

CARBAMAZEPINE SANDOZ®

Carbamazepine tablets

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Carbamazepine Sandoz.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the final page. More recent information on the medicine may be available.

You should ensure that you speak to your pharmacist or doctor to obtain the most up to date information on the medicine. You can also download the most up to date leaflet from www.novartis.com.au

Those updates may contain important information about the medicine and its use of which you should be aware.

All medicines have risks and benefits. Your doctor has weighed the risks of you or your child taking this medicine against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Carbamazepine Sandoz is used for

Carbamazepine Sandoz has several uses:

- to control epilepsy, a condition in which there are repeated seizures (fits). There are many different types of seizures, ranging from mild to severe
- to control sudden, repeated attacks of facial pain, known as trigeminal neuralgia
- to control mania, a mental condition with episodes of overactivity, elation or irritability
- to control bipolar mood disorder where periods of mania alternate with periods of depression.

Carbamazepine Sandoz belongs to a group of medicines called anticonvulsants. These medicines are thought to work by regulating the way messages in the brain are passed on by nerves so that seizures do not happen. This medicine also regulates other nerve functions in the body.

Carbamazepine Sandoz may be used alone or in combination with other medicines to treat your condition.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is available only with a doctor's prescription. There is no evidence that his medicine is addictive.

Before you take Carbamazepine Sandoz

When you must not take it

Do not take this medicine if you have an allergy to:

- carbamazepine, the active ingredient, or any of the other ingredients listed at the end of this leaflet
- any other medicine containing carbamazepine
- tricyclic antidepressants, which are medicines used to treat depression.

Tell your doctor if you are allergic to oxcarbazepine or to phenytoin. These two medicines are also used to treat epilepsy.

Some people who are allergic to oxcarbazepine or phenytoin are also allergic to carbamazepine.

Some of the symptoms of an allergic reaction may include:

- shortness of breath

- wheezing or difficulty breathing
- swelling of the face, lips, eyelids, throat, mouth, tongue or other parts of the body
- rash, itching or hives on the skin.

Do not take this medicine if you are taking a medicine called a monoamine oxidase inhibitor (MAOI) or have been taking it within the past 14 days.

Taking this medicine with a MAOI, or within 14 days of taking a MAOI, may cause a serious reaction with a sudden increase in body temperature, extremely high blood pressure and severe convulsions.

Do not take this medicine if you have or have had any of the following medical conditions:

- severe liver or heart disease
- a disease of the blood with a reduced number of red or white blood cells or platelets (risk of bone marrow depression)
- an irregular heartbeat caused by a condition called A-V block
- systemic lupus erythematosus, also called SLE
- hepatic porphyria, a disturbance in the production of porphyrin, a pigment important for liver function and blood formation.

- baby is less than 4 weeks of age

If you are not sure whether any of the above conditions apply to you, ask your doctor.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

In that case, return it to your pharmacist.

If you are not sure whether you should start taking this medicine, talk to your doctor or pharmacist.

Before you start to take it

Tell your doctor if you are allergic to any other medicines, foods, preservatives or dyes.

Your doctor will want to know if you are prone to allergies.

Tell your doctor if you have or have had any medical conditions, especially the following:

- heart problems
- glaucoma
- prostate problems or if you cannot retain your urine
- liver or kidney problems

- problems with your blood in the past that were caused by medicines you were taking
- a mental disorder such as depression or schizophrenia.

Tell your doctor if you are of Asian descent, particularly if you are Chinese or Thai.

Your doctor may want to do a genetic test before you take this medicine for the first time.

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 Carbamazepine Sandoz.

Tell your doctor if you are pregnant or intend to become pregnant.

There is a possible risk of physical birth abnormalities to your baby if you take this medicine during pregnancy.

You may need to change your medication. Your doctor will discuss with you the potential risk of taking Carbamazepine Sandoz during pregnancy since it may cause harm or abnormalities in your baby during pregnancy and soon after birth. Risk of neurodevelopmental disorders (how the brain functions leading to difficulties in social, emotional and mental function) cannot be excluded among children born to women with epilepsy treated with carbamazepine alone or in combination with other antiepileptic drugs during pregnancy.

But, if you have epilepsy, it is very important to control your fits while you are pregnant. Your doctor can help you decide whether or not you should take Carbamazepine Sandoz in this case.

Tell your doctor if you are breastfeeding or plan to breastfeed.

This medicine passes into breast milk but it is unlikely to affect your baby. With the advice of your doctor you may breastfeed provided that you watch your baby for any signs of an unwanted side effect. If your baby develops a skin rash, becomes very sleepy or has other unusual symptoms, do not breastfeed again until you speak to your doctor.

If you have not told your doctor about any of the above, tell him/her before you start taking Carbamazepine Sandoz.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines and Carbamazepine Sandoz may interfere with each other. These include:

- MAOI medicines. This medicine must not be taken together with a MAOI or within 14 days of taking a MAOI.

- other medicines used to treat depression such as fluvoxamine, nefazodone, paroxetine, bupropion, citalopram, tricyclic antidepressants and trazodone
- other medicines used to treat seizures including oxcarbazepine, levetiracetam, valproic acid, brivaracetam, lamotrigine, topiramate and phenytoin
- some medicines used to treat mental disorders such as clozapine, haloperidol, thioridazine, lithium, olanzapine, risperidone, quetiapine and ziprasidone
- some medicines used to treat heart problems or high cholesterol
- some medicines used to help you sleep or calm you down
- some pain relievers such as paracetamol, dextro-propoxyphene, tramadol and ibuprofen
- warfarin, a medicine used to prevent blood clots
- some diuretics (fluid tablets), which are medicines used to reduce water retention and high blood pressure
- some antibiotics and antifungal medicines used to treat infections, such as erythromycin, clarithromycin, doxycycline, itraconazole, ketoconazole, fluconazole, voriconazole and rifampicin
- corticosteroids such as prednisolone and dexamethasone

- St John's wort, an ingredient in many medicines that you can buy without a prescription from a pharmacy, health food shop or supermarket
- antihistamines such as loratadine and terfenadine, which are medicines used to prevent or relieve the symptoms of allergies such as hay fever
- isoniazid, a medicine used to prevent and treat tuberculosis
- acetazolamide, a medicine used to reduce fluid retention and to treat glaucoma and some types of seizures
- cimetidine and omeprazole, medicines used to treat stomach or duodenal ulcers
- ticlopidine, a medicine used to prevent blood clotting
- theophylline and aminophylline, medicines used to treat asthma
- some medicines used to prevent rejection of organ transplants and to treat severe rheumatoid arthritis and some skin diseases, such as cyclosporin and everolimus
- some medicines used to treat cancer, such as cisplatin, doxorubicin and imatinib
- methadone, a medicine used to control severe pain and to treat heroin addiction
- metoclopramide, a medicine used to treat nausea and vomiting

- isotretinoin, a medicine used to treat acne
- danazol, a medicine used to treat endometriosis
- a vitamin called nicotinamide
- muscle relaxants such as dantrolene and oxybutynin
- medicines used to treat HIV such as indinavir, ritonavir and saquinavir
- levothyroxine, a medicine used to treat underactive thyroids
- praziquantel, a medicine used to treat worm infections of the blood
- medicines containing oestrogen and progesterone, including hormone replacement therapy and hormonal contraceptives.

The above medicines may be affected by Carbamazepine Sandoz or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Tell your doctor if you are using hormonal contraceptives (e.g. birth control pills or injections).

If you begin taking this medicine while you are using hormonal contraceptives, they may not work as well as they should.

Unplanned pregnancies can happen. Your doctor can suggest another form of birth control (non-hormonal) while you are taking Carbamazepine Sandoz.

Tell your doctor immediately if you notice irregular vaginal bleeding or spotting.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take Carbamazepine Sandoz

Follow all directions given to you by your doctor or pharmacist carefully.

These directions may differ from the information contained in this leaflet.

If you do not understand the instructions, ask your doctor or pharmacist for help.

How much to take

Your doctor will tell you how much Carbamazepine Sandoz you need to take each day. This may depend on your age, your medical condition and whether or not you are taking other medicines.

Your doctor will usually start your treatment with a low dose and then slowly increase it to the lowest amount needed to

control your condition. Some people will need higher doses than other people will.

How to take it

Swallow the tablets with a full glass of water.

When to take it

Take your medicine during or after a meal.

This helps to prevent stomach upset.

Carbamazepine Sandoz is usually taken in 2 or 3 doses during the day. But your doctor may tell you to take it more or less often, depending on your situation.

If you forget to take it

If your next dose is not due for more than 2 or 3 hours, take the missed dose as soon as you remember. Then take your next dose at the usual time and continue on with your normal schedule.

If your next dose is due within 2 or 3 hours, skip the missed dose. Take your next dose at the usual time and continue on with your normal schedule.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

Do not stop taking Carbamazepine Sandoz or lower the dose without first checking with your doctor. Do not let yourself run out of medicine over the weekend or on holidays.

Stopping your medicine suddenly or lowering the dose may cause unwanted side effects or make your condition worse. If you are taking this medicine to treat epilepsy, you could develop seizures (fits). Your doctor will usually reduce the dose slowly before you can stop taking it completely.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much

Carbamazepine Sandoz. Do this even if there are no signs of discomfort or poisoning.

Keep the telephone numbers for these places handy.

Some of the symptoms of an overdose may include agitation, disorientation, fainting, vomiting, difficulty breathing, fast and irregular heartbeat, blurred vision, shakiness and slurred speech. If you are taking the controlled release (CR) tablets, it may take longer for you to notice these effects.

While you are taking Carbamazepine Sandoz

Things you must do

If you become pregnant while taking this medicine, tell your doctor immediately.

Your doctor can discuss with you the risks of taking it while you are pregnant.

Be sure to keep all of your doctor's appointments so that your progress can be checked.

To help prevent unwanted side effects from happening, your doctor may want to do some tests before you start taking Carbamazepine Sandoz and from time to time during the course of your treatment.

Contact your doctor immediately if at any time you have thoughts of harming or killing yourself.

A number of people being treated with antiepileptics have had such thoughts or behaviour.

Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed.

Otherwise your doctor may think that it was not effective and change your treatment unnecessarily.

Before having any surgery or emergency treatment, tell the doctor or dentist in charge that you are taking this medicine.

This medicine may interfere with some of the medicines used during surgery.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Carbamazepine Sandoz.

Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.

Things you must not do

Do not stop taking your medicine or lower the dosage without checking with your doctor.

Do not use Carbamazepine Sandoz to treat any other complaints unless your doctor tells you to.

Do not give this medicine to anyone else, even if their symptoms seem similar to yours or they have the same condition as you do.

Things to be careful of

Avoid drinking grapefruit juice while you are being treated with this medicine.

Grapefruit juice may interact with Carbamazepine Sandoz and affect how your body uses this medicine.

Be careful driving or operating machinery until you know how Carbamazepine Sandoz affects you. Children should be careful when riding bicycles or climbing trees.

This medicine may cause dizziness, drowsiness, blurred vision, double vision or lack of muscle coordination in some people, especially when you first start to use it or when the dose is increased.

Be careful when drinking alcohol while you are taking this medicine.

The combination could make you more sleepy, dizzy or light-headed than usual. Your doctor may suggest you avoid alcohol while you are being treated with Carbamazepine Sandoz.

When outdoors, wear protective clothing and use at least a 15+ sunscreen. Do not use a sunlamp or tanning bed or booth.

This medicine may cause your skin to be much more sensitive to sunlight than it normally is. Exposure to sunlight may cause a skin rash, itching, redness or severe sunburn. If your skin does appear to be burning, tell your doctor.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Carbamazepine Sandoz.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

If you are over 65 years of age you may have an increased chance of getting side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- dizziness or light-headedness
- tiredness or drowsiness
- eye pain

- weakness, unsteadiness when walking
- headache
- restlessness, agitation or confusion
- difficulty in speaking or slurred speech
- numbness or tingling in hands or feet
- muscle pain or cramps
- nausea (feeling sick) or vomiting, loss of appetite
- weight gain
- stomach pain or discomfort
- diarrhoea
- constipation
- dry mouth
- swollen, red, sore tongue
- mouth ulcers or cold sores
- change in sense of taste
- blurred or double vision, swollen runny eyes, difficulty seeing
- ringing or buzzing in the ears or other changes in hearing

- frequent need to urinate (pass water)
- sweating
- hair loss
- acne
- change in skin colour
- excessive hairiness, especially in women
- sexual disturbances such as impotence
- breast enlargement in men
- unusual secretion of breast milk
- loss of muscle coordination.

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- signs of allergy such as swelling of the face, lips, tongue, eyelids, throat, mouth or other parts of the body; wheezing or troubled breathing; difficulty swallowing, itching, hives, chest discomfort or tightness, loss of consciousness
- skin rash, redness, blisters or peeling skin, accompanied by fever, chills, headache, cough, body aches

- sudden increase in body temperature, accompanied by sweating, fast heart beat and muscle stiffness, altered consciousness, high blood pressure, excessive salivation
- constant "flu-like" symptoms (chills, fever, sore throat, swollen glands, aching joints, lack of energy)
- unusual bleeding or bruising under the skin, nosebleeds
- shortness of breath and dizziness when exercising
- frequent infections or fever
- severe chills, sore throat, swollen glands or mouth ulcers
- persistent nausea or vomiting, loss of appetite and feeling generally unwell, which may be accompanied by pain in the abdomen, fever, itching, a yellow colour to skin or eyes, dark coloured urine or light coloured bowel motions
- diarrhoea, abdominal pain and fever
- severe upper stomach pain, often with loss of appetite and vomiting
- more frequent or more severe seizures (fits)
- sudden onset of uncontrollable muscle spasms affecting the eyes, head, neck and body
- trembling, uncontrolled body movements
- lethargy, confusion

- depression, aggressive behaviour, recurrence of a previous mental illness, hallucinations (seeing or hearing things that are not there)
- swelling of the feet and legs or weight increase due to fluid build-up
- change in behaviour, weakness
- change in heartbeat (fast, slow, irregular), sometimes with fainting or chest pain
- passing less urine than normal which may be accompanied by lack of energy, vomiting, headache and confusion
- blood in the urine
- symptoms of sunburn such as redness, itching, swelling or blistering that may happen more quickly than normal
- red blotchy rash mainly on the face which may be accompanied by fatigue, fever, nausea, loss of appetite
- swelling and redness along a vein or nerve, which is extremely tender when touched
- signs that blood clots may have formed, such as sudden severe headache, sudden loss of coordination or vision, pain in the calves, thighs or chest
- severe headache accompanied by stiff neck, muscle spasms and extreme sensitivity to bright light

- a fall due to dizziness, drowsiness, decrease in blood pressure or confusion.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

Other side effects not listed above may also occur in some people. Some of these side effects (for example, changes in sodium levels, thyroid function, structure of bones, cholesterol level or blood pressure) can only be found when your doctor does tests from time to time to check your progress.

After taking Carbamazepine Sandoz

Storage

- Keep your medicine in the original container until it is time to take it.
- Store the medicine in a cool dry place.
- Do not store Carbamazepine Sandoz or any other medicine in the bathroom or near a sink.
- Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.
Carbamazepine Sandoz will keep well if it is cool and dry.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

Carbamazepine Sandoz comes in two types of tablets:

Carbamazepine Sandoz 100mg - White round flat tablets with bevelled edges. One side bears the imprint "GEIGY", the other "B/W" and a score.

Carbamazepine Sandoz 200mg - White round flat tablets with bevelled edges. One side bears the imprint "CG", the other "G/K" and a score.

Available in blisters of 100 tablets.

Ingredients

Active ingredients:

- Carbamazepine Sandoz 100mg - 100mg carbamazepine
- Carbamazepine Sandoz 200mg - 200mg carbamazepine.

Inactive ingredients:

- cellulose-microcrystalline

- carmellose sodium
- silica-colloidal anhydrous
- magnesium stearate.

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Sponsor

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This leaflet was revised in

January 2025.

Australian Register Number(s)

100mg tablets: AUST R 78217 (blisters)

200mg tablets: AUST R 78211 (blisters)

Internal code:

(car090125c) based on PI (car090125i)