

Package leaflet: information for the patient**Carbamazepină Slavia 200 mg tablets**
Carbamazepine

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any additional questions, ask your physician or pharmacist.
- This medicine has been described only for you. You should not give it to other people. It can harm them, even if they present the same disease symptoms as you.
- If you experience any adverse reactions, contact your physician, pharmacist or nurse. These include any possible adverse reactions not mentioned in this leaflet. See section 4.

What is in this leaflet

1. What Carbamazepină Slavia is and what it is used for
2. What you need to know before you use Carbamazepină Slavia
3. How to use Carbamazepină Slavia
4. Possible adverse reactions
5. How to store Carbamazepină Slavia
6. Package contents and other information

1. What Carbamazepină Slavia is and what it is used for

Carbamazepină Slavia belongs to a group of medicines called antiepileptics (medicines for convulsions). It can also relieve some types of pain and keep certain disposition disorders under control.

Carbamazepină Slavia is used:

- to treat certain types of seizures (epilepsy);
- to treat painful conditions of the face, such as "trigeminal neuralgia";
- to control severe mood disorders that do not respond to other medicines.

2. What you need to know before you use Carbamazepină Slavia

You can use Carbamazepină Slavia only after a complete medical examination.

Risk of serious skin reactions in patients of Han Chinese or Thai origin, associated with carbamazepine or chemically related compounds, can be anticipated by analysing blood samples taken from these patients. Your physician should be able to tell you if blood tests are necessary before taking Carbamazepină Slavia.

Do not take Carbamazepină Slavia:

- if you are allergic to carbamazepine to similar drugs such as oxcarbazepine or other related substances, such as tricyclic antidepressants (amitriptyline or imipramine). If you are allergic to carbamazepine there is a 25% risk of also being allergic to oxcarbazepine;
- if you are allergic to any of the other components of this medicine (listed in section 6). Signs of

hypersensitivity include swelling of the face, lips or tongue (angioedema), breathing problems, runny nose, itchy skin, blistering or peeling skin;

- if you have any heart disease;
- if you have had problems with the hematogenous marrow in the past;
- if you have a blood disorder called porphyria;
- if you are taking or have taken in the last 14 days medicines that belong to a group of antidepressants monoamine oxidase inhibitors (MAOIs).

If any of these cases occur, inform your physician before using Carbamazepină Slavia. If you think you may be allergic, ask for your physician's advice.

Warnings and precautions

Before using Carbamazepină Slavia, consult your physician or pharmacist.

A small number of people who have been treated with anti-epileptic drugs such as carbamazepine have had thoughts of harming or killing themselves. If you ever have such thoughts, get in touch with your physician immediately, regardless of the moment.

Serious skin conditions (Stevens-Johnson syndrome, toxic epidermal necrolysis) have been reported in the use of carbamazepine. Often, these conditions are manifested by ulcers in the mouth, throat, nose, genitals and conjunctiva (swollen and red eyes). These ulcerations are often preceded by cold symptoms such as: fever, headache or body aches. Sometimes pustules appear all over the surface of the body, with subsequent exfoliation of the skin. The greatest risk of these adverse reactions is in the first months of treatment, as well as in patients of Asian origin (Han Chinese or Thai). In the second case, the risk can be anticipated through a blood test.

Your physician can tell you if blood tests are needed before taking Carbamazepină Slavia.

If you notice a rash or other manifestations on the skin, stop taking Carbamazepină Slavia and contact your physician immediately.

If you experience dizziness, drowsiness, low blood pressure, confusion due to the treatment with Carbamazepină Slavia, there is a risk of falling.

You should also ask yourself the following questions before taking Carbamazepină Slavia. If the answer to any of these questions is YES, discuss treatment with your physician or pharmacist, because Carbamazepină Slavia may not be the right medicine for you.

- Are you pregnant or planning to become pregnant?
- Are you breastfeeding?
- Do you have epilepsy with mixed seizures that include absences?
- Do you have any mental illness?
- Are you allergic to an epilepsy medicine called phenytoin, primidone, or phenobarbital?
- Do you have liver problems?
- Do you have kidney problems associated with low sodium in the blood, or do you have kidney problems and are taking certain medicines that lower the level of sodium in the blood (diuretics such as hydrochlorothiazide, furosemide)?
- Are you elderly?
- Do you have eye problems such as glaucoma (increased pressure in the eye) or have difficulty keeping urine?

Your physician may want for you to have several blood tests before starting taking Carbamazepină Slavia and from time to time during treatment. This is fairly usual and you don't need to worry.

There is a risk of harm to the fetus if Carbamazepină Slavia is used during pregnancy. Women of fertile potential must use effective methods of contraception during treatment with Carbamazepină Slavia and for two weeks after the last dose (see *Pregnancy and breast-feeding*).

Carbamazepină Slavia with other medicines

Tell your physician or pharmacist if you are using, have recently used or might use any other medicines.

Carbamazepine's mechanism of action causes it to affect or be affected by many other medicines or food you consume. It is very important to tell your physician what other medicines or dietary supplements you are taking. It is possible that in the case of some medicines it may be required a change in dose or even the interruption of their administration.

Tell your physician or pharmacist if you are using, have recently used or might use any other medicines, especially if you are taking:

- hormonal contraceptives (pills, patches, injections or implants). Carbamazepină Slavia affects the way these contraceptives work and you may have breakthrough bleeding. Also, the effectiveness of contraceptives can decrease, there being a risk of getting pregnant. Your physician can advise you on these aspects and you may have to use other methods of contraception. If you are a woman of fertile age you must use an effective method of contraception throughout treatment and for a period of 28 days after discontinuation of treatment;
- hormone replacement therapy (TSH: thyroid stimulating hormone). Carbamazepine decreases the effect of TSH;
- medicines for anxiety or depression;
- corticosteroids (or "steroids"). You may take such medications for inflammatory conditions such as asthma, irritable bowel syndrome, muscle or joint pain;
- anticoagulants to stop blood clotting;
- antibiotics (for example, ciprofloxacin), to treat bacterial infections, including those of the skin or for tuberculosis;
- antifungals used to treat mycotic infections (fungi);
- analgesics containing paracetamol, dextropropoxyphene, tramadol, methadone or buprenorphine;
- other medicines for epilepsy (e.g. phenytoin, primidone, phenobarbital, brivaracetam);
- antihypertensive drugs or for other heart conditions;
- antihistamines (medicines used to treat pollen allergy, hay fever, itching, etc.);
- diuretics (medicines that "eliminate water");
- cimetidine or omeprazole (medicines used to treat gastric ulcers);
- isotretinoin (medicine used to treat acne);
- metoclopramide or aprepitant (medicines for nausea and vomiting);
- acetazolamide (medicine used to treat glaucoma - increased pressure in the eye);
- danazol or gestrinone (medicines used in endometriosis);
- theophylline or aminophylline (medicines used to treat asthma);
- ciclosporin, tacrolimus or sirolimus (immunosuppressive drugs used after transplant of organs and sometimes used in arthritis or psoriasis);
- medicines for schizophrenia (e.g. paliperidone, aripiprazole);
- antineoplastics (for example, temsirolimus, cyclophosphamide, laptanib);
- antimalarials (e.g. mefloquine);
- anti-HIV drugs;
- levothyroxine (medicine used in hyperthyroidism);
- tadalafil (medicine used in impotence);
- albendazole (medicine used in parasitic infections);
- bupropion (used in anti-smoking therapy);
- St. John's Wort;
- medicines or food supplements with vitamin B3 (nicotinamide).

Carbamazepină Slavia with food, drinks and alcohol

Do not drink alcohol during treatment with Carbamazepină Slavia. Alcohol consumption during treatment may affect you more than usual.

Do not drink grapefruit juice or eat grapefruit, as this may increase the risk of adverse reactions during treatment with Carbamazepină Slavia.

Pregnancy, breastfeeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or intend to become pregnant, ask your physician or pharmacist for advice before taking this medicine.

Pregnancy

Your physician will discuss with you the potential risk of taking Carbamazepină Slavia during pregnancy because the treatment may cause damage or abnormalities to the unborn child. You must talk to your physician about epilepsy treatment before becoming pregnant. If you stay pregnant while taking Carbamazepină Slavia tablets you must tell the physician immediately. It is important that epilepsy remains well controlled, but, as with other antiepileptic drugs, there are risks of harm to the fetus. Make sure you understand the risks and benefits of administering Carbamazepină Slavia tablets very clearly.

Carbamazepină Slavia can cause major birth defects. If you take Carbamazepină Slavia during pregnancy, your baby is up to 3 times more likely to have a birth defect than those of women who are not taking an antiepileptic drug. Major birth defects have been reported, including neural tube defects (opening at the level of the spine), birth defect of the face such as cleft lip and palate, congenital head defect, heart defects, congenital defect of the penis involving the urinary opening (hypospadias), as well as finger defects. The fetus should be closely monitored if you have taken Carbamazepină Slavia during pregnancy.

Problems with neurodevelopment (brain development) have been reported in children born to mothers who have used Carbamazepină Slavia during pregnancy. Some studies have shown that carbamazepine negatively affects neurodevelopment of children exposed to it in utero, while other studies have not found such effect. The possibility of an effect on neurodevelopment cannot be excluded.

Breastfeeding

Mothers who are on active treatment with Carbamazepină Slavia can breastfeed their babies, but must tell the physician as soon as possible if they notice that the baby is experiencing adverse reactions such as excessive sleepiness, skin reaction or yellow skin and eyes, dark urine or discolored stools.

Fertility

If you are a fertile woman and are not planning to become pregnant, you should use effective birth control methods during treatment with Carbamazepină Slavia. Carbamazepină Slavia can affect how hormonal contraceptives, such as birth control pills, work by making them less effective in preventing pregnancy. Talk to your physician, who will determine with you the most appropriate type of contraception to use while taking Carbamazepină Slavia. If the treatment with Carbamazepină Slavia is discontinued, you must continue to use effective contraception for two more weeks after stopping the treatment with carbamazepine. Irregularity of the menstrual period can occur in women who take hormonal contraceptives (contraceptive drugs) and Carbamazepină Slavia.

If you are a fertile woman and plan to become pregnant, talk to your physician before stopping contraception and before becoming pregnant, about switching to other appropriate treatments to avoid exposure of the unborn child to carbamazepine.

If you are or think you may be pregnant, tell your physician immediately. You should not stop taking

the medicine until you have discussed this with your physician. Stopping the treatment without consulting your physician can cause seizures that could be dangerous for you and your unborn child. Your physician may decide to change your treatment.

If you take Carbamazepină Slavia during pregnancy, your baby is also exposed to risk of bleeding immediately after birth. Your physician can give you and your baby a medicine to prevent this.

Driving vehicles and use of machineries

Carbamazepină Slavia may make you feel drowsy, dizzy or have blurred vision, double vision or lack of muscle coordination, especially at the beginning of treatment or when increasing the dose. If you are affected in this way or if your vision is impaired, you should not drive or use machinery.

3. How to use Carbamazepină Slavia

Always use this medicine exactly as your physician, pharmacist or nurse has told you. Talk to your physician, pharmacist or nurse if you are not sure.

The physician will tell you how many tablets of Carbamazepină Slavia to take and when to take them. Always carefully follow his/her instructions. It is important to take the tablets at the right time. If you are not sure, ask your physician or pharmacist. Keep taking tablets for as long as you have been told, unless you have problems. In this case, consult your physician.

Your physician will usually start your treatment with Carbamazepină Slavia with a fairly low dose, which can then be increased to suit your condition. The required dose varies from patient to patient. You can take Carbamazepină Slavia tablets during, after or between meals. Swallow the tablets with water. You are usually told to take one dose two or three times a day.

Dosage

Treatment of epilepsy

Adults: 800 to 1,200 mg per day, although higher doses may be needed. If you are an elderly patient a dose reduction may be necessary.

Children

Between 5 and 10 years: 400 to 600 mg, daily.

Between 10 and 15 years: 600 to 1,000 mg per day.

Carbamazepină Slavia tablets are not recommended for children under 5 years of age.

Treatment of trigeminal neuralgia: usual dose 600 – 800 mg per day. The maximum dose is 1,200 mg per day. If you are elderly, you may need a lower dose.

Treatment of mood changes, the usual dose is: 400-600 mg per day.

If you take more Carbamazepină Slavia than you should

If you accidentally take too many tablets, tell your physician immediately or go to the nearest hospital. You may need medical attention. Take the medicine box with you, so that they can know what medicine you have taken.

If you forget to take Carbamazepină Slavia

If you forget to take a dose, take it as soon as you remember. However, if it's almost time for the next dose, do not take the missed dose again; just go back to your regular usage schedule.

Do not take a double dose to make up for missed doses.

If you have any further questions about this medicine, ask your physician or the pharmacist.

4. Possible adverse reactions

As any other medicine, Carbamazepină Slavia may be associated with adverse reactions, even if they will not occur in every patient.

Some side effects can be very serious.

Stop taking Carbamazepină Slavia and contact your physician immediately if the following occur:

- severe reactions on the skin: eczema, redness, blisters on the lips, eyes or mouth, scaling, accompanied by fever (these reactions may be more common in patients of Chinese or Thai origin);
- mouth ulcers, bruises or unexplained bleeding;
- sore throat, fever or both;
- yellowing of the skin or the whites of the eyes;
- swelling of the ankles, calves or feet;
- any signs of a nervous condition or confusion;
- muscle or joint pain, rash on the nose and cheeks, breathing problems (these can be manifestations of lupus erythematosus, a rare adverse reaction);
- fever, eczema, joint pain, abnormal blood and liver tests (these may be signs of systemic immunological impairment);
- bronchospasm with wheezing and coughing, breathing problems, fainting, eczema or swelling of the face (these may be signs of a severe allergic reaction);
- pain in the stomach area;
- falls due to dizziness, drowsiness, low blood pressure, disorientation.

Other reported adverse reactions

Very common adverse reactions (may occur in more than 1 in 10 patients):

- decrease in the number of white blood cells (leukopenia - condition that favours the appearance of infections);
- dizziness, fatigue;
- inability to coordinate movements, loss of balance;
- nausea, vomiting;
- changes in the serum values of certain liver enzymes (usually without other symptoms);
- skin reactions, which can be serious.

Common adverse reactions (may occur in less than 1 in 10 patients):

- tendency to easy bruising of the skin or bleeding;
- fluid retention (edema);
- weight gain;
- decrease in sodium levels in the blood, which can lead to confusion;
- headaches, visual disturbances (for example, double vision, blurred vision);
- dry mouth.

Uncommon adverse reactions (may occur in less than 1 in 100 patients):

- involuntary movements (tics, tremors);
- involuntary movements of the eyeballs;
- diarrhea, constipation.

Rare adverse reactions (may occur in less than 1 in 1,000 patients):

- damage to the lymph nodes;
- systemic allergic reaction, accompanied by fever, skin rashes, joint pain, kidney and other organs disorders;
- deficiency of folic acid;

- decrease in appetite;
- liver problems (including jaundice);
- hallucinations, depression, restlessness, aggressive behavior, agitation, confusion;
- speech difficulties;
- numbness or tingling in the palms and soles, muscle weakness;
- increase in blood pressure (manifested by dizziness, fatigue, nervousness, flushing, headache) or low blood pressure (with symptoms such as fainting or dizziness, disorientation, blurry vision);
- changes in heartbeat;
- stomach pains;
- manifestations of systemic lupus erythematosus (red spots, especially on the face, accompanied by fatigue, fever, nausea, loss of appetite).

Very rare adverse reactions (may occur in less than 1 in 10,000 patients):

- hematological changes (for example, anemia);
- severe skin rashes that can be life-threatening, including Stevens-Johnson syndrome (may be common in patients of Chinese or Thai origin);
- porphyria (hemoglobin metabolism disorder);
- meningitis;
- breast swelling, inadequate milk secretion - both in women and in men;
- osteomalacia (manifested by pain when walking and curvature of the long bones of the lower limbs), osteoporosis;
- abnormal thyroid function tests;
- increased levels of blood fats (including HDL-cholesterol, triglycerides);
- changes in taste;
- conjunctivitis, cataract, glaucoma;
- hearing disorders;
- heart and vascular problems, including deep vein thrombosis (manifested by sensitivity, pain, inflammation, local heat, skin pigmentation, prominent superficial veins);
- respiratory or pulmonary problems;
- inflammation of the tongue and mouth;
- liver failure;
- increased sensitivity of the skin to sunlight, changes in skin pigmentation, acne, hair loss, excessive sweating;
- excessive growth of facial and body hair;
- muscle pains or spasms;
- kidney failure, drops of blood in the urine, increase or decrease in the need to urinate or difficulty in urination;
- sexual dysfunctions (impotence or low libido).

Adverse reactions with unknown frequency (cannot be estimated from the available data):

- reactivation of infection with the human herpes virus (serious, if the immune system is depressed);
- diarrhea, abdominal pain and fever (signs of inflammation of the colon);
- drowsiness;
- memory disorders;
- complete loss of nails;
- fractures;
- decrease in bone density;
- severe skin reactions accompanied by feeling sick and changes in blood parameters.

Don't be alarmed by this list. Most people take Carbamazepină Slavia tablets without problems.

If any of the symptoms become bothersome or if you notice anything else not mentioned here, please

consult your physician. He/She may want to give you another drug.

Bone disorders, including osteopenia, osteoporosis (thinning of the bone) and fractures, have been reported. Tell your physician or pharmacist if you are taking long-term antiepileptic drugs, if you have a history of osteoporosis or if you are taking steroids.

Adverse reactions reporting

If you present any adverse reactions, please address your physician or pharmacist. Those include any adverse events that are not mentioned in this leaflet. Also, you can report adverse reactions through the national reporting system, detailed and published on the National Agency for Medicines and Medical Devices of Romania <http://www.anm.ro/>. By reporting the adverse reactions, you can contribute to the provision of additional information regarding the safety of this medicine.

National Agency for Medicines and Medical Devices of Romania,

48 Aviator Sănătescu Street, 1st District,

Bucharest 011478-RO,

Phone: +4 0757 117 259,

Fax: +4 0213 163 497,

E-mail: adr@anm.ro

5. How to store Carbamazepină Slavia

Keep at temperatures below 25°C, in the original package.

Do not leave this medicine within the reach and sight of children.

Do not use this medicine beyond the expiration date written on the box after 'EXP'. The expiration date refers to the last day of the respective month.

Do not discard any medicine in the sewage or trash. Ask your pharmacist about discarding any drugs you will no longer use. Those measures will help you in the environmental protection.

6. Package contents and other information

What does Carbamazepină Slavia contain

- The active ingredient is carbamazepine. Each tablet contains 200 mg carbamazepine.
- Other ingredients: croscarmellose sodium, povidone K 30, talcum, magnesium stearate, silicified microcrystalline cellulose.

What Carbamazepină Slavia looks like and package composition

White to off-white round tablets with flat surfaces, uniform appearance and diameter of 9 mm.

Box containing 2 blisters transparent PVC/Al with 10 tablets each.

Box containing 5 blisters transparent PVC/Al with 10 tablets each.

Marketing authorization holder and manufacturer

Marketing authorization holder

S.C. Slavia Pharm S.R.L.

44C Theodor Pallady Blvd.

032266, Bucharest, Romania

This leaflet was revised in March 2022.