

Package leaflet: Information for the patient

Carbagen® 100 mg Tablets **Carbagen® 200 mg Tablets** **Carbagen® 400 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 only. 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 Carbagen is and what it is used for
2. What you need to know before you take Carbagen
3. How to take Carbagen
4. Possible side effects
5. How to store Carbagen
6. Contents of the pack and other information

1. What Carbagen is and what it is used for

Carbagen contains carbamazepine, which belongs to a group of medicines called antiepileptics. Carbagen can be used to treat the following different conditions:

- Some forms of epilepsy.
- Pain in the face caused by trigeminal neuralgia (nerve pain).
- To help control serious mood disorders when some other medicines don't work.

If you are not sure why you are taking this medicine, ask your doctor.

2. What you need to know before you take Carbagen

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

Serious skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis) have been reported with the use of carbamazepine, appearing initially as reddish target-like spots or circular patches 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 potentially life-threatening skin rashes are often preceded by influenza-like symptoms fever, headache, body ache (flu-like symptoms). The rash may progress to widespread blistering or peeling of the skin. The highest risk for occurrence of serious skin reactions is within the first months of treatment.

If you have developed Stevens-Johnson syndrome or toxic epidermal necrolysis with the use of carbamazepine, you must not be re-started on carbamazepine at any time.

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.

Do not take Carbagen:

- if you are allergic to carbamazepine or any of the ingredients of this medicine (see section 6). Signs of a hypersensitivity reaction include swelling of the face or mouth (angioedema), breathing problems, runny nose, skin rash, blistering or peeling
- if you are allergic to similar drugs such as oxcarbazepine or phenytoin or a tricyclic antidepressant (e.g. amitriptyline)
- if you have a heart condition or had a problem with your bone marrow
- if you or a member of your family has the rare blood pigment disorder called porphyria
- if you are already taking medicine to treat a mental illness called a monoamine oxidase inhibitor (MAOI), such as phenelzine (or have taken an MAOI in the last two weeks).

Warnings and precautions

Talk to your doctor or pharmacist before taking Carbagen:

- if you have heart disease
- if you have a history of liver or kidney disease
- if you have kidney problems associated with low sodium blood level or if you have kidney problems and you are taking certain medicines that lower sodium blood levels (diuretics such as hydrochlorothiazide or furosemide)
- if you have glaucoma (increased pressure in the eye)
- if you have a difficulty to retain your urine
- if you have suffered from a mental illness in the past
- if you are elderly
- if you suffer from the sort of epilepsy where you get mixed seizures, which include absences
- if you have blood disorders (including those caused by other drugs) or if you have ever suffered a reaction to any other medicine, which has affected your blood, for example a low white blood cell count (leucopenia)
- if you have had interrupted courses of treatment with carbamazepine.

Your doctor may want to have regular blood and liver tests and in some cases, urine tests, before you start taking Carbagen and from time to time during your treatment. This is quite usual and nothing to worry about.

Children and adolescents

Do not give this medicine to children less than 5 years old.

Other medicines and Carbagen

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines:

- other antiepileptics e.g. lamotrigine, phenytoin, fosphenytoin, primidone, sodium valproate, phenobarbitone, ethosuximide, oxcarbazepine, tiagabine, topiramate, vigabatrin, levetiracetam, progabide, eslicarbazepine
- anticoagulants to thin the blood e.g. warfarin, acenocoumarol, rivaroxaban, dabigatran, apixaban, edoxaban
- cimetidine or omeprazole, to treat heartburn or stomach ulcers
- medicine to treat mental illness e.g. lithium, haloperidol, thioridazine, olanzapine, risperidone, clozapine, quetiapine
- paliperidone or aripiprazole, to treat schizophrenia
- sedatives e.g. clobazam, clonazepam, alprazolam, valnoctamide
- antidepressants e.g. imipramine, fluoxetine, amitriptyline, clomipramine, nortriptyline, mianserin, sertraline, paroxetine, fluvoxamine, citalopram, trazodone
- the herbal remedy St John's wort (*Hypericum perforatum*) should not be taken while taking Carbagen. Consult your doctor before stopping the St John's wort preparation

- metoclopramide or aprepitant, often used to treat sickness
- antibiotics e.g. doxycycline, isoniazid, erythromycin, clarithromycin, ciprofloxacin
- isoniazid, rifampicin (used to treat tuberculosis)
- antifungals e.g. itraconazole, fluconazole, ketoconazole, voriconazole, albendazole
- corticosteroids e.g. prednisolone, dexamethasone
- ciclosporin, tacrolimus or sirolimus, immunosuppressants
- painkillers containing paracetamol, dextropropoxyphene, methadone, tramadol, buprenorphine
- medicine to treat heart conditions e.g. felodipine, isradipine, digoxin, verapamil, diltiazem
- diuretics ('water' tablets) e.g. furosemide, hydrochlorothiazide
- acetazolamide, to treat glaucoma
- muscle relaxants, often used during operations e.g. pancuronium
- isotretinoin, used to treat acne
- theophylline and aminophylline, for asthma
- danazol and gestrinone (used in the treatment of endometriosis)
- hormonal contraceptives e.g. pills, patches, injections or implants; as the effectiveness of these may be reduced and there will be a risk of getting pregnant. Your doctor can advise you about an alternative form of contraception.
- Hormone Replacement Therapy (HRT) e.g. products containing oestrogens and/or progesterones. Carbagen can make HRT less effective
- tadalafil, used to treat erectile dysfunction
- drugs to treat cancer e.g. imatinib, lapatinib, toremifene, cisplatin, doxorubicin, temsirolimus, cyclophosphamide
- drugs to treat HIV known as protease inhibitors (e.g. indinavir, ritonavir, saquinavir)
- levothyroxine to treat hypothyroidism
- the anti-smoking aid, bupropion
- antihistamines to treat allergies and hayfever, such as loratadine
- medicine or supplements containing Vitamin B (nicotinamide).

Carbagen with drink and alcohol

Do not drink alcohol while taking Carbagen as this may increase the chance of side effects. The risk of side effects may also be increased if you eat grapefruit or drink grapefruit juice.

Pregnancy and breast-feeding

If you are planning to become pregnant, talk to your doctor first. If you do get pregnant while taking Carbagen you must tell the doctor straightaway. With all anti-epileptic treatment, there is a risk of harm to the unborn baby, but it is important that your epilepsy remains well controlled. If you are pregnant and need to take an anticonvulsant, you are likely to be taking only one anticonvulsant. Your doctor will monitor you and your unborn child closely. It is important that you fully understand the risks and benefits, to both you and your baby, of taking Carbagen tablets.

Carbamazepine can pass into breast milk. Talk to your doctor before you decide to breast-feed. If you do breast feed and you take Carbagen, tell your doctor straight away if your child becomes very drowsy or suffers from skin reactions or yellow skin and eyes, dark urine or pale stools.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this any medicine.

Driving and operating machines

Carbagen tablets can make you feel dizzy or drowsy especially at the start of treatment or when the dose is changed. If you are affected in this way, or if your eyesight is affected or you have a lack of muscular coordination, you should not drive or operate machinery.

3. How to take Carbagen

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

Your doctor is likely to start treatment with a low dose and slowly increase it to suit your own needs. Ask your doctor or pharmacist if you are unsure about the correct dose but the recommended doses are as follows:

EPILEPSY

Adults: The recommended starting dose is 100 mg to 200 mg of Carbagen once or twice daily. Your doctor will slowly increase this dose to control your fits until the best response is obtained, often 800 to 1200 mg daily in divided doses, although higher doses may be necessary.

Use in children and adolescents: Carbagen tablets should not be given to children under 5 years old. The recommended daily dose for children between 5 and 10 years old is 400 mg to 600 mg of Carbagen, divided up throughout the day. Children over 10 years old may be given a total daily dose of between 600 mg and 1000 mg of Carbagen, divided up throughout the day. Adolescents above the age of 15 years can take the same dose as the adults (800 to 1200 mg).

Your doctor will use another antiepileptic medicine e.g. phenytoin, if Carbagen is withdrawn suddenly.

TRIGEMINAL NEURALGIA

The starting dose is 200 to 400 mg daily (100 mg twice daily in elderly patients). Your doctor may increase the dose until you are free from pain. In the majority of patients a dosage of 200 mg three or four times a day is enough to treat the pain. In some cases, a dose of up to 1600 mg Carbagen daily may be needed. Once the pain goes away (remission), the doctor will slowly reduce your dose of Carbagen. The maximum recommended dose is 1200 mg a day. If possible the doctor may gradually stop your treatment until another attack occurs.

TREATMENT OF MOOD SWINGS

The starting dose is 400 mg of Carbagen daily, divided up throughout the day. This dose may be increased slowly until your symptoms are controlled or until the maximum daily dose of 1600 mg of Carbagen is reached. The usual daily dose range is 400 – 600 mg in divided doses.

Elderly

Elderly patients may be more sensitive to the effects of Carbagen so the doctor may prescribe smaller doses than those stated above.

Method of administration

Swallow the tablet whole, with a glass of water. Do not chew, crush or suck the tablet
Take during, after or between meals.

If you take more Carbagen than you should

If you take more Carbagen than you should, contact your doctor or local hospital emergency department immediately. Take the container and any remaining tablets with you.

If you experience difficulty in breathing, a fast and irregular heartbeat, loss of consciousness, fainting, shakiness, sickness and/or vomiting, your dose may be too high. Stop taking your medicine and inform your doctor without delay.

If you experience retention of urine, fluid retention, water intoxication and reported rhabdomyolysis (striated muscles), stop taking your medicine and inform your doctor without delay.

If you forget to take a dose

If you forget to take a dose take it as soon as you remember unless it is nearly time for your next dose. Do not take double dose to make up for a forgotten dose.

If you stop taking Carbagen suddenly

If you stop taking Carbagen suddenly you may suffer unpleasant side effects. Always ask your doctor first.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Side effects are more common at the start of treatment, but usually disappear after a few days or when the dose is adjusted to be right for you.

Tell your doctor or go to your nearest hospital emergency department immediately if you suffer from the following serious side effects:

Very common: may affect more than 1 in 10 people

- a low white cell count (leucopenia) causing more infections than usual.

Uncommon: may affect up to 1 in 100 people

- severe peeling of the skin which can affect a large area of your body

Rare: may affect up to 1 in 1,000 people

- have difficulty breathing, experience chest pain, wheezing and coughing, a rash, itching, facial swelling or feel faint, all symptoms of a severe allergic reaction
- fever, skin rash, joint pain, and abnormalities in blood and liver function tests (these may be the signs of a multi-organ sensitivity disorder)
- suffer from pain in your joints and muscles, have a rash across the bridge of your nose and cheeks, and have problems breathing (symptoms of the rare reaction, systemic lupus erythematosus)
- experience yellowing of your skin or the whites of your eyes, which may in some cases indicate inflammation of the liver.

Very rare: may affect up to 1 in 10,000 people

- notice any unusual signs of mental illness or confusion
- potentially life-threatening skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis) have been reported (see section 2). Symptoms include worsening of a skin rash, blistering of the lips, eyes or mouth or a severe skin reaction accompanied by fever. These reactions may be more frequent in those of Chinese and Thai origin.
- suffer from a sore throat, high temperature or both
- a sudden increase in body temperature, extremely high blood pressure and severe convulsions (neuroleptic malignant syndrome)
- have severe or persistent pain in the stomach region that spreads to the lower back, often with nausea and vomiting (pancreatitis)
- meningitis (signs and symptoms include fever, feeling sick, being sick, headache, stiff neck, extreme sensitivity to sunlight, twitching of muscles, abnormal blood test results)
- feel feverish or notice unexplained bruising or bleeding of your skin which could show you have anaemia (a change in your blood)
- heart and circulatory problems including a blood clot (thrombosis), which can cause tenderness, swelling, pain chest, shortness of breath; heart failure (symptoms include shortness of breath, swelling of feet or legs due to fluid build-up, getting tired easily after light physical activity)
- blood changes including:
 - decreases in white blood cells (agranulocytosis) causing more infections than usual with symptoms like fever, severe chills, sore throat or mouth ulcers
 - conditions in which red blood cells, white blood cells and platelets are all reduced in number
- liver failure (symptoms include yellowing of your skin or the white of your eyes, dark urine, light coloured bowel motions, nausea, vomiting, and feeling generally unwell)
- severe allergic reactions (signs include wheezing, coughing, difficulty in breathing, feeling faint, rash, itching, swelling of the face, lips, mouth, tongue or throat).

Not known: frequency cannot be estimated from the available data

- severe skin reactions, accompanied by feeling unwell, fever and changes in blood results.

Other side effects that can occur:

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

- feeling dizzy, tired or drowsy
- difficulty controlling movements and feeling unsteady
- feeling or being sick
- skin reactions, including hives (urticaria) which may be severe
- changes in liver enzyme levels (usually without any symptoms).

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

- swollen ankles or lower legs, fluid retention weight gain
- low sodium levels in the blood causing headache, confusion, being sick, lethargy, muscular twitching, convulsions
- double vision, eyesight changes e.g. blurred vision
- dry mouth
- headache
- changes in the blood including an increased tendency to bruise or bleed
- eosinophilia (increase in some white blood cells)
- increase in alkaline phosphatase (an enzyme found in body tissues such as liver and bone).

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

- abnormal movements or uncontrollable muscle spasms involving the arms, legs, eye, head, neck and other parts of the body
- shaking (tremor)
- diarrhoea or constipation
- increased levels of certain enzymes in the body (seen in a blood test).

Rare (may affect up to 1 in 1000 people):

- folic acid deficiency
- increased levels of white blood cells in the body (seen in a blood test), fever
- disease of the lymph glands
- hallucinations (seeing or hearing things that are not there)
- depression or mood changes
- feeling restless, aggressive or agitated
- feeling confused
- numbness or tingling in the hands or feet, weakness of the arms or legs
- muscle weakness, loss of muscle control, speech problems, uncontrolled movements of the face and tongue
- loss of appetite
- raised or low blood pressure
- changes in heart rhythm
- stomach pain
- itching (pruritus).
- upward eye movement; rolling of eyes to right or left

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

- porphyria (a disorder of blood pigment)
- swelling of the breasts, leaking of milk from the breasts, which may occur in both males and females
- softening of the bones, osteoporosis
- abnormal results from thyroid tests
- raised fat levels in the blood
- changes in taste or hearing, ringing in the ears
- 'sticky' eyes (conjunctivitis), cataracts, raised pressure in the eyes
- a racing or slowed heartbeat, feeling faint, collapse

- prominent superficial veins
- difficulty breathing, pneumonia, inflammation of the lungs, fever
- sore mouth or tongue, swollen tongue
- changes in skin pigmentation
- purple or red-brown spots visible through the skin (purpura)
- skin sensitive to light, acne, excessive sweating, hair loss or growth on the body or face
- joint pain, muscle pain or muscle cramp
- kidney problems, difficulty passing urine or passing more urine than usual, blood or protein in the urine
- sexual difficulties including reduced male fertility, loss of sexual desire or drive, inability to get or maintain an erection
- a decreased quantity of immunoglobulins in the blood (hypogammaglobulinaemia) which leads to a lowered immunity and an increase in the number of infections.

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

- There have been reports 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 antiepileptic medication, have a history of osteoporosis, or take steroids.
- abdominal pain and fever (signs of inflammation of the colon)
- reactivation of herpes virus infection
- complete loss of nails
- memory loss
- dizziness, drowsiness, decrease in blood pressure, confusion, due to carbamazepine treatment, this may lead to falls.

Reporting of side effects

If you get any side effects talk to your doctor, pharmacist or nurse. This includes any side effect not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Carbagen

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 foil, carton or bottle after 'EXP'. The expiry date refers to the last day of that month. Store your medicine in a dry place below 25°C.

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 Carbagen contains

There are three strengths of your medicine available. Each tablet contains either 100 mg, 200 mg or 400 mg of the active substance carbamazepine.

The other ingredients are cellulose, microcrystalline; starch, pregelatinised; silica, colloidal anhydrous; talc; magnesium stearate and sodium starch glycollate (Type A).

What Carbagen looks like and contents of the pack

Your medicine comes as a white tablet. On one side, the 100 mg tablet is marked 'CB/100', the 200 mg tablet is marked 'CB/200' and the 400 mg tablet is marked 'CB/400', nothing is marked on the reverse.

Carbagen is available in plastic bottles or foil blisters in packs of 5, 7, 10, 14, 15, 20, 21, 25, 28, 30, 50, 56, 60, 84, 90, 100, 112, 120, 168, 180, 250, 500 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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