

Brightside Specialty Pharmacy

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Patient Education for TEGRETOL XR 400 MG TABLET



Do not chew or crush tablets. OK to divide before swallowing if scored. Dispense Medication Guide and explain to patient before use. May cause drowsiness or dizziness. Use caution driving. Seek immediate medical attention if rash/hypersensitivity occurs. Bone marrow suppression risk. Look for infection/sore throat/fatigue. Depression or thoughts of suicide should be reported to MD ASAP. If Asian, a special blood test is recommended before starting drug. May harm unborn baby. Use with caution during pregnancy.

Do not chew or crush. OK to split tablet if scored. Before use, important to read the Medication Guide. May make you drowsy or dizzy. Drive with caution. Call doctor immediately if any rash occurs. Call MD for fatigue/sore throat/infection/bleeding. Immediately report to MD any thoughts of suicide. If Asian, blood tests may be needed. Ask MD. Discuss risk vs benefits of use during pregnancy.

.....Education Section.....

IMPORTANT:

HOW TO USE THIS INFORMATION: This is a summary and

does NOT have all possible information about this product. This information does not assure that this product is safe, effective, or appropriate for you. This information is not individual medical advice and does not substitute for the advice of your health care professional. Always ask your health care professional for complete information about this product and your specific health needs.

CARBAMAZEPINE EXTENDED-RELEASE - ORAL

(KAR-ba-MAZ-e-peen)

COMMON BRAND NAME(S):

Carbatrol, Equetro, Tegretol XR

WARNING:

Carbamazepine may rarely cause very serious (possibly fatal) skin reactions. Some people in certain ethnic groups (such as people of Asian/South Asian descent) are at greater risk. Your doctor may order a blood test to measure your risk before you start this medication. If the blood test shows you are at greater risk, your doctor should discuss the risks and benefits of carbamazepine and other treatment choices with you. Such skin reactions have developed mostly within the first few months of treatment. Get medical help right away if you develop any of the following symptoms: skin rash/blisters/peeling, itching, or swelling. Ask your doctor or pharmacist for more details.

This drug has rarely caused very serious blood disorders (aplastic anemia, agranulocytosis). Your doctor will monitor your blood counts to minimize the chance of these side effects. Keep all medical and lab appointments. Get medical help right away if any of these rare but very serious side effects occur: signs of infection (such as sore throat that doesn't go away, fever, swollen lymph nodes), unusual weakness/tiredness, shortness of breath, or easy bleeding/bruising.

USES:

Carbamazepine is used to prevent and control seizures.

This medication is known as an anticonvulsant or anti-epileptic

drug. It is also used to relieve certain types of nerve pain (such as trigeminal neuralgia). This medication works by reducing the spread of seizure activity in the brain and restoring the normal balance of nerve activity.

Some forms of this medication are also used to treat bipolar disorder. Carbamazepine can help to decrease extreme changes in mood and help you feel less agitated.

HOW TO USE:

Read the Medication Guide provided by your

pharmacist before you start taking carbamazepine and each time you get a refill. If you have any questions, ask your doctor or pharmacist.

If you are taking the extended-release tablets, take this medication by mouth with food as directed by your doctor, usually 2 times a day. Do not crush or chew extended-release tablets. Doing so can release all of the drug at once, increasing the risk of side effects. Also, do not split the tablets unless they have a score line and your doctor or pharmacist tells you to do so. Swallow the whole or split tablet without crushing or chewing. Inspect the tablets for chips and cracks. Do not take any damaged tablets.

If you are taking the extended-release capsules, take this medication by mouth with or without food as directed by your doctor, usually 2 times a day. Swallow the capsules whole. Do not crush or chew the capsules.

If you have trouble swallowing the capsules, you may open them and sprinkle the contents onto a teaspoonful of applesauce or other soft food. Swallow all of the drug/food mixture right away. Do not chew the mixture or prepare a supply in advance.

The dosage is based on your medical condition and response to treatment. To reduce your risk of side effects, your doctor may direct you to start this medication at a low dose and gradually increase your dose. Follow your doctor's instructions carefully.

Avoid eating grapefruit or drinking grapefruit juice while taking this medication unless your doctor or pharmacist says you may do so safely. Grapefruit can increase the chance of side effects with this medicine. Ask your doctor or pharmacist for more details.

Take this medication regularly to get the most benefit from

it. To help you remember, take it at the same times each day. Keep taking this medication even if you feel well.

Do not stop taking this medication without consulting your doctor. Some conditions (such as seizures) may become worse when this drug is suddenly stopped. Your dose may need to be gradually decreased.

Tell your doctor if your condition does not get better or if it gets worse.

SIDE EFFECTS:

See also Warning section.

Nausea, vomiting, dizziness, drowsiness, constipation, dry mouth, or unsteadiness may occur. If any of these effects last or get worse, tell your doctor or pharmacist promptly.

An empty tablet shell may appear in your stool. This effect is harmless because your body has already absorbed the medication.

Remember that this medication has been prescribed because your doctor has judged that the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects.

Tell your doctor right away if you have any serious side effects, including: headaches that are severe or don't go away, signs of liver problems (such as nausea/vomiting that doesn't stop, loss of appetite, stomach/abdominal pain, yellowing eyes/skin, dark urine), signs of kidney problems (such as change in the amount of urine), mouth sores, fainting, fast/slow/irregular heartbeat, unusual eye movements (nystagmus), vision changes (such as blurred vision), joint pain, swelling of the ankles/feet, pain/redness/swelling of the arms or legs, numbness/tingling of the hands/feet, signs of low levels of sodium in the blood (such as severe drowsiness, mental/mood changes including confusion, seizures).

A small number of people who take anticonvulsants for any condition (such as seizure, bipolar disorder, pain) may experience depression, suicidal thoughts/attempts, or other mental/mood problems. Tell your doctor right away if you or your family/caregiver notice any unusual/sudden changes in your mood, thoughts, or behavior such as signs of depression, suicidal thoughts/attempts, thoughts about harming yourself.

A very serious allergic reaction to this drug is rare. However, get medical help right away if you notice any symptoms of a serious allergic reaction, including: rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing.

This is not a complete list of possible side effects. If you notice other effects not listed above, contact your doctor or pharmacist.

In the US -

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or at www.fda.gov/medwatch.

In Canada - Call your doctor for medical advice about side effects. You may report side effects to Health Canada at 1-866-234-2345.

PRECAUTIONS:

Before taking carbamazepine, tell your doctor or

pharmacist if you are allergic to it; or to other anti-seizure medications (such as fosphenytoin, oxcarbazepine, phenobarbital, phenytoin, primidone) or to tricyclic antidepressants (such as amitriptyline, desipramine); or if you have any other allergies. This product may contain inactive ingredients, which can cause allergic reactions or other problems. Talk to your pharmacist for more details.

Before using this medication, tell your doctor or pharmacist your medical history, especially of: decreased bone marrow function (bone marrow depression), blood disorders (such as porphyria, anemia), glaucoma, heart disease (such as coronary artery disease, heart failure, irregular heartbeat), kidney disease, liver disease, mental/mood disorders (such as depression), mineral imbalances (such as low levels of sodium or calcium in the blood).

This drug may make you dizzy or drowsy. Alcohol or marijuana (cannabis) can make you more dizzy or drowsy. Do not drive, use machinery, or do anything that needs alertness until you can do it safely. Avoid alcoholic beverages. Talk to your doctor if you are using marijuana (cannabis).

This medication may make you more sensitive to the sun. Limit your time in the sun. Avoid tanning booths and sunlamps. Use sunscreen and wear protective clothing when outdoors. Get medical help right away if you get sunburned or have skin blisters/redness.

Before having surgery, tell your doctor or dentist about all the products you use (including prescription drugs, nonprescription drugs, and herbal products).

Older adults may be more sensitive to the side effects of this drug, especially confusion, unsteadiness, or irregular heartbeat. Confusion and unsteadiness can increase the risk of falling. Older adults may also be at greater risk of developing a type of mineral imbalance (low levels of sodium in the blood), especially if they are also taking "water pills" (diuretics).

During pregnancy, this medication should be used only when clearly needed. It may harm an unborn baby. However, since untreated seizures or bipolar disorder are serious conditions that can harm both a pregnant woman and her unborn baby, do not stop taking this medication unless directed by your doctor. If you are planning pregnancy, become pregnant, or think you may be pregnant, discuss with your doctor right away the benefits and risks of using this medication during pregnancy. If you are pregnant, prenatal care that includes tests for birth defects is recommended. Since birth control pills, patches, implants, and injections may not work if used with this medication (see also Drug Interactions section), discuss reliable forms of birth control with your doctor.

This medication passes into breast milk. Consult your doctor before breast-feeding.

DRUG INTERACTIONS:

See also How to Use section.

Drug interactions may change how your medications work or increase your risk for serious side effects. This document does not contain all possible drug interactions. Keep a list of all the products you use (including prescription/nonprescription drugs and herbal products) and share it with your doctor and

pharmacist. Do not start, stop, or change the dosage of any medicines without your doctor's approval.

Some products that may interact with this drug are: certain azole antifungals (isavuconazonium, voriconazole), orlistat.

Taking MAO inhibitors with this medication may cause a serious (possibly fatal) drug interaction. Avoid taking MAO inhibitors (isocarboxazid, linezolid, metaxalone, methylene blue, moclobemide, phenelzine, procarbazine, rasagiline, safinamide, selegiline, tranylcypromine) during treatment with this medication. Most MAO inhibitors should also not be taken for two weeks before treatment with this medication. Ask your doctor when to start or stop taking this medication.

Other medications can affect the removal of carbamazepine from your body, which may affect how carbamazepine works. Examples include macrolide antibiotics (such as erythromycin), rifamycins (such as rifabutin), St. John's wort, among others.

Carbamazepine can speed up the removal of other drugs from your body, which may affect how they work. Examples of affected drugs include artemether/lumefantrine, certain drugs used to prevent blood clots (anticoagulants such as apixaban, rivaroxaban), certain calcium channel blockers (such as nifedipine, nimodipine), nefazodone, HIV NNRTIs (such as delavirdine, efavirenz, etravirine, rilpivirine), praziquantel, ranolazine, among others.

This medication may decrease the effectiveness of hormonal birth control such as pills, patch, or ring. This could cause pregnancy. Discuss with your doctor or pharmacist if you should use reliable backup birth control methods while taking this medication. Also tell your doctor if you have any new spotting or breakthrough bleeding, because these may be signs that your birth control is not working well.

Tell your doctor or pharmacist if you are taking other products that cause drowsiness including alcohol, marijuana (cannabis), antihistamines (such as cetirizine, diphenhydramine), drugs for sleep or anxiety (such as alprazolam, diazepam, zolpidem), muscle relaxants (such as carisoprodol, cyclobenzaprine), and opioid pain relievers (such as codeine, hydrocodone).

Check the labels on all your medicines (such as allergy or cough-and-cold products) because they may contain ingredients that cause drowsiness. Ask your pharmacist about using those products safely.

This medication may interfere with certain lab tests (such as thyroid function, some pregnancy tests), possibly causing false test results. Make sure lab personnel and all your doctors know you use this drug.

OVERDOSE:

If someone has overdosed and has serious symptoms such as passing out or trouble breathing, call 911. Otherwise, call a poison control center right away. US residents can call their local poison control center at 1-800-222-1222. Canada residents can call a provincial poison control center. Symptoms of overdose may include: slowed breathing, loss of consciousness, muscle twitching, uncontrolled movements, very fast heartbeat.

NOTES:

Do not share this medication with others.

Lab and/or medical tests (such as complete blood count, blood mineral levels, kidney/liver function, eye exams, carbamazepine blood levels) should be done before you start taking this medication and while you are taking it. Keep all medical and lab appointments. Consult your doctor for more details.

MISSED DOSE:

If you miss a dose, take it as soon as you

remember. If it is near the time of the next dose, skip the missed dose. Take your next dose at the regular time. Do not double the dose to catch up.

STORAGE:

Store at room temperature away from light and moisture.

Do not store in the bathroom. Keep all medications away from children and pets.

Do not flush medications down the toilet or pour them into a drain unless instructed to do so. Properly discard this product when it is expired or no longer needed. Consult your pharmacist or local waste disposal company.

MEDICAL ALERT:

Your condition can cause complications in a

medical emergency. For information about enrolling in MedicAlert, call 1-888-633-4298 (US) or 1-800-668-1507 (Canada).

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