Package Leaflet: Information for the patient

Carbamazepine Essential Pharma 125 and 250 mg Suppositories

Read all of this leaflet carefully before you start to use 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 Carbamazepine Essential Pharma Suppositories are and what they are used for
2. What you need to know before you use Carbamazepine Essential Pharma Suppositories
3. How to use Carbamazepine Essential Pharma Suppositories
4. Possible side effects
5. How to store Carbamazepine Essential Pharma Suppositories
6. Contents of the pack and other information

1. What Carbamazepine Essential Pharma Suppositories are and what they are used for

Carbamazepine, the active ingredient in Carbamazepine Essential Pharma Suppositories, is an anti-convulsant medicine (prevents fits).

Carbamazepine Essential Pharma Suppositories are used to treat some forms of epilepsy. They are useful in the short term, (maximum 7 days), for patients who cannot take medicines by mouth, e.g. after surgery or if unconscious.

2. What you need to know before you use Carbamazepine Essential Pharma Suppositories

Your doctor may want you to have a number of blood tests before you are treated with Carbamazepine and sometimes during your treatment. This is quite usual and nothing to worry about.

Do not use Carbamazepine Essential Pharma Suppositories
- If you are allergic to carbamazepine or similar drugs such as oxcarbazepine (Trileptal), 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 think you may be allergic to any of the other ingredients of Carbamazepine Essential Pharma Suppositories (listed in 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 have any heart problems,
- If you have ever had problems with your bone marrow,
- If you have a blood disorder called porphyria,
- If you have taken drugs called monoamine oxidase inhibitors (MAOIs), used to treat depression, within the last 14 days.

Warning and precautions
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.

If you experience any of the below signs and symptoms suggestive of allergic reactions, stop taking carbamazepine and contact your doctor immediately:

- Immediate allergic reactions such as skin rash, itching, hives and swelling, sometimes of the face and mouth (angioedema). These allergic reactions may be severe (anaphylaxis).
- Serious skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis). 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.
- In very rare cases, patients of Japanese descendance can develop a very fast progressing form of diabetes (fulminant type 1 diabetes), usually in association with an allergic skin reaction. This disease can be fatal within 24 hours. If you have a rash, plausibly related to carbamazepine use and you experience symptoms like increased thirst and hunger, frequent need to urinate, nausea and vomiting, stomach pain, weakness or fatigue, shortness of breath, fruity-scented breath, and confusion, immediately seek medical attention.

Some people may have a reduced response to carbamazepine treatment, if they bear a specific genetic variant of a transporter protein (ABCB1 transporter). If carbamazepine is not working as expected and your disease is not adequately controlled, your doctor may decide to test you for the presence of this specific gene and adjust the treatment.

If you experience dizziness, drowsiness, decrease in blood pressure, confusion, due to carbamazepine treatment, this may lead to falls.

You should also ask yourself these questions before you use Carbamazepine Essential Pharma Suppositories. If the answer to any of these questions is YES, discuss your treatment with your doctor or pharmacist because Carbamazepine Essential Pharma Suppositories might not be the right medicine for you.

- Are you pregnant or planning to become pregnant?
- Are you breast-feeding?
- Do you suffer from the sort of epilepsy where you get mixed seizures which include absences?
- Do you have any mental illness?
- Are you allergic to an epilepsy medicine called phenytoin, primidone or phenobarbital?
- Do you have liver problems?
- Do 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)?
- Are you elderly?
- Do you have any eye problems such as glaucoma (increased pressure in the eye) or do you have difficulty retaining your urine?

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

It is important to tell your doctor or pharmacist if you are taking any other medicines for epilepsy at the same time as carbamazepine and you are pregnant, think you may be pregnant, or are planning to have a baby (see also the information in Section 2 on pregnancy and breast-feeding).

Other medicines and Carbamazepine Essential Pharma Suppositories

Because of the way that Carbamazepine Essential Pharma works, it can affect, and be affected by, lots of other things that you might be eating or medicines that you are taking. It is very important to make sure that your doctor knows all about what else you are taking, including anything that you have bought from a chemist or health food shop. It may be necessary to change the dose of some medicines or stop taking something altogether.

Tell the doctor if you are taking

- Hormonal contraceptives, e.g. pills, patches, injections, or implants. Carbamazepine Essential Pharma 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 contraceptive to use while you are taking Carbamazepine Essential Pharma.
- Hormone Replacement Therapy (HRT). Carbamazepine Essential Pharma can make HRT less effective.
- Any medicines for depression or anxiety.
- 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.
- Antibiotics to treat infections including skin infections and TB (e.g. ciprofloxacin).
- Antifungals to treat fungal infections.
- Painkillers containing paracetamol, dextropropoxyphene, tramadol, methadone or buprenorphine.
- Other medicines to treat epilepsy.
- Medicines for high blood pressure or heart problems.
- Diuretics (water tablets).
- Cimetidine or omeprazole (medicines to treat gastric ulcers).
- Isotretinoin (a medicine for the treatment of acne).
- Metoclopramide or aprepitant (anti-sickness medications).
- 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).
- Ciclosporin, tacrolimus or sirolimus (immunosuppressants, used after transplant operations, but also sometimes in the treatment of arthritis or psoriasis).
- Drugs to treat schizophrenia (e.g. paliperidone, aripiprazole).
- Cancer drugs (e.g. temsirolimus, cyclophasphamide, lapatinib).
- The anti-malarial drug, mefloquine.
- Drugs to treat HIV.
- Levothyroxine (used to treat hypothyroidism).
- Tadalafil (used to treat impotence).
- Albendazole (used to treat worms).
- Bupropion (used to help stop smoking).
- A herbal remedy called St John's Wort or Hypericum.
- Drugs or supplements containing Vitamin B (nicotinamide).

Carbamazepine Essential Pharma Suppositories with food, drink and alcohol

- Drinking alcohol may affect you more than usual. Discuss whether you should stop drinking with your doctor.
- Eating grapefruit, or drinking grapefruit juice, may increase your chance of experiencing side effects.

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.

Pregnancy

If you are a woman who is able to have a baby and are not planning a pregnancy, you should use effective contraception during treatment with Carbamazepine Essential Pharma. Carbamazepine Essential Pharma 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 Carbamazepine Essential Pharma. If treatment with Carbamazepine Essential Pharma is discontinued you should continue using effective contraception for at least two more weeks following discontinuation.

If you are pregnant, or think you may be pregnant, you must tell your doctor straight away and discuss possible risks the epilepsy medicine you are taking might pose to your unborn baby.

If you are planning to become pregnant you should discuss your epilepsy treatment with your doctor as early as possible before you become pregnant.

You should not stop your treatment without discussing this with your doctor. Suddenly stopping may lead to breakthrough seizures which may harm you and your unborn baby. It is important that your epilepsy remains well controlled.

Taking carbamazepine during pregnancy increases the chance that the baby may have a physical birth abnormality (major congenital malformations). Studies with women treated with carbamazepine for epilepsy have shown that on average 4-5 babies in every 100 will have serious physical birth abnormalities. This is compared with 2 to 3 babies in every 100 born to women who do not have epilepsy.

These abnormalities can develop early in pregnancy, even before you know you are pregnant. The most common types of major congenital malformations reported for carbamazepine include spina bifida (where the bones of the spine are not properly developed); facial and skull malformations including cleft lip/palate; skeletal, heart, urinary tract and sexual organ malformations.

Studies have found that the risk of physical birth abnormalities increases with increasing doses of carbamazepine. Therefore, it is important that where possible you are prescribed the lowest dose to control your epilepsy.

Problems with neurodevelopment (development of the brain) have been reported in babies born to mothers who used carbamazepine 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.

Ask your doctor about taking folic acid when trying for a baby and during pregnancy. Folic acid may lower the general risk of serious physical birth abnormalities that exists with all pregnancies.
Taking more than one epilepsy medicine at the same time may also increase the risk of physical birth abnormalities. This means that where possible, your doctor should consider using one epilepsy medicine to control your epilepsy.

Studies suggest that taking carbamazepine during pregnancy does not increase the risk the child may have difficulties with learning and thinking ability.

If you take Carbamazepine Essential Pharma Suppositories 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 being treated with Carbamazepine Essential Pharma Suppositories can breastfeed 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, skin reaction or yellow skin and eyes, dark urine or pale stools.

Fertility (Women of childbearing potential)
You should use an effective method of contraception throughout your treatment with Carbamazepine Essential Pharma Suppositories and for a period of 28 days, after discontinuation of treatment. Irregularity of the menstrual period may occur in women taking hormonal contraceptives (birth control medicines) and Carbamazepine Essential Pharma Suppositories. The hormonal contraceptive may become less effective and you should consider using a different or additional non-hormonal contraceptive method. Ask your doctor about effective contraception.

Driving and using machines
Carbamazepine Essential Pharma Suppositories 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.

3. How to use Carbamazepine Essential Pharma Suppositories

The doctor will tell you the dose you need. Always follow his/her instructions carefully. The dose will be on the pharmacist's label. Check the label carefully. It is important to use the suppositories at the right times. If you are not sure, ask your doctor or pharmacist. Keep using the suppositories for as long as you have been told, unless you have any problems. In that case, check with your doctor.
Suppositories are designed to be inserted into the back passage (rectum). **Never take them by mouth.**

For how to insert the suppositories see the end of the leaflet.

Your doctor will work out the dose that you need. It varies from person to person.

The maximum dose is 1,000 mg per day. Elderly people might need a lower dose.

If you use more Carbamazepine Essential Pharma Suppositories than you should
If you accidentally insert too many suppositories, or if anyone swallows any suppositories, tell your doctor or your nearest hospital casualty department. Take your pack with you so that people can see what medicine you are having.

If you forget to use Carbamazepine Essential Pharma Suppositories
If you forget to use a suppository, use it as soon as you remember, but if it is almost time for your next dose, skip the missed dose and continue as usual.

Do not use a double dose to make up for a missed dose.

4. Possible side effects

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

<u>Some side effects can be serious</u>
Stop using the suppositories and tell your doctor straight away if you notice:
- 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
- Mouth ulcers or unexplained bruising or bleeding
- Sore throat or high temperature, or both

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

The side effects listed below have also been reported
More than 1 in 10 people have experienced:
Leucopenia (a reduced number of the cells which fight infection making it easier to catch infections); dizziness and 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 which may be severe.

Up to 1 in 10 people have experienced:
Changes in the blood including an increased tendency to bruise or bleed; fluid retention and swelling; weight increase; low sodium in the blood which might result in confusion; headache; double or blurred vision; dry mouth; rectal irritation.

Up to 1 in 100 people have reported:
Abnormal involuntary movements including tremor or tics; abnormal eye movements; diarrhoea; constipation.

Up to 1 in 1,000 people have reported:
Disease of the lymph glands; folic acid deficiency; a generalised allergic reaction including rash, joint pain, fever, problems with the liver, kidneys and other organs; 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 to heart beat; stomach pain; liver problems including jaundice; symptoms of lupus.

Up to 1 in 10,000 people have reported:
Changes to the composition of the blood including anaemia; porphyria; meningitis; 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; increased blood fat levels; taste disturbances; conjunctivitis; glaucoma; 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; lung or breathing problems; severe skin reactions including Stevens-Johnson syndrome (these reactions may be more frequent in patients of Chinese or Thai origin); sore mouth or tongue; liver failure; increased sensitivity of the skin to sunlight; alterations in skin pigmentation; 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.

The following have also been reported, but the frequency cannot be estimated from the available information:

Severe skin reactions accompanied by feeling unwell and changes in blood results. Diarrhoea, abdominal pain, and fever (signs of inflammation of the colon), reactivation of herpes virus infection (can be serious when immune system is depressed), complete loss of nails, fracture, decrease in the measure of the bone density, drowsiness, memory loss, purple or reddish-purple bumps that may be itchy. High levels of ammonia in the blood (hyperammonaemia). The symptoms of hyperammonaemia may include irritability, confusion, vomiting, loss of appetite, and sleepiness.

Do not be alarmed by this list. Most people use Carbamazepine Essential Pharma Suppositories without any problems.

If any of the symptoms become troublesome, or if you notice anything else not mentioned here, please go and see your doctor. He/she may want to give you a different medicine.

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 Carbamazepine Essential Pharma Suppositories

Store below 30ºC.

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 and label after EXP. 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 Essential Pharma Suppositories contains
- The active ingredient is carbamazepine
- The other ingredients are hydroxypropyl methylcellulose and hard fat.

What Carbamazepine Essential Pharma Suppositories looks like and contents of the pack
The suppositories are white or off-white in colour and come in two strengths. The lower dose contains 125 mg of carbamazepine and the suppository weighs about 1 gram. The higher dose contains 250 mg of carbamazepine and the suppository weighs about 2 grams. There are 5 suppositories in each pack.

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Manufacturer

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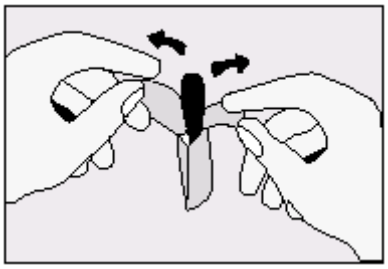
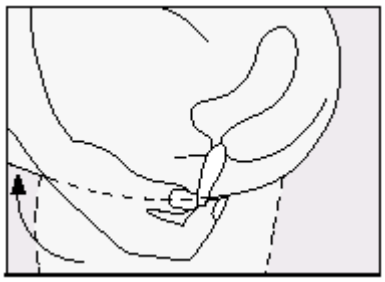
France

How to insert the suppositories

- Empty your bowels before inserting a suppository.
- Wash your hands.
- Take out the strip of suppositories and tear off one along the perforation.
- Tear the foil wrapping apart at the notch and take out the suppository.



- Lie on one side with your knees pulled up towards your chest.
- Gently push the suppository pointed end first into your back passage (rectum) with your finger. Push the suppository in as far as possible as shown in the diagram.



- Lower your legs and, if possible, stay still for a few minutes.
- If you feel as if you need to push the suppository out, try to resist this by lying still with your buttocks pressed together. It is important to keep the suppository in the rectum to allow it to melt and the medicine to be absorbed. Pushing the suppository high into the rectum with your finger will help to reduce this feeling.
- Wash your hands.

The procedure is the same for a child. Once they have emptied their bowels, get them to lie down on their front or side. Gently push the suppository into the child's back passage until it disappears. Try and stop the child moving around for a few minutes to reduce the risk of the suppository coming out.

If a doctor or nurse is giving the suppository to an unconscious patient, the procedure will be similar to that described above.

This leaflet was revised in May 2025.