PACKAGE LEAFLET: Information for the patient

KARBAMAZEPINE

Tablets – 200 mg

(Carbamazepine)

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects becomes worse or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. WHAT KARBAMAZEPINE IS AND WHAT IT IS USED FOR

Karbamazepine is an antiepileptic of carboxamide group, which also carries psychotropic and neurotropic action. The mechanism of action of carbamazepine has not yet been clarified. Apparently the stabilization of the neuronal membrane is the basis of antiepileptic action. The psychotropic effect is used for the treatment of epilepsy and depressive psychosis.
Carbamazepine calms the paroxysmal pain in trigeminal and glossopharyngeal neuralgia.

Karbamazepine is indicated in:

- epilepsy (partial seizures with complex symptomatology and simple symptomatology);
- primarily or secondarily generalised epilepsy, with tonic-clonic seizures and some mixed forms of epilepsy;
- mania and as prophylaxy treatment in manic-depressive (bipolar) disorders unresponsive to lithium;
- trigeminal neuralgia and glossopharyngeal neuralgia.

Your doctor may have given you Karbamazepine for another reason. Ask your doctor if you want to know why you were given Karbamazepine.

2. BEFORE YOU TAKE KARBAMAZEPINE

Do not take Karbamazepine if:

- you are hypersensitive (allergic) to carbamazepine or to similar structural drugs (such as tricyclic antidepressants) or to the excipients of Karbamazepine;
- you are using concomitantly monoamine oxidase inhibitors (IMAO) (before administration of carbamazepine, MAO inhibitors should have been discontinued since at least two weeks);
- you suffer from atrioventricular block;
- you have history of previous bone marrow depression;
- you have history of acute and intermittent porphyria.

If you think that you have any of the above conditions, do not take the tablets, talk to your doctor and follow the instructions.

Serious skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis) have been reported with the use of carbamazepine. Frequently, the rash can involve ulcers of the mouth, throat, nose, genitals and conjunctivitis (red and swollen eyes). These serious skin rashes are often preceded by flu-like symptoms such as fever, headache, body ache. The rash may progress to widespread blistering and peeling of the skin. The highest risk for occurrence of serious skin reactions is within the first months of treatment.

These serious skin reactions can be more common in people from some Asian countries. The risk of these reactions in patients of Han Chinese or Thai origin may be predicted by testing a blood sample of these patients. Your doctor should be able to advise if a blood test is necessary before taking carbamazepine.
If you develop a rash or these skin symptoms, stop taking carbamazepine and contact your doctor immediately.

Take special care with Karbamazepine

Karbamazepine is not a simple analgesic, for this reason it should not be used for pain relief. The drug should be used only under medical care.
Ask your doctor before taking Karbamazepine:

- if you suffer from severe cardiovascular diseases;
- if you suffer from liver function disorders; always before starting treatment, blood tests and liver function tests should be performed; the blood tests should be repeated every week during the first month and then monthly; liver function tests also should be performed periodically;
- if skin allergic reactions appear or tests show worsening of liver function, then the treatment with carbamazepine should be stopped;
- if you suffer from renal function disorders;
- if you are an elderly patient, the dose of Karbamazepine should be determined carefully;
- if treatment with Karbamazepine has to be stopped immediately, then switch to another antiepileptic should be combined with diazepam;
- in case of occurrence of nonprogressive fluctuating asymptomatic leukopenia, which occurs frequently; in this case it is not required the interruption of treatment with Karbamazepine; however, treatment with this drug should be discontinued if the patient suffers from a progressive leukopenia, accompanied by clinical manifestation, such as fever or sore throat;
- if you suffer from petit mal or myoclonic seizures;
- if you have glaucoma.

Karbamazepine should be withdrawn gradually and under specialist supervision.

Contact your doctor immediately if you have suicidal ideation.

Carbamazepine use may be associated with antiepileptic hypersensitivity syndrome. The symptoms usually start between 1 and 8 weeks of exposure; fever, rash, and lymphadenopathy are most commonly seen. Other systemic signs include: liver dysfunction, haematological, renal, and pulmonary abnormalities, vasculitis, and multi-organ failure. If signs or symptoms of hypersensitivity syndrome occur, withdraw the drug immediately and seek for medical advice.

Taking other medicines

Tell your doctor or pharmacist if you are taking or have taken recently other drugs, including those without prescription such as:

- cimetidin, danazol, diltiazem, erythromicin, clarithromycin, fluoxetin, isoniazid, nicotinamide, propoxyphene, ketoconazole, itraconazole, verapamil, sodium valproate – these are drugs that can increase carbamazepine levels in serum;
- cisplatin, doxorubicin, rifampicin, phenobarbital, primidone, theophylline – these are drugs that may lower carbamazepine levels in serum;
- oral contraceptives, haloperidol, anticoagulants, valproic acid, felodipine, tricyclic antidepressants and lamotrigine, because their serum levels may be decreased by carbamazepine.

These drugs may be affected by Karbamazepine or may affect the way it acts. For this reason, during concomitant use you may need to decrease or increase the dose of Karbamazepine. Your doctor or pharmacist will advise you.

This list is not complete and there may be other drugs that interact with Karbamazepine.

Taking Karbamazepine with food and drinks

There are no data showing that the food affects the absorption of Karbamazepine. Concomitant use with alcohol and grapefruit juice is not recommended.

Pregnancy

Tell your doctor or pharmacist if you are pregnant, or planning to get pregnant because it is not yet determined the safety of the use of carbamazepine in pregnancy. Your doctor or pharmacist will discuss the risks and benefits of taking it during pregnancy.

Breastfeeding

Tell your doctor or pharmacist if you are breast-feeding because its safety and efficacy in children younger than 6 years is not yet determined.

Driving and using machines

Karbamazepine may cause dizziness, drowsiness and blurred vision. For this reason, patients should be very careful while driving or using machines.

Important information about some of the excipients of Karbamazepine

Karbamazepine tablets contain lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE KARBAMAZEPINE

Always take Karbamazepine exactly as your doctor has told you. If you feel that the effect of Karbamazepine is too strong or too weak, talk to your doctor or pharmacist.
The tablets should be taken during or after meals with some liquid.
It is better to take the tablets at the same time each day.

Epilepsy.

When possible, antiepileptic drugs should be given alone. It is advisable to start treatment with Karbamazepine with low doses, which are then increased individually until the desired therapeutic effect. Determination of plasmatic levels may help in establishing the optimal dosage, mainly when carbamazepine is used in combined therapy. During transition to carbamazepine treatment, the dose of the other antiepileptic drug should be withdrawn gradually.
Adults and children over 15 years: initially 200 mg 1 or 2 times daily, then the dose is increased slowly up to 400 mg 2 or 3 times daily, until an optimal effect is achieved.

Children: 10 – 20 mg / kg weight, it means up to 1 year 100 – 200 mg daily; 1 – 5 years, 200 – 400 mg daily; 5 – 10 years, 400 – 600 mg daily; 10 – 15 years, 0.6 – 1 g daily, taken in divided doses.

Trigeminal neuralgia: the initial dose is 100 mg twice daily (first day); the dose may be increased to 200 mg daily and then 200 mg 3 or 4 times daily until pain relief is obtained; then the dose is reduced gradually to an acceptable level.

Manic depressive psychosis: the usual dose is 400 – 600 mg daily.
Moreover, the dose may be needed to be increased or reduced.
Your doctor may ask you to take Karbamazepine for a longer time. Ask your doctor for advice if you are not sure for how long you should take this drug.

If you take more Karbamazepine than you should

If you take more Karbamazepine than you should, or if the children have been taking this medicine by accident, please contact your doctor, the hospital, or call the emergency to get an opinion of the risk and advice on the action to be taken.

If you forget to take Karbamazepine

If you forget a dose, take the next dose when it is the normal time to take it.
Do not take a double dose to make up for the forgotten dose.
If you have any further questions on the use of this medicinal product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Karbamazepine is generally well tolerated by the organism if the prescribed doses are respected and if attention is paid to the instructions. But like all medicines, Karbamazepine also can cause side effects, although not everybody may get them. Sometimes they may be serious, sometimes not. These side effects usually disappear spontaneously after 7 to 14 days or by reducing temporarily the dose. Do not panic from this list of possible side effects. You may not get any of them.

Very common (may affect more than 1 in 10 people):

- nausea and vomiting;
- headache, dizziness, drowsiness, ataxia;
- skin allergic reactions are also reported;
- leucopenia and thrombocytopenia;
- hepatitis.

Common (may affect up to 1 in 10 people):

- hyponatremia is noticed, because of antidiuretic effect of carbamazepine and may be associated with vomiting, headache and mental confusion;
- weight gain;
- dry mouth;
- visual accommodation disorder;
- diplopia.

Uncommon (may affect up to 1 in 100 users):

- constipation;
- diarrhoea;
- eye disorders;
- tic;
- tremor;
- exfoliative dermatitis.

Rare (may affect up to 1 in 1,000 users):

- disease of the lymph glands;
- folic acid deficiency;
- a generalised allergic reaction including rash;
- joint pain;
- fever;
- problems with the kidneys and other organs;
- hallucinations;

- depression;
- loss of appetite;
- restlessness;
- aggression;
- confusion or agitation (mainly in the beginning of the treatment);
- speech disorders;
- numbness or tingling in the hands and feet;
- muscle weakness;
- high blood pressure (which may make you feel dizzy, with a flushed face, headache, fatigue and nervousness);
- low blood pressure (the symptoms of which are feeling faint, light headed, dizzy, confused, having blurred vision);
- changes to heart beat;
- liver problems including jaundice;
- symptoms of lupus;
- agranulocytosis;
- thromboembolism;
- cardiac impulse conduction disorders.

Very rare (may affect up to 1 in 10,000 users):

- changes to the composition of the blood including anaemia;
- porphyria;
- meningitis;
- swelling of the breasts and discharge of milk which may occur in both males and females;
- abnormal thyroid function tests;
- osteomalacia (which may be noticed as pain on walking and bowing of the long bones in the legs);
- osteoporosis;
- increased blood fat levels;
- taste disturbances;
- conjunctivitis;

- glaucoma;
- cataracts;
- hearing disorders;
- heart and circulatory problems including deep vein thrombosis (DVT), the symptoms of which could include tenderness, pain, swelling, warmth, skin discoloration and prominent superficial veins;
- lung or breathing problems;
- severe skin reactions including Stevens-Johnson syndrome, toxic epidermal necrolysis;
- sore mouth or tongue;
- liver failure;
- increased sensitivity of the skin to sunlight;
- alterations in skin pigmentation;
- acne;
- excessive sweating;
- hair loss;
- increased hair growth on the body and face;
- muscle pain or spasm;
- sexual difficulties which may include reduced male fertility, loss of libido or impotence;
- kidney failure;
- proteinuria;
- blood spots in the urine;
- increased or decreased desire to pass urine or difficulty in passing urine.

Not known (frequency cannot be estimated from the available data):

- severe skin reactions, accompanied by feeling unwell and changes in blood results;
- signs of inflammation of the colon (diarrhoea, abdominal pain, and fever);
- reactivation of herpes virus infection (can be serious when immune system is depressed);
- loss of nails;
- fracture;
- decrease in the measure of the bone density;
- memory loss;

- purple or reddish-purple bumps that may be itchy.

When side effects are reversible, the treatment is not interrupted. When effects are moderate or severe, the dose of Karbamazepine should be reduced or the treatment should be stopped.

If any of the side effects becomes worse or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE KARBAMAZEPINE

Keep out of the reach and sight of children.
Do not use Karbamazepine after the expiry date which is stated on the package.
Do not store above 25°C.

6. FURTHER INFORMATION

What Karbamazepine contains

The active substance is carbamazepine.
Each tablet contains 200 mg carbamazepine.
The excipients are: starch, lactose, gelatin, magnesium stearate, talc, sodium starch glycolate.

Contents of the pack

Box with 30 tablets.

Marketing Authorisation Holder (MAH) and manufacturer:

PROFARMA sh.a.,
St. “Skënder Vila”,
Tirana, Albania.
Tel.: +355 4 23 89 602

This leaflet was last revised in August 2023.