

Carbagen[®] 400 mg prolonged- release 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 of pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

Your medicine is available using the above name but will be referred to as Carbagen in this leaflet.

What is in this leaflet

- What Carbagen is and what it is used for
- What you need to know before you take Carbagen
- How to take Carbagen
- Possible side effects
- How to store Carbagen
- Contents of the pack and other information

1. What Carbagen is and what it is used for

Carbagen is specially formulated to release the active ingredient gradually.

Carbamazepine, the active ingredient, can affect the body in several different ways. It is an anticonvulsant medicine (prevents fits), it can also modify some types of pain and can control mood disorders.

Carbagen is used

- to treat some forms of epilepsy
- to treat a painful condition of the face called trigeminal neuralgia
- to help control serious mood disorders when some other medicines don't work.

2. What you need to know before you take Carbagen

A small number of people being treated with antiepileptics 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. 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 carbamazepine.

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.

If you develop a rash or these skin symptoms, stop taking Carbagen, and contact your doctor immediately and tell them that you are taking this medicine.

Do not take Carbagen

- if you are allergic to carbamazepine or similar medicines such as oxcarbazepine, or to any of a related group of medicines known as tricyclic antidepressants (such as amitriptyline or imipramine). If you are allergic to carbamazepine there is a one in four (25%) chance that you could also have an allergic reaction to oxcarbazepine,
- if you are allergic to any of the other ingredients of Carbagen (listed in section 6),
- if you have any heart problems,
- if you have ever had problems with your bone marrow,
- if you have or ever had blood disorders such as acute intermittent porphyria, variegate porphyria or porphyria cutanea tarda,
- if you have taken medicines called monoamine oxidase inhibitors (MAOIs), used to treat depression, within the last 14 days,
- if you are taking voriconazole for a fungal infection,
- if you are taking anything containing St. John's wort,
- if you experience uncoordinated movements, dizziness, drowsiness, sleepiness, confusion, decrease in blood pressure, due to carbamazepine treatment, which may lead to falls.

Warnings and precautions

Talk to your doctor or pharmacist before taking Carbagen

- if you have liver or kidney disease
- if you suffer from glaucoma (increased pressure in the eye). It is important to visit your optician regularly while taking Carbagen
- if you suffer from the sort of epilepsy where you get mixed seizures which include absences (clouding of consciousness)
- if you are elderly
- if you are allergic to an epilepsy medicine called phenytoin
- if you have a condition called hypothyroidism and are taking hormone replacement therapy (HRT)
- if you suffer from urinary retention, an inability to urinate

Avoid strong sunlight or excessive lengths of time in strong sunlight as this may trigger skin reactions.

You may be required to regularly provide blood and/or urine samples before and during treatment to check the levels of carbamazepine in your blood and to identify any problems before they become serious.

There is a risk of harm to the unborn child if Carbagen is used during pregnancy. Women of childbearing age should use effective contraception during treatment with Carbagen and for two weeks after the last dose (see Pregnancy and breast-feeding).

Other medicines and Carbagen

Because of the way that Carbagen works, it can affect, and be affected by lots of other things that you might be eating or medicines you are taking.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including herbal medicines. This is especially important for the following:

- Hormone contraceptives, e.g. pills, patches, injections or implants. Carbagen may affect how hormonal contraceptives work and make them less effective at preventing pregnancy. Talk to your doctor, who will discuss with you the most suitable type of contraception to use while you are taking Carbagen
- Hormone Replacement Therapy (HRT) such as tibolone. Carbagen can make HRT less effective.
- Any medicines for depression or anxiety such as alprazolam, amitriptyline, citalopram, clobazam, clomipramine, desipamine, fluoxetine, fluvoxamine, imipramine, mianserin, midazolam, nefazodone, nortriptyline, paroxetine, sertraline, trazodone or viloxazine.
- Corticosteroids ('steroids') such as dexamethasone or prednisolone. You might be taking these for inflammatory conditions such as asthma, inflammatory bowel disease, muscle and joint pains.
- Anticoagulants to stop your blood clotting such as acenocoumarol, dicoumarol, phenprocoumon, ticlopidine, warfarin, rivaroxaban, dabigatran, apixaban and edoxaban.
- Antibiotics to treat infections including skin infections and TB such as ciprofloxacin, clarithromycin, doxycycline, erythromycin, isoniazid, josamycin, rifampicin, rifabutin or troleandomycin.
- Antifungals to treat fungal infections such as caspofungin, fluconazole, itraconazole, ketoconazole or voriconazole.
- Painkillers containing paracetamol, dextropropoxyphene, fentanyl, ibuprofen, phenazone, propoxyphene, tramadol, methadone or buprenorphine.
- Other medicines to treat epilepsy such as clobazam, clonazepam, felbamate, flunarizine, fosphenytoin, lamotrigine, eslicarbazepine, levetiracetam, methosuximide, oxcarbazepine, phenobarbital, phensuximide, phenytoin, primidone, progabide, stiripentol, tiagabine, topiramate, valproic acid, valpromide, vigabatrin or zonisamide, brivaracetam.
- Medicines for high blood pressure or heart problems such as atorvastatin, cerivastatin, digoxin, diltiazem, felodipine, hydroquinidine, isradipine, ivradipine, propranolol, quinidine, simvastatin or verapamil.
- Antihistamines (medicines to treat allergy such as hayfever, itch, etc) such as loratadine or terfenadine.
- Diuretics (water tablets) such as hydrochlorothiazide or furosemide.
- Cimetidine or omeprazole (medicines to treat gastric ulcers).
- Isotretinoin (a medicine for the treatment of acne).
- Metoclopramide (an anti-sickness medication).
- Lithium (a medicine for bipolar disorder).
- Medicines for sickness or nausea (antiemetics) such as aprepitant.
- Acetazolamide (a medicine to treat glaucoma - increased pressure in the eye).
- Danazol or gestrinone (treatments for endometriosis).
- Theophylline or aminophylline (used in the treatment of asthma).
- Medicines that reduce the activity of the body's natural defences (immunosuppressant) such as ciclosporin (used after transplant operations, but also sometimes in the treatment of arthritis or psoriasis), everolimus, sirolimus or tacolimus.
- Medicines to treat schizophrenia such as aripiprazole, bromperidol, clozapine, haloperidol, loxapine, olanzapine, paliperidone, quetiapine, risperidone or ziprasidone.
- Cancer medicines such as cisplatin cyclophosphamide, doxorubicin, imatinib, lapatinib, procarbazine, temsirolimus or toremifene.
- The antimalarial medicine, mefloquine.
- Medicines to treat HIV such as indinavir, ritonavir or saquinavir.
- Levothyroxine (used to treat hypothyroidism).
- Muscle relaxant medicines such as pancuronium, dantrolene or oxybutynin.
- Bupropion (used to help stop smoking).
- Methylphenidate (used to treat attention-deficit, hyperactivity disorder (ADHD)).
- Medicines or supplements containing Vitamin B (nicotinamide).
- Medicines to treat parasitic worm infections such as albendazole or praziquantel.
- Tadalafil – a medicine used for men with erection problems.

If you are taking medicines for depression, tell your doctor or hospital staff that you are taking carbamazepine if you need to have a blood test to monitor the levels of medicine in your blood.

Carbagen with food, drink and alcohol

Do not take your tablets with grapefruit or grapefruit juice as this may increase the likelihood of side effects from Carbagen. Drinking alcohol may affect you more than usual. You should not drink alcohol during treatment.

Pregnancy, breast-feeding and fertility

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 medicine.

Carbagen can cause major birth defects. If you take Carbagen during pregnancy your baby has up to 3 times the risk of having a birth defect than women not taking an antiepileptic medication. Major birth defects including neural tube defect (opening in the spine), birth defect of the face such as cleft of the upper lip and palate, birth defect of the head, heart defects, birth defect of the penis involving the urinary opening (hypospadias) and finger defects have been reported. Your unborn baby should be closely monitored if you have taken Carbagen while pregnant. Problems with neurodevelopment (development of the brain) have been reported in babies born to mothers who used Carbagen during pregnancy. Some studies have shown that carbamazepine negatively affects neurodevelopment of children exposed to carbamazepine in the womb, while other studies have not found such an effect. The possibility of an effect on neurodevelopment cannot be ruled out.

If you are a woman of childbearing age and are not planning a pregnancy, you should use effective contraception during treatment with Carbagen. Carbagen may affect how hormonal contraceptives, such as the contraceptive (birth control) pill, work and make them less effective at preventing pregnancy. Talk to your doctor, who will discuss with you the most suitable type of contraception to use while you are taking Carbagen. If treatment with Carbagen is discontinued you should continue using effective contraception for two more weeks following discontinuation.

If you are a woman of childbearing age and are planning a pregnancy, talk to your doctor before you stop contraception and before you become pregnant about switching to other suitable treatments in order to avoid exposing the unborn baby to carbamazepine.

If you are or think you might be pregnant, tell your doctor straight away. You should not stop taking your medicine until you have discussed this with your doctor. Stopping your medication without consulting your doctor could cause seizures which could be dangerous to you and your unborn child. Your doctor may decide to change your treatment. If you take Carbagen during pregnancy, your baby is also at risk for bleeding problems right after birth. Your doctor may give you and your baby a medicine to prevent this.

Breast-feeding

Mothers taking Carbagen can breast-feed their babies, but you must tell the doctor as soon as possible if you think that the baby is suffering side effects such as excessive sleepiness or skin reactions because you are taking Carbagen.

Fertility

Taking this medicine may affect male fertility. If you have any questions talk to your doctor.

Driving and using machines

Carbagen may 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 (blurred or double vision), you should not drive or operate machinery.

Carbagen contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

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 will usually start Carbagen at a fairly low dose which can then be increased to suit you individually. The dose needed varies between patients. You may be told to take a dose two or three times a day.

To treat epilepsy the recommended doses are:

Adults:

The recommended starting dose is 100-400 mg a day in one or two doses. The dose may then be increased to 800-1,200 mg a day, in two doses, although higher doses may be necessary. If you are elderly you might require a lower dose.

Use in children and adolescents:

Aged 5-10 years: The recommended starting dose is 200 mg at night (or 100 mg morning and night). The dose may then be increased to 300-600 mg a day in two doses.

Aged 10-15 years: The recommended starting dose is 200 mg at night (or 100 mg morning and night). The dose may then be increased to 500-1,000 mg a day in two doses.

Carbagen is not recommended for children under 5.

To treat trigeminal neuralgia the recommended starting dose is 100-400 mg a day. The dose may be increased to: 600-800 mg a day in two doses, with a maximum dose of 1600 mg.

To treat mood swings the recommended starting dose is 100-400 mg a day. The dose may be increased to: 400-600 mg a day in two doses with a maximum dose of 800 mg.

Method of administration

For oral use.

You can take Carbagen during, after or between meals. **Swallow the tablets whole with a drink. Do not chew them.** If you have difficulty swallowing the tablets you can add them to a glass of water where the tablets will break apart. If you do this you **must** drink all of the mixture **as soon as the tablets have broken apart**. The tablet can be divided into equal doses.

If you take more Carbagen than you should

If you take too many Carbagen immediately tell your doctor or your nearest hospital casualty department. Take the medicine pack with you so that people can see what you have taken. You may feel sick, be sick, constipated, you may be unable to urinate, hallucinate, be confused, have blurred vision, slurred speech, uncontrollable eye movements, dilated pupils, uncontrollable movements such as muscle spasms, loss of coordination, shallow, difficulty or stopping breathing, respiratory, changes to your heart beat or a heart attack.

If you forget to take Carbagen

Take it as soon as you remember unless it is almost time for your next dose. **Do not** take a double dose to make up for a forgotten tablet.

If you stop taking Carbagen

Do not stop taking your tablets suddenly. Speak to your doctor first. If your dose needs to be reduced, this will be done slowly.

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.

Some side effects can be serious

Stop taking Carbagen and tell your doctor straight away if you notice:

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

- an increase in the number of infections you get which may cause fever, severe chills, sore throat, or mouth ulcers (this may indicate you have a low number of white blood cells in your body)

Uncommon (may affect up to 1 in 100 people)

- difficulty breathing, especially with exercise. You may have a dry, hacking cough or wheezing with rapid or irregular heartbeats, swelling to ankles, feet or lower legs, loss of appetite, dizziness, tiredness or confusion (this may indicate your heart isn't working properly)
- fever, skin rash, swollen glands, joint pain, and abnormalities in blood and liver function tests (these may be the signs of a multi-organ sensitivity disorder)
- difficulty thinking, seeing or hearing things that aren't there (hallucinations), increased agitation or false-beliefs (delusions)

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

- tingling, pins and needles sensation, numbness, burning or sharp stabbing pain in your hands and feet, feel physically weak or uncoordinated (this may indicate you have inflammation in or damaged some of the nerves in the body)
- yellowing of your skin or whites of the eyes, dark urine, pale stools, tiredness, fever, nausea, weakness, drowsiness and abdominal pain, with test results showing abnormal liver function (these may indicate you have problems with your liver or a blockage in the bile duct)
- pain in your joints and muscles, a rash across the bridge of the nose and cheeks and problems with breathing (these may be the signs of a rare reaction known as systemic lupus erythematosus)
- inability to completely empty your bladder. You may have a poor urinary stream with an interrupted flow, be straining to urinate with a delay in trying to urinate and urinating (these signs indicate you may have a condition called urinary retention)

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

- tiredness, shortness of breath, cold hands or feet or pale skin, difficulty in healing after a cut or unexplained bruising or bleeding (this may indicate you have a low number of red blood cells or platelets in your body)
- wheezing and coughing, difficulty in breathing, feeling faint, rash, itching or swelling in the face, lips, tongue or throat (these may be the signs of a severe allergic reaction)
- severe abdominal pain, red urine, severe constipation or hallucinations (these are signs that you have a condition called porphyria). Your skin may also become fragile and blister when exposed to light
- shortness of breath, difficulty swallowing or difficulty walking. You may shake or have uncontrollable movements (this may indicate you have a condition called neuroleptic malignant syndrome)
- sensitivity to light, stiff neck, body aches, sore throat, severe headache, flu-like symptoms (these may indicate you have a type of meningitis that can't be passed on to others)
- circulatory problems such as cold hands and feet, prominent veins in the neck, rapid shallow breathing or weak, irregular heart beat
- Serious skin reactions such as rash, red skin, blistering and bleeding of the lips, eyes or mouth, or skin peeling accompanied by fever have been reported (these may indicate Stevens-Johnson syndrome or toxic epidermal necrolysis – see section 2). These reactions may be more frequent in patients of Chinese or Thai origin
- severe pain in the area near the stomach that spreads to the back (this may indicate you have problems with your pancreas)
- producing little or no urine, pain or difficulty when passing urine, cloudy or dark urine, blood in the urine or lower back pain (these may indicate serious problems with your kidneys)
- increase in eye pressure (this is known as glaucoma)
- lung or breathing problems with fever, coughing which may produce phlegm or blood, or chills

Not known (cannot be estimated from the available data)

- infection caused by human herpes virus 6
- falls (due to uncoordinated movements, dizziness, drowsiness, sleepiness, confusion, decrease in blood pressure)
- high levels of ammonia in the blood (hyperammonaemia). The symptoms of hyperammonaemia may include irritability, confusion, vomiting, loss of appetite, and sleepiness.

Other side effects include:

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

- Dizziness, tiredness or drowsiness
- feeling unsteady or finding it difficult to control movements
- feeling or being sick
- changes in liver enzyme levels (usually without any symptoms)
- skin reactions, with or without fever, for example a red itchy rash (known as hives) which may be severe

Common (may affect up to 1 in 10 people)

- fluid retention and swelling
- weight increase
- low sodium or other salts (electrolytes) in the blood that might result in confusion or behavioural changes.
- headache
- double or blurred vision, problems with your eye
- dry mouth, loss of appetite

Uncommon (may affect up to 1 in 100 people)

- fever, skin rash, swollen glands, joint pain, and abnormalities in blood and liver function tests (these may be the signs of a multi-organ sensitivity disorder)
- confusion, agitation (these may occur especially in the elderly)
- feeling sad or low (also known as depression)
- aggression
- abnormal involuntary movements including tremor, spasms, or tics
- lack of drive or motivation
- abnormal eye movements
- ringing in the ear (also known as tinnitus)
- irregular or slow heartbeat, you may faint
- chest pain, a thumping sensation in your chest together with breathlessness
- diarrhoea, constipation
- itchy skin, scaly or flaky skin, areas of redness which may be sore and tender due to inflammation of blood vessels
- hair loss
- excessive sweating
- increase in urea or nitrogen containing compounds in the blood

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

- lumps on the neck or armpit (may be signs of a disease of the lymph glands)
- sore mouth or dark skin (may be signs of a lack of folic acid in the body)
- restlessness
- over-excitabile moods with uninhibited behaviour
- involuntary movements of the face (such as a grimace) or twisting or writhing movements of the body
- speech problems
- muscle weakness causing loss of movement
- swelling of the breasts and discharge of milk which may occur in both males and females
- cloudy vision
- high blood pressure (which may make you feel dizzy, with flushed face, headache, fatigue and nervousness)
- low blood pressure (the signs of which are feeling faint, light headed, dizzy, confused, having blurred vision)
- stomach pain
- increased or decreased desire to pass urine

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

- unable to eat a large meal or feeling full without eating, discomfort, fullness or pain in the upper left side of the stomach. You may also be tired, have weight loss or bleed easily. These are signs you may have an enlarged spleen
- persistent fear of (and desire to avoid) a particular object or situation (phobias)
- abnormal thyroid function tests
- osteomalacia (which may be noticed as pain on walking and bowing of the long bones in the legs)
- brittle bones (known as osteoporosis)
- increased blood fat levels, increased blood cortisol or prolactin levels in the blood
- taste disturbances
- itchy, watery, sore eyes with crusty eyelids (known as conjunctivitis)
- hearing disorders such as pitch changes in sound, loss of hearing or increased sensitivity to sound
- swelling or redness along a vein which is painful or tender to touch or skin discoloration and prominent superficial veins (may be signs of circulatory problems such as a blood clot)
- inflammation or swelling of the stomach, mouth (gums) or tongue
- increased sensitivity of the skin to sunlight
- changes in skin colour
- acne
- increased hair growth on the body and face
- purple or brown spots on the skin
- pain in the joints or muscles
- sexual difficulties which may include reduced male fertility such as abnormal sperm
- loss of libido or impotence

Not known (cannot be estimated from the available data)

- problems with your memory
- diarrhoea which may contain mucus or blood. You may have stomach pain or a fever
- single small skin lesion
- shedding of finger and toe nails
- broken bones

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.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: 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 carton after EXP. The expiry date refers to the last day of that month. This medicine has no special storage requirements.

If your medicine shows any sign of deterioration or discolouration, you should seek the advice of your pharmacist who will tell you what to do.

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

- The active substance is carbamazepine.
- Each prolonged-release tablet contains 400mg of carbamazepine.
- The other ingredients are ammonio methacrylate copolymer type B (contains sorbic acid and sodium hydroxide), methacrylic acid-ethyl acrylate copolymer (contains sodium laurilsulfate and polysorbate), triacetin, talc, microcrystalline cellulose, crospovidone, colloidal anhydrous silica and magnesium stearate.

What Carbagen looks like and contents of the pack

The tablets are white or yellowish, round, flat, cloverleaf shaped tablets with double-sided cross break-mark and four notches on the band. Carbagen is available in blister packs of 30 and 60 prolonged-release tablets.

Manufacturer and Product Licence Holder

Manufactured by Mylan Hungary Kft, H-2900, Komarom, Mylan utca 1, Hungary.

Procured from within the EU by Product Licence holder: Star Pharmaceuticals Ltd, 5 Sandridge Close, Harrow, Middlesex HA1 1XD. Repackaged by Servipharm Ltd.

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