you drowsy. Do not drive a car or operate machinery until you know how this medication affects you.
- remember that alcohol can add to the drowsiness caused by this medication.
- you should know that your mental health may change in unexpected ways and you may become suicidal (thinking about harming or killing yourself or planning or trying to do so) while you are taking carbamazepine for the treatment of epilepsy, mental illness, or other conditions. A small number of adults and children 5 years of age and older (about 1 in 500 people) who took anticonvulsants such as carbamazepine to treat various conditions during clinical studies became suicidal during their treatment. Some of these people developed suicidal thoughts and behavior as early as one week after they started taking the medication. There is a risk that you may experience changes in your mental health if you take an anticonvulsant medication such as carbamazepine, but there may also be a risk that you will experience changes in your mental health if your condition is not treated. You and your doctor will decide whether the risks of taking an anticonvulsant medication are greater than the risks of not taking the medication. You, your family, or your caregiver should call your doctor right away if you experience any of the following symptoms: panic attacks; agitation or restlessness; new or worsening irritability, anxiety, or depression; acting on dangerous impulses; difficulty falling or staying asleep; aggressive, angry, or violent behavior; mania (frenzied, abnormally excited mood); talking or thinking about wanting to hurt yourself or end your life; withdrawing from friends and family; preoccupation with death and dying; giving away prized possessions; or any other unusual changes in behavior or mood. Be sure that your family or caregiver knows which symptoms may be serious so they can call the doctor if you are unable to seek treatment on your own.
- if you have fructose intolerance (an inherited condition in which the body lacks the protein needed to break down fructose [a fruit sugar found in certain sweeteners such as sorbitol]), you should know that the oral suspension is sweetened with sorbitol. Tell your doctor if you have fructose intolerance.

What special dietary instructions should I follow?

Talk to your doctor about eating grapefruit or drinking grapefruit juice while taking this medicine.

What should I do if I forget a dose?

Take the missed dose as soon as you remember it. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

What side effects can this medication cause?

Carbamazepine may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:

- dizziness
- thinking abnormal
- difficulty speaking
- uncontrollable shaking of a part of the body
- constipation
- dry mouth

Some side effects can be serious. If you experience any of these symptoms or those listed in the IMPORTANT WARNING and SPECIAL PRECAUTION sections, call your doctor immediately:

- confusion
- rash
- fast, slow, or pounding heartbeat
- yellowing of the skin or eyes
- dark urine
- pain on the right side of your stomach area
- loss of appetite
- nausea
- vomiting
- vision changes
- fatigue
- swelling of your face, eyes, eyelids, lips, or tongue
- difficulty swallowing or breathing
- headache, new or increased number of seizures, difficulty concentrating, confusion, weakness, or unsteadiness
- severe rash with one or more of the following: fever, muscle or joint aches, red or swollen eyes, blisters or peeling skin, mouth sores, or swelling of your face or neck

Carbamazepine may cause other side effects. Call your doctor if you have any unusual problems while taking this medication.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online (<http://www.fda.gov/Safety/MedWatch> [<http://www.fda.gov/Safety/MedWatch>]) or by phone (1-800-332-1088).

What should I know about storage and disposal of this medication?

Keep this medication in the container it came in, tightly closed, and out of reach of children. Store it at room temperature, away from light, excess heat and moisture (not in the bathroom).

It is important to keep all medication out of sight and reach of children as many containers (such as weekly pill minders and those for eye drops, creams, patches, and inhalers) are not child-resistant and young children can open them easily. To protect young children from poisoning, always lock safety caps and immediately place the medication in a safe location – one that is up and away and out of their sight and reach. <http://www.upandaway.org> [<http://www.upandaway.org>]

Unneeded medications should be disposed of in special ways to ensure that pets, children, and other people cannot consume them. However, you should not flush this medication down the toilet. Instead, the best way to dispose of your medication is through a medicine take-back program. Talk to your pharmacist or contact your local garbage/recycling department to learn about take-back programs in your community. See the FDA's Safe Disposal of Medicines website (<http://goo.gl/c4Rm4p> [<http://goo.gl/c4Rm4p>]) for more information if you do not have access to a take-back program.

In case of emergency/overdose

In case of overdose, call the poison control helpline at 1-800-222-1222. Information is also available online at <https://www.poisonhelp.org/help> [<https://www.poisonhelp.org/help>] . If the victim has collapsed, had a seizure, has trouble breathing, or can't be awakened, immediately call emergency services at 911.

Symptoms of overdose may include the following:

- unconsciousness
- seizures
- restlessness
- muscle twitching
- abnormal movements
- shaking of a part of your body that you cannot control
- unsteadiness
- drowsiness
- dizziness
- vision changes
- irregular or slowed breathing

- rapid or pounding heartbeat
- nausea
- vomiting
- difficulty urinating

What other information should I know?

Before having any laboratory test, tell your doctor and the laboratory personnel that you are taking carbamazepine.

Carbamazepine can interfere with the results of home pregnancy tests. Talk to your doctor if you think you might be pregnant while you are taking carbamazepine. Do not try to test for pregnancy at home.

The extended-release tablet does not dissolve in the stomach after swallowing. It slowly releases the medicine as it passes through your digestive system. You may notice the tablet coating in your stool.

Do not let anyone else take your medication. Ask your pharmacist any questions you have about refilling your prescription.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

Brand names

- Carbatrol[®]
- Epitol[®]

- Equetro[®]
- Tegretol[®]

- Tegretol[®]-XR

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