

Package Leaflet: Information for the user

Gericarb 100 mg Tablets Gericarb 200 mg Tablets (Carbamazepine)

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

- 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 signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Gericarb is and what it is used for
2. What you need to know before you take Gericarb
3. How to take Gericarb
4. Possible side effects
5. How to store Gericarb
6. Contents of the pack and other information

1. What Gericarb is and what it is used for

Gericarb contains the active substance carbamazepine. It belongs to a group of medicines called antiepileptics (medicine for seizures).

Gericarb can be used to treat diseases, including:

- certain types of seizures (epilepsy).
Epilepsy is a condition that causes repeated seizures (fits). Seizures occur when messages from the brain to the muscles are not properly passed on by the nerve pathways in the body. Gericarb helps to control the passing-on of these messages. Gericarb also regulates nerve functions for the other diseases mentioned below.
- neurological diseases, such as nerve pain caused by trigeminal neuralgia. It must not be used for common aches or pains.
- certain psychiatric conditions, such as episodes of bipolar mood disorders and to help treat mania and prevent depression in those with a manic-depressive illness
- to help treat patients withdrawing from alcohol abuse

Gericarb is also used in children to treat some forms of epilepsy.

2. What you need to know before you take Gericarb

Your doctor may want you to have a number of blood tests before you start taking Gericarb and from time to time during your treatment. The risk of serious skin reactions in patients of Han Chinese or Thai origin associated with carbamazepine or chemically related compounds 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 Gericarb.

Do not take Gericarb if you

- are allergic to carbamazepine or similar medicines such as oxcarbazepine and tricyclic antidepressants (such as amitriptyline or imipramine)
- are allergic to any of the other ingredients of this medicine (listed in section 6) Symptoms of an allergic reaction include an itchy runny nose, asthma or a skin rash

- have severe heart disease or have had any abnormalities of heart rate or rhythm
- have a condition which affects your bone marrow or have had serious blood illnesses in the past
- suffer from blood disorder called porphyria
- taking medicines to treat depression called monoamine oxidase inhibitor (MAOI) or have taken them within 2 weeks
- are taking a herbal remedy containing St. John's wort (*Hypericum perforatum*)

If any of the above applies to you, tell your doctor before taking Gericarb.

If you think you may be allergic, ask your doctor for advice.

Warnings and precautions

Talk to your doctor or pharmacist before taking Gericarb if:

- you have blood illnesses (including those caused by other drugs)
- you have ever suffered a reaction to any other medicine, which has affected your blood, for example a low white blood cell count (leucopenia)
- you have ever shown unusual sensitivity (rash or any other signs of allergy) to oxcarbazepine or to any other medicines.
- you have the type of epilepsy where you suffer from mixed seizures including absences
- you were told by your physician that you suffered from mental illness
- you have or have had heart, liver or kidney disease in the past
- you have difficulty emptying your bladder (urinary retention)
- you have an under-active thyroid (hypothyroidism)
- you have thinning of the bones (osteopenia or osteoporosis)
- you have glaucoma (increased pressure in the eye)

If you have any questions about this, ask your doctor or health professional

Thoughts of harming or killing yourself

If at any time you have thoughts of harming or killing yourself, immediately contact your doctor. A small number of people being treated with anti-epileptics such as carbamazepine have had thoughts of harming or killing themselves.

Serious skin reactions

Tell your doctor immediately if you get serious skin reaction. Serious skin rash – Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), Drug Rash with Eosinophilia and Systemic Symptoms (DRESS) or Acute Generalised Exanthematous Pustulosis (AGEP) have been reported during treatment with Gericarb.

Initially, reddish target-like spots or circular patches appear, often with central blisters on the trunk. 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 influenza-like symptoms fever, headache, body ache (flu-like symptoms). 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 Gericarb. If you develop a rash or these skin symptoms, stop taking Gericarb and contact your doctor immediately.

Serious blood or bone marrow problems

Tell your doctor straight away if you get signs of serious blood or bone marrow problems such as fever and sore throat, with possible unexplained bruising or burst blood vessels under your skin.

Liver and kidney problems

If you notice symptoms suggestive of hepatitis, such as jaundice (yellowing of skin and eyes), tell your doctor immediately.

If you cannot retain your urine or you have kidney problems associated with low sodium blood level. If you have kidney problems and you are taking also certain medicines that lower sodium blood level (diuretics such as hydrochlorothiazide, furosemide), discuss with your doctor before taking Gericarb.

Seizures

If you experience an increase in the number of seizures, tell your doctor immediately.

Children, adolescents and older people

Gericarb may be safely used in children and in elderly patients, keeping to the doctor's instructions. If necessary, special information will be given, such as on careful dosage and close observation needed (see also section 3. How to take Gericarb and section 4. Possible side effects).

Other medicines and Gericarb

Tell your doctor or your pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription, because these might interact with Gericarb (carbamazepine). It is particularly important for Gericarb, since many other medicines interact with it. You may need a change in your dose or, sometimes, to stop one of the medicines.

If you are taking any of the following medicines, tell your doctor or pharmacist:

- Monoamine oxidase inhibitors (MAOIs), used to treat depression, within the last 14 days
- other antiepileptics particularly phenobarbitone, phenytoin or oxcarbazepine, and also primidone, ethosuximide, lamotrigine, tiagabine, topiramate, clobazam, clonazepam, valproic acid, stiripentol, vigabatrin, levetiracetam
- Antibiotics to treat infections, such as erythromycin, clarithromycin, isoniazid, rifampicin, doxycycline, ciprofloxacin and antituberculosis medicine such as rifampicin
- antifungal medicine such as itraconazole, ketoconazole, fluconazole, voriconazole
- antiviral medicine for HIV treatment, such as ritonavir, indinavir, saquinavir
- painkillers containing dextropropoxyphene, tramadol, or methadone, and other anti-inflammatory medicines such as ibuprofen, paracetamol, buprenorphine, dicoumarol
- corticosteroids, e.g. prednisolone, dexamethasone ("steroids") for inflammatory conditions such as asthma, inflammatory bowel disease or muscle and joint pains
- muscle relaxants such as pancuronium, oxybutynin, dantrolene
- acetazolamide (to treat glaucoma)
- medicine for heart problems or high blood pressure, e.g. verapamil, diltiazem, digoxin or felodipine, simvastatin, atorvastatin, lovastatin
- theophylline and aminophylline, for asthma treatment
- antihistamines such as loratadine, terfenadine
- antihelmintics such as praziquantel, albendazole
- cimetidine, omeprazole (for the treatment of gastric ulcers)
- levothyroxine (L-thyroxine), for hypothyroidism
- isotretinoin (to treat acne)
- antimalarial medicine such as mefloquine
- diuretics ('water' tablets) such as furosemide, hydrochlorothiazide
- anticoagulant medicines (blood thinning tablets like warfarin)
- nicotinamide in high doses
- ticlodipine (a platelet aggregation inhibitor)
- antipsychotics medicines for depression or anxiety and to treat schizophreniz, such as lithium, alprazolam, midazolam, paroxetine, haloperidol, imipramine, desipramine, viloxazine, fluoxetine, thioridazine, olanzapine, quetiapine. risperidone, clozapine, mianserin, citalopram, sertraline, aripiprazole, paliperidone, trazodone, clomipramine
- immunosuppressant, used after transplant operations or treatment of arthritis and psoriasis, such as ciclosporin, everolimus, tacrolimus, sirolimus
- anticancer medicine such as cisplatin, doxorubicin, imatinib, temsirolimus
- aprepitant, to prevent vomiting and nausea e.g. metoclopramide
- St John's wort (*Hypericum Perforatum*), a herbal remedy. The remedy should not be taken at the same time as this medicine. If you already take St. John's wort, consult your doctor before stopping the St. John's wort preparations

- danazol or gestrinone (a treatment for endometriosis)
- hormone contraceptives (birth control medicines). The contraceptive effect may be less effective. (see section ‘Pregnancy’)
- medicines containing oestrogens, progesterones, such as tribolone, toremifene
- tadalafil, for erectile dysfunction
- bupropion, often used to help stop smoking

Gericarb with food, drink and alcohol

Do not drink alcohol when you are on Gericarb. Do not drink Grapefruit juice or eat grape fruit as it may increase the effect of Gericab.

Pregnancy

Gericarb affects the way hormone contraceptives work in your body. You may get irregular bleeding or spotting. It may also make the contraceptive less effective. Other contraceptive methods should be considered.

If you are pregnant, think you may be pregnant or planning to have a baby, ask your doctor for advice before taking this medicine. It is important to control epileptic seizures during pregnancy. However, there is a possible risk to your baby if you take antiepileptic medication (medicine for seizures) during pregnancy.

Your doctor will discuss with you the potential risk of taking Gericarb during pregnancy. Do not stop your treatment with Gericarb during pregnancy without first checking with your doctor.

Breast-feeding

Tell your doctor if you are breast-feeding. The active ingredient in Gericarb passes into the breast milk. As long as your doctor agrees in your special case, and your child is closely watched for side effects, you may breast-feed your child. However, if you think that the baby is having side effects such as excessive sleepiness, skin reactions or gets yellowish skin or eyes, stop breast-feeding and tell your doctor.

Driving and using machines

Gericab may make you feel drowsy or dizzy, or may cause blurred vision, double vision or you may have a lack of muscle coordination especially when starting treatment or increasing the dose. Do not drive, cycle or operate machines if you suffer these side effects.

Ask your doctor or pharmacist for advice before taking any medicine.

3. How to take Gericarb

Always take this medicine exactly as your doctor or pharmacist has told you. Do not exceed the recommended dose. Check with your doctor or pharmacist if you are not sure.

How much to take

Your doctor will usually start Gericarb at a fairly low dose which can then be increased to suit you individually. The dose needed varies between patients, you are usually told to take a dose two or three times a day.

For the Treatment of *epilepsy*

Adults: The recommended dose is 100 mg to 200 mg once or twice a day. Your doctor will slowly increase this dose to 800 mg to 1200 mg, divided into 2 or 3 intake. Higher dose such as 1,600 to 2,000 mg may be necessary.

Children and adolescents: The recommended dose is 10 – 20 mg/kg bodyweight daily. The dose is slowly increase based on their age:

Aged 5 to 10 years: between 400 and 600 mg a day

Aged 10 to 15 years: between 600 and 1,000 mg a day

Ages 15 years and older: same as adult does (as above)

Gericarb is not recommended for very young children. Other forms of this medicine may be more suitable for children under 5, ask your doctor or pharmacist.

Elderly: Elderly patients may require a lower dose than adults.

For treatment of **trigeminal neuralgia** and other nerve pains

The recommended dose for adults is 200 mg to 400 mg 3 to 4 times a day. The maximum dose is 1200 mg a day. For elderly patients a lower dose of 100 mg twice daily may treat the pain.

For treatment of **serious mood disorders**

The recommended starting dose is 100 to 200 mg daily. This dose may be slowly increased until the symptoms are controlled. The usual dosage range is between 400 mg to 600 mg daily.

For **alcohol withdrawal symptoms**

The recommended total daily dose is 600 mg to 800 mg.

How to take Gericarb

Swallow the tablets with a glass of water. The score line is only there to help you break the tablet if you have difficulty swallowing it whole.

Gericarb may be taken before, after or with your meals.

If you take more Gericarb than you should

Contact your doctor or nearest hospital emergency department **immediately**. Take the container and any remaining tablets with you. You may experience difficulty in breathing, a fast and irregular heartbeat, loss of consciousness, fainting, shakiness, sickness and/or vomiting.

If you forget to take Gericarb

Take it as soon as you remember. If it is almost time for your next dose, do not take the missed one; just go back to your regular dosing timetable. **Do not** take a double dose to make up for a forgotten dose.

If you stop taking Gericarb

Do not stop taking your medicine suddenly as your fits may become worse. It is recommended that you stop taking your medicine gradually, over a period of 6 months. Always ask your doctor first. If your dose needs to be reduced, this will be done slowly. Your doctor will tell you if and when you can stop taking this medicine.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Gericarb can cause side effects, although not everybody gets them.

Tell your doctor straight away if you notice any of the following serious side effects, you may need urgent medical attention:

- thoughts of harming or killing yourself
- potentially life-threatening skin rash, with blistering or peeling, mouth or genital ulcers often with flu-like symptoms or a reduction on blood cells leading to unexplained bruising or bleeding (these may be signs of SJS, TEN, DRESS or AGEP. See section 2)
- signs of bone disorders including osteopenia and osteoporosis (thinning of the bone) and fractures. Check with your doctor or pharmacist if you are on long-term anti-epileptic medication, have a history of osteoporosis, or take steroids
- signs of serious blood or bone marrow problems such as fever and sore throat, with possible unexplained bruising or burst blood vessels under your skin
- bronchospasm with wheezing and coughing, difficulty in breathing, feeling faint, rash, itching or facial swelling (these may be signs of a serious allergic reaction)

- fever, muscle stiffness with confusion and unusual changes in blood pressure (these may be signs of a serious brain problem)
- fever, feeling or being sick, headache, stiff neck and extreme sensitivity to bright light (these may be signs of meningitis)
- having more fits (seizures)
- yellowing of your skin or the whites of your eyes (these may be signs of liver problems)
- being sick, diarrhoea, weight loss, with changes to or blood in your urine, changes in your heart beat, muscle cramps or itching (these may be signs of kidney failure)
- any changes in your mental health, including depression, agitation, confusion, loss of appetite, hearing or seeing things which are not there
- pain in your joints and muscles, a rash across the bridge of your nose and cheeks (these may be signs of a rare reaction known as lupus erythematosus)
- fever, skin rash, joint pain, and abnormalities in blood and liver function tests, that could go on to affect other organs as well (these may be signs of a multi-organ sensitivity disorder)
- pain in the area around the stomach
- severe diarrhoea, abdominal pain and fever (these may be signs of an inflamed colon)

Other side effects include:

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

- dizziness
- loss of muscle coordination
- feeling drowsy or unusually tired
- feeling or being sick
- minor skin reactions, including itchy rash, hives, redness and peeling
- low white blood cell count or change in liver enzyme levels (shown in blood tests)

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

- fluid retention, swollen feet, legs or ankles
- weight gain
- low sodium levels in the blood causing weakness, headache, and confusion
- dry mouth
- blurred or double vision

Uncommon effects (may affect up to 1 in 100 people)

- tremor or unusual muscle movements such as tics, abnormal eye movements
- diarrhoea or constipation

Rare effects (may affect up to 1 in 1,000 people)

- folate deficiency
- swollen lymph glands
- slurred speech or difficulty speaking
- numbness or tingling in the hands or feet, loss of movement
- burning, shooting or stabbing pain
- changes in heart rhythm
- high or low blood pressure, leading to dizziness, fatigue, nervousness, feeling faint or confused
- muscle weakness
- high white blood cell count (shown in blood test)

Very rare effects (may affect up to 1 in 10,000 people)

- change in taste
- sensitivity of skin to sunlight (porphyria)
- changes in skin pigmentation, acne
- sweating
- increased hair growth or loss
- sore tongue or mouth
- joint or muscle pain, muscle spasms

- swelling of the breasts, leaking of milk from the breasts (in both males and females)
- abnormal thyroid function tests
- sexual difficulties, including reduced male fertility, loss of libido, impotence
- weakening of bones and thinning of bones, lead to increased fractures
- rise in blood fats (cholesterol) levels
- eye changes such as conjunctivitis, cataracts, glaucoma
- hearing changes such as ringing in the ears, change in pitch perception
- change in heart rhythm, fainting, blood clots (causing tenderness, pain, swelling), worsening of heart and circulatory disease
- breathlessness, pneumonia (breathing problems)
- kidney problems, blood spots in urine or difficulty in passing urine
- low red blood cell count (anaemia) or low level of all blood cells (shown in blood tests)

Not known (it is now known how often these happen):

- Feeling drowsy
- memory loss
- purple or reddish-purple bumps on your skin that may be itchy
- complete loss of your nails
- reactivation of herpes virus infection (which can be serious when the immune system is depressed)

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance Earlsfort Terrace IRL - Dublin 2 Tel: +353 1 6764971 Fax: +353 1 6762517 Website: www.hpra.ie e-mail: medsafety@hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Gericarb

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date, which is stated on the blister and the carton. The expiry date refers to the last day of the month.

Do not store above 25°C. Store in the original packaging.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Gericarb contains

The active substance is carbamazepine. Each tablet contains 100mg or 200mg of carbamazepine. The other ingredients are microcrystalline cellulose, pregelatinised maize starch, colloidal anhydrous silica, magnesium stearate, talc and sodium starch glycolate (Type A).

What Gericarb looks like and contents of the pack

The tablets are white and plain on one side; the 100mg tablet is marked 'CB breakline 100' and the 200mg tablet is marked 'CB breakline 200'.

Gericarb Tablets are available in bottles of 100, 250 or 500 tablets.

Not all pack sizes may be marketed

Marketing Authorisation Holder

Generics [UK] Limited

Station Close, Potters Bar, Hertfordshire EN6 1TL, United Kingdom.

Manufacturer

McDermott Laboratories Ltd. T/A Gerard Laboratories, Baldoyle, Dublin 13, Ireland

This leaflet was last revised in July 2015