

Package leaflet: Information for the patient

Carbamazepine SUN 100 mg/5 ml Oral Suspension

carbamazepine

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

- Keep this leaflet. You may need to read it again.
- If you have further questions, please 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

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1. What Carbamazepine SUN is and what it is used for

Carbamazepine SUN is a pale orange suspension that contains carbamazepine, the active ingredient. Carbamazepine SUN is an anti-convulsant medicine (prevents fits), it can also modify some types of pain and can control mood disorders.

Carbamazepine SUN 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 Carbamazepine SUN

Do not take Carbamazepine SUN

- if you are allergic to carbamazepine or similar drugs such as oxcarbazepine (Trileptal), or to any of a related group of drugs known as tricyclic antidepressants (such as amitriptyline or imipramine) or any of the other ingredients of this medicine (listed in section 6). 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 have any heart problems
- if you have ever had problems with your bone marrow
- if you have a blood disorder called porphyria (an inherited enzyme disorder)
- if you have taken drugs called monoamine oxidase inhibitors (MAOIs), used to treat depression, within the last 14 days.

Warnings and precautions

Talk to your doctor or pharmacist before taking Carbamazepine SUN if

- you suffer from the sort of epilepsy where you get mixed seizures which include absences
- you have any mental illness

- you are allergic to phenytoin (another epilepsy medicine)
- you have liver problems
- you have kidney problems associated with low sodium blood level or do you have kidney problems and you are taking certain medicines that lower sodium blood levels (diuretics such as hydrochlorothiazide, furosemide)
- you are elderly
- you have eye problems such as glaucoma (increased pressure in the eye)
- you have difficulty retaining urine

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. 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 develop a rash or these skin symptoms, stop taking carbamazepine and contact your doctor immediately.

Other medicines and Carbamazepine SUN

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

Taking some medicines together can be harmful. Remember that the doctor at the hospital may not have been informed if you have recently begun a course of treatment for another illness. In particular tell your doctor if you are taking

- hormone contraceptives, e.g. pills, patches, injections or implants. Carbamazepine affects the way contraceptive works in your body, and you may get breakthrough bleeding or spotting. It may also make the contraceptive less effective and there will be a risk of getting pregnant. Your doctor will be able to advise you about this, and you should think about using other contraceptives
- Hormone Replacement Therapy such as tibolone. Carbamazepine can make HRT less effective
- drugs to treat depression or anxiety, such as lithium, alprazolam, viloxazine, fluoxetine, desipramine, fluvoxamine
- medicines to treat mental illness (including schizophrenia), e.g. clozapine, olanzapine, risperidone, haloperidol, thioridazine, paliperidone or aripiprazole
- corticosteroids ('steroids'). 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 warfarin
- antibiotics and medicines to treat TB (tuberculosis) such as doxycycline, rifampicin, erythromycin, clarithromycin, or isoniazid
- antifungals to treat fungal infections such as itraconazole, fluconazole, ketoconazole or voriconazole
- painkillers containing paracetamol, dextropropoxyphene, tramadol, methadone or buprenorphine
- other antiepileptics such as clobazam, clonazepam, phenytoin, phenobarbitone, primidone, tiagabine, lamotrigine, topiramate, ethosuximide, valproic acid, felbamate or oxcarbazepine
- medicines to treat blood pressure or heart problems, such as digoxin, felodipine, nifedipine, nilvadipine, verapamil or diltiazem
- antihistamines (medicines to treat allergies) such as loratadine or terfenadine
- diuretics ('water' tablets) e.g. furosemide, hydrochlorothiazide
- cimetidine or omeprazole (medicines to treat gastric ulcers)
- isotretinoin (medicine for the treatment of acne)
- aprepitant or metoclopramide (medicines often used to treat sickness)
- acetazolamide (medicine to treat glaucoma – increased pressure in the eye)
- danazol or gestrinone (medicines for the treatment of endometriosis)

- theophylline or aminophylline (medicines for the treatment of asthma)
- cyclosporin, tacrolimus or sirolimus (immunosuppressants, medicines used after transplant operations, but also sometimes in the treatment of arthritis or psoriasis)
- medicines to treat cancer such as toremifene, cisplatin or doxorubicin
- anti-malaria medicine mefloquine (medicine used to treat malaria)
- medicines to treat HIV known as protease inhibitors such as indinavir, saquinavir or ritonavir
- thyroxine (medicine used to treat hypothyroidism)
- tadalafil (medicine used to treat impotence)
- albendazole (medicine used to treat worms)
- bupropion (medicine used to help stop smoking)
- a herbal remedy St. John's wort (*Hypericum perforatum*)
- medicines or supplements containing vitamin B such as nicotinamide.

Carbamazepine with food, drink and alcohol

Drinking alcohol may affect you more than usual. Discuss with your doctor whether you should stop drinking.

Eating grapefruit, or drinking grapefruit juice, may increase your chance of experiencing side effects. You can take Carbamazepine SUN during, after or between meals.

Pregnancy and breast-feeding

You must discuss your epilepsy treatment with your doctor well before you become pregnant. If you do get pregnant while you are taking Carbamazepine SUN you must tell the doctor straightaway. It is important that your epilepsy remains well controlled, but, as with other anti-epilepsy treatments, there is a risk of harm to the foetus. Make sure you are very clear about the risks and the benefits of taking Carbamazepine SUN.

If you are taking Carbamazepine SUN you can breast-feed your 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, skin reaction or yellow skin and eyes, dark urine or pale stools.

Driving and using machines

Carbamazepine SUN can make you feel dizzy or drowsy, or may cause blurred vision, double vision, or you may have a lack of muscular coordination, 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, you should not drive or operate machinery.

Carbamazepine SUN contains sorbitol (E420), potassium sorbate and orange yellow S

This medicine contains:

- sorbitol (E420). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.
- potassium sorbate. Each 5 ml of suspension contains less than 1 mmol (39 mg) of potassium, i.e. essentially "potassium free".
- orange yellow S, which may cause allergic reactions.

3. How to take Carbamazepine SUN

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

The recommended dose is:

Epilepsy

- Adults: The usual dose is 800-1,200 mg a day, although higher doses may be necessary
- Elderly: You might need a lower dose.
- Children aged up to and over 1 year: usually 10-20 mg/kg body weight daily in several divided doses. Your doctor will tell you how much liquid the child should take.

Trigeminal neuralgia

The usual dose is 600-800 mg a day. The maximum dose is 1,200 mg a day. If you are elderly you might require a lower dose. Once the pain is controlled, your doctor will probably reduce the dose.

Mood swings

The usual dose is 400-600 mg a day.

Method of administration

Your doctor will usually start Carbamazepine SUN at a fairly low dose which can then be increased to suit you individually. The dose needed varies between patients. Shake the bottle before you measure out your dose. You are usually told to take a dose two or three times a day. Carbamazepine SUN is given orally, either before, during or between meals.

If you take more Carbamazepine SUN than you should

If you accidentally take too much Carbamazepine SUN, tell your doctor or your nearest hospital casualty department. Take your medicine pack with you so that people can see what you have taken.

If you forget to take Carbamazepine SUN

If you forget to take a dose, take one as soon as you remember. Do not take a double dose to make up for a forgotten dose.

If you stop taking Carbamazepine SUN

Do not stop taking your medicine suddenly, as this may result in you having a seizure. Only stop taking your medicine if your doctor tells you to do so.

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.

Serious side effects

If you develop any of the following side effects, stop taking Carbamazepine SUN and contact your doctor immediately

- serious skin reactions such as rash, red skin, blistering of the lips, eyes or mouth, or skin peeling accompanied by fever. These reactions may be more frequent in patients of Chinese or Thai origin.
- changes in the blood, including unexplained bleeding or bruising, or making it easier to catch infections with mouth ulcers, sore throat, or high temperature
- liver problems or failure, including jaundice with yellowing of your skin or the whites of your eyes
- swollen ankles, feet or lower legs
- any signs of nervous illness or confusion
- 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 lupus erythematosus)
- fever, skin rash, joint pain, and abnormalities in blood and liver function tests (these may be the signs of a multi-organ sensitivity disorder)
- bronchospasm with wheezing and coughing, difficulty in breathing, feeling faint, rash, itching or facial swelling (these may be the signs of a severe allergic reaction)
- pain in the area near the stomach
- severe skin reactions, accompanied by feeling unwell and changes in blood results
- reactivation of herpes virus infection (can be serious when immune system is depressed).

The following side effects have also been reported

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

- dizziness

- drowsiness
- tiredness
- feeling unsteady or finding it difficult to control movements
- feeling or being sick
- changes in liver enzyme levels (usually without any symptoms)
- skin reactions, including urticaria (hives), which may be severe.

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

- fluid retention and swelling
- weight increase
- low sodium in the blood which might result in confusion
- headache
- double or blurred vision
- dry mouth.

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

- abnormal involuntary movements including tremor or tics
- abnormal eye movements
- diarrhoea
- constipation.

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

- disease of the lymph glands
- folic acid deficiency (can be detected with a blood test by your doctor)
- hallucinations
- depression
- loss of appetite
- restlessness
- aggression
- agitation
- confusion
- speech disorders
- numbness or tingling in the hands and feet
- muscle weakness
- high blood pressure (which may make you feel dizzy, with a flushed face, headache, fatigue and nervousness)
- low blood pressure (the symptoms of which are feeling faint, light headed, dizzy, confused, having blurred vision)
- changes in heart beat
- stomach pain.

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

- changes to the composition of the blood including anaemia
- porphyria
- meningitis (inflammation of the brain lining)
- swelling of the breasts and discharge of milk which may occur in both male and females
- abnormal thyroid function tests
- osteomalacia (which may be noticed as pain on walking and bowing of the long bones in the legs)
- osteoporosis (brittle bones)
- increased blood fat levels
- taste disturbances
- conjunctivitis (red eyes)
- glaucoma (increased pressure in the eyes)
- cataracts
- hearing disorders

- heart and circulatory problems including deep vein thrombosis (DVT), the symptoms of which could include tenderness, pain, swelling, warmth, skin discoloration and prominent superficial veins
- sore mouth or tongue
- increased sensitivity of the skin to sunlight
- changes in skin colour (alteration in skin pigments)
- acne
- excessive sweating
- hair loss
- increased hair growth on the body and face
- muscle pain or spasm
- sexual difficulties which may include reduced male fertility
- loss of libido or impotence
- kidney failure
- blood spots in the urine
- increased or decreased desire to pass urine or difficulty in passing urine.

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

- diarrhoea, abdominal pain and fever (signs of inflammation of the colon)
- complete loss of nails
- fracture
- decrease in the measure of the bone density
- memory loss
- purple or reddish-purple bumps that may be itchy.

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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Carbamazepine SUN

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

Store below 25°C. Keep the bottle tightly closed between doses.

Do not use this medicine after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

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 Carbamazepine SUN contains

- The active substance is carbamazepine. 5ml of suspension contains 100 mg of carbamazepine.
- The other ingredients are: poloxamer 188, sucralose, xanthan gum, potassium sorbate, propylene glycol, citric acid monohydrate, orange yellow S, sorbitol (E420), natural and artificial flavour orange and water, purified.

What Carbamazepine SUN looks like and content of the pack

Bottles with a child resistant plastic cap.
Pack sizes: 300 ml and 500 ml.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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Polarisavenue 87
2132 JH Hoofddorp
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