

Package Leaflet: Information for the patient

Carbamazepine Essential Pharma 125 and 250 mg Suppositories Carbamazepine

Read all of this leaflet carefully before you start using 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 Essential Pharma Suppositories contain a medicine called carbamazepine. Carbamazepine can affect the body in several different ways. Carbamazepine Essential Pharma Suppositories help to control messages passed from the brain to muscles along the nerve pathways in the body. It is an anti-epileptic medicine (prevents fits).

Carbamazepine Essential Pharma Suppositories are used to treat some forms of epilepsy in adults and children, for up to 7 days, when treatment by mouth is not possible. This might be if you are having an operation, for example.

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

Do not use Carbamazepine Essential Pharma Suppositories

- if you are allergic to carbamazepine or similar medicines such as oxcarbazepine (Trileptal), or to any of a related group of medicines called tricyclic antidepressants (such as amitriptyline or imipramine)
- if you are allergic to any of the other ingredients of this medicine (listed in section 6). Signs of an allergic reaction include swelling of the face or mouth (angioedema), breathing problems, runny nose, skin rash, blistering or peeling
- if you have severe heart disease or have had any abnormalities of heart rate or rhythm
- if you have had serious blood illnesses in the past
- if you have ever had problems with your bone marrow
- if you have a blood problem called porphyria
- if you have taken medicines called monoamine oxidase inhibitors (MAOIs), used to treat depression, within the last 14 days
- if you are taking herbal preparations containing St. John's wort (*Hypericum perforatum*).

Do not use Carbamazepine Essential Pharma Suppositories if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before using Carbamazepine Essential Pharma Suppositories.

Warnings and precautions

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

Thoughts of harming or killing yourself

A small number of people being treated with anti-epileptics, such as carbamazepine, have had thoughts of harming or killing themselves. If you have these thoughts, talk to your doctor straight away (or ask someone else to).

Look out for signs of serious blood or bone marrow problems

Tell your doctor straight away (or ask someone else to) if you get signs of serious blood or bone marrow problems such as fever and sore throat, with possible unexplained bruising or burst blood vessels under your skin.

Look out for serious skin reactions

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

- Skin rash, itching, hives and swelling, sometimes of the face and mouth (angioedema). These allergic reactions may be severe (anaphylaxis).
- Serious skin reactions such as skin rash, with blistering or peeling, mouth or genital ulcers often with flu-like symptoms or a reduction in blood cells leading to unexplained bruising or bleeding (these may be signs of Stevens-Johnson Syndrome (SJS), Toxic Epidermal Necrolysis (TEN), Drug Rash with Eosinophilia and Systemic Symptoms (DRESS) or Acute Generalised Exanthematous Pustolosis (AGEP)). These types of reactions are more likely in the first few months of treatment. Serious skin reactions are more likely in certain groups of people (such as people of Han Chinese, Thai, Japanese or European origin). This can be predicted in a blood test before treatment starts. Your doctor will be able to advise you whether this blood test is necessary for you.

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

Patients at risk of hyponatraemia

Hyponatremia is a condition that occurs when the level of sodium in your blood is abnormally low. It is known to occur with carbamazepine. 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, furosemide), then you should discuss your treatment with your doctor or pharmacist because Carbamazepine Essential Pharma Suppositories might not be the right medicine for you.

Seizures

If you experience an increase in the number of seizures, tell your doctor immediately.

Talk to your doctor or pharmacist before using Carbamazepine Essential Pharma Suppositories

- if you have blood problems (including those caused by other medicines)
- if you are allergic to an epilepsy medicine called phenytoin, primidone or phenobarbital
- if you have the form of epilepsy where you have mixed fits which include absences
- if you have ever had any heart, liver or kidney problems
- if you are over 65 years of age
- if you have an under-active thyroid (hypothyroidism)
- if you have any eye problems such as glaucoma (increased pressure in the eye)

- if you have difficulty emptying your bladder (urinary retention)
- if you have problems with your mental health
- if you have thinning of the bones (osteopenia or osteoporosis).

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before using Carbamazepine Essential Pharma Suppositories.

Other medicines and Carbamazepine Essential Pharma Suppositories

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is because of the way Carbamazepine Essential Pharma Suppositories work. It can affect and be affected by lots of other things that you might be eating or medicines you are taking. It is very important to make sure that your doctor knows all about what else you are taking, including anything you have bought from a chemist or health food shop. It may be necessary to change the dose of some medicines or stop taking them altogether.

In particular, **do not use** Carbamazepine Essential Pharma Suppositories and tell your doctor if you are taking:

- monoamine oxidase inhibitors (MAOIs), used to treat depression, within the last 14 days
- herbal preparations containing St. John's wort (*Hypericum perforatum*).

Do not use Carbamazepine Essential Pharma Suppositories if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before using Carbamazepine Essential Pharma Suppositories.

Tell your doctor or pharmacist if you are taking:

- hormonal contraceptives, e.g. pills, patches, injections or implants. Carbamazepine Essential Pharma Suppositories 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 contraception to use while you are taking Carbamazepine Essential Pharma Suppositories
- any other medicines for depression or anxiety such as desipramine, fluoxetine, viloxazine, imipramine, lithium, haloperidol, thioridazine
- corticosteroids ("steroids") such as prednisolone, dexamethasone. You might be taking these for inflammatory conditions such as asthma, inflammatory bowel disease or muscle and joint pains
- anticoagulants to stop your blood clotting such as warfarin
- antibiotics to treat infections including tuberculosis (TB) such as erythromycin, ciprofloxacin, doxycycline, isoniazid, rifampicin
- antifungals to treat fungal infections such as itraconazole, ketoconazole, fluconazole
- painkillers containing paracetamol, dextropropoxyphene, tramadol or methadone
- other medicines to treat epilepsy such as phenytoin, oxcarbazepine, phenobarbitone, clobazam, clonazepam, ethosuximide, primidone, valproic acid, brivaracetam
- medicines for high blood pressure or heart problems such as verapamil, diltiazem, digoxin, felodipine
- terfenadine (a medicine to treat allergy such as hay fever or itching)
- diuretics (water tablets)
- cimetidine or omeprazole (medicines to treat gastric ulcers)
- analgesics or anti-inflammatory medicines such as ibuprofen, paracetamol
- 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 (an immunosuppressant, used after transplant operations, but also sometimes in the treatment of arthritis or psoriasis)
- everolimus (an immunosuppressant)

- medicines to treat schizophrenia such as olanzapine, clozapine, risperidone
- cancer medicines such as cisplatin, doxorubicin, imatinib
- the anti-malarial medicine, mefloquine
- medicines to treat HIV such as indinavir, saquinavir, ritonavir
- levothyroxine (used to treat hypothyroidism)
- muscle relaxant medicines such as oxybutynin, dantrolene
- bupropion (used to help stop smoking)
- medicines for erectile dysfunction e.g. tadalafil
- medicines or supplements containing vitamin B (e.g. nicotinamide)
- ticlopidine (an anti-platelet drug)
- praziquantel or albendazole (used to treat worms)
- any other medicine that lowers the salt (sodium) level in your blood (your doctor can advise).

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before using Carbamazepine Essential Pharma Suppositories.

Operations or tests

- Your doctor may want you to have a number of blood tests before you start using Carbamazepine Essential Pharma Suppositories and from time to time during your treatment. This is quite usual and nothing to worry about.
- Before having any kind of blood tests or surgery, including dental or emergency treatment, tell the doctor in charge that you are using Carbamazepine Essential Pharma Suppositories.

Carbamazepine Essential Pharma Suppositories with alcohol, food and drink

- Do not drink alcohol while you are using this medicine. This is because it may affect you more than usual. Talk to your doctor if you have any questions about drinking alcohol.
- Do not eat grapefruit or drink grapefruit juice while you are using this medicine. This is because it 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.

Carbamazepine Essential Pharma Suppositories can cause major birth defects. If you take Carbamazepine Essential Pharma Suppositories 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 Carbamazepine Essential Pharma Suppositories while pregnant.

Problems with neurodevelopment (development of the brain) have been reported in babies born to mothers who used Carbamazepine Essential Pharma Suppositories 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 Carbamazepine Essential Pharma Suppositories. Carbamazepine Essential Pharma Suppositories 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 Suppositories. If treatment with Carbamazepine Essential Pharma Suppositories 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 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.

Mothers using Carbamazepine Essential Pharma Suppositories can breast-feed their babies, but you must tell the doctor as soon as possible if you think that the baby is having side effects such as excessive sleepiness, skin reactions or gets yellowish skin or eyes because you are using Carbamazepine Essential Pharma Suppositories.

Driving and using machines

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

The condition you are using Carbamazepine Essential Pharma Suppositories for may also affect your ability to drive, cycle or operate machinery.

3. How to use Carbamazepine Essential Pharma Suppositories

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

How much to use

Carbamazepine Essential Pharma Suppositories are always (except possibly on the first day) given in divided doses, i.e. 2, 3 or 4 times a day.

To treat epilepsy when treatment by mouth is not possible:

Adults, children and young people

Your doctor will tell you exactly what dose of Carbamazepine Essential Pharma Suppositories to use. The maximum dose is 1,000 mg a day (250 mg four times a day) for up to 7 days.

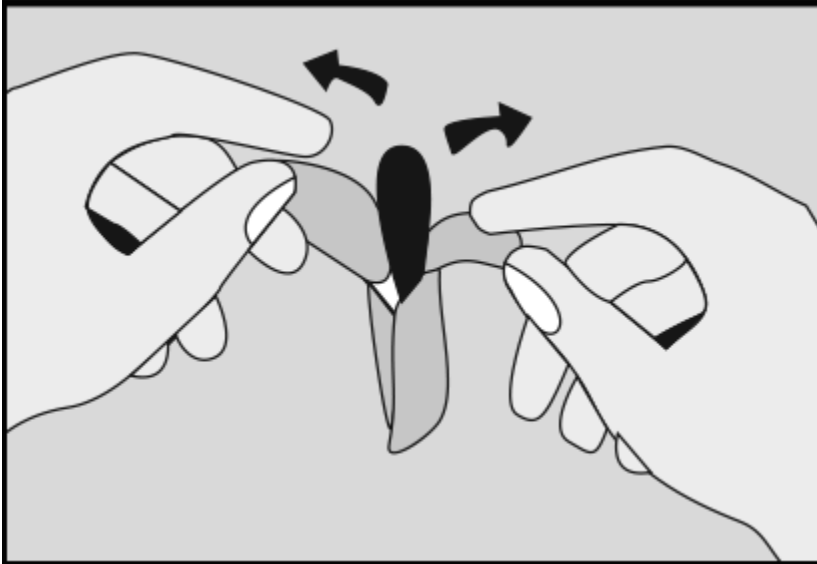
Older patients might require a lower dose. Carbamazepine Essential Pharma Suppositories are not recommended for very young children (i.e. under 5 years of age).

Using this medicine

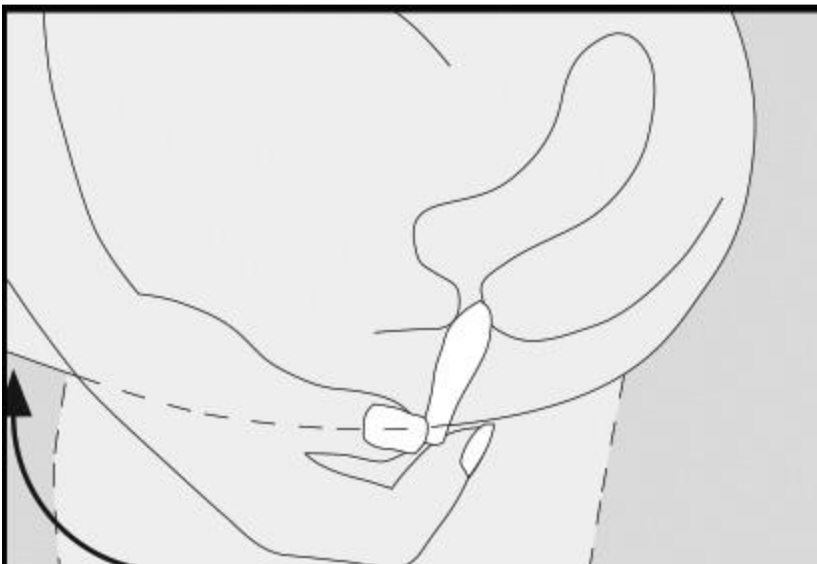
Carbamazepine Essential Pharma Suppositories are designed for insertion into the back passage (rectum). **Never take them by mouth.**

How to insert the suppositories

- Empty your bowels before inserting a suppository.
- Wash your hands.
- Tear the foil wrapping apart at the notch.
- Take the suppository out of the foil wrapping.



- 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 inside the back passage (rectum) to allow it to melt and the medicine to be absorbed. Pushing the suppository high into the back passage (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 (rectum) until it disappears. Try and stop your child from moving around for a few minutes to reduce the risk of the suppository coming out.

Under certain circumstances, for example if the patient is unconscious, a doctor or nurse will give the suppository. If this happens, the procedure will be very similar to that described above.

If you use more Carbamazepine Essential Pharma Suppositories than you should

If you accidentally use too many Carbamazepine Essential Pharma Suppositories, tell your doctor or your nearest hospital casualty department straight away. Take your medicine pack with you so that people can see what you have used. You may have difficulty breathing, a fast or uneven heart beat, feel faint or shaky, feel or be sick or become unconscious.

If you forget to use Carbamazepine Essential Pharma Suppositories

If you forget to use a dose, use one as soon as you remember it. If it is nearly time for your next dose, though, just use the next dose and forget about the one you missed. Do not use a double dose to make up for a forgotten dose.

If you stop using Carbamazepine Essential Pharma Suppositories

Keep using your suppositories for as long as you have been told, unless you have any problems. In that case, check with your doctor. Carbamazepine Essential Pharma Suppositories should not be used for longer than 7 days. When you have finished using the suppositories, you will go back to using the other form of carbamazepine that you were using before, such as tablets or oral solution.

Do not stop using carbamazepine suddenly. Stopping treatment with carbamazepine suddenly may worsen your seizures. It is recommended that you stop using carbamazepine gradually, over a period of 6 months.

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.

Tell your doctor straight away (or ask someone else to) if you notice any of the following serious side effects – you may need urgent medical attention:

- thoughts of harming or killing yourself
- serious skin reactions such as skin rash, with blistering or peeling, mouth or genital ulcers often with flu-like symptoms or a reduction in blood cells leading to unexplained bruising or bleeding (these may be signs of SJS, TEN, DRESS or AGEP). (refer to section 2 for further information on serious skin reactions)
- signs of serious blood or bone marrow problems such as fever and sore throat, with possible unexplained bruising or burst blood vessels under your skin
- bronchospasm with wheezing and coughing, difficulty in breathing, feeling faint, rash, itching or facial swelling (these may be signs of a serious allergic reaction)
- fever, muscle stiffness with confusion and unusual changes in blood pressure (these may be signs of a serious brain problem)
- fever, feeling or being sick, headache, stiff neck and extreme sensitivity to bright light (these may be signs of meningitis)
- having more fits (seizures)
- yellowing of your skin or the whites of your eyes (these may be signs of liver problems)
- being sick, diarrhoea, weight loss, with changes to or blood in your urine, changes in your heart beat, muscle cramps or itching (these may be signs of kidney failure)
- any changes in your mental health, including depression, agitation, confusion, loss of appetite, hearing or seeing things which are not there
- pain in your joints and muscles, a rash across the bridge of your nose and cheeks (these may be signs of a rare reaction known as lupus erythematosus)
- fever, skin rash, joint pain, and abnormalities in blood and liver function tests, that could go on to affect other organs as well (these may be signs of a multi-organ sensitivity disorder)
- pain in the area around the stomach

- severe diarrhoea, abdominal pain and fever (these may be signs of an inflamed colon).
 - You experience a fall due to dizziness, drowsiness, decrease in blood pressure, confusion
- Tell your doctor straight away (or ask someone else to) if you notice any of the serious side effects above.

Other side effects include:

Talk to your doctor or pharmacist if you get any side effects.

Very common: may affect more than 1 in 10 people

Dizziness and tiredness; feeling unsteady or finding it difficult to control movements; feeling or being sick; low white blood cell count or changes in liver enzyme levels (shown in blood tests); minor skin reactions, including itching, redness, raised bumps and peeling.

Common: may affect up to 1 in 10 people

Weight increase; swollen ankles, feet or lower legs; low sodium in the blood which might result in confusion; headache; double or blurred vision; dry mouth; irritation in or around your back passage (rectum); low platelet count or higher levels of a protein called “ALP” in your body (shown in blood tests).

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; speech disorders; numbness or tingling in the hands and feet; a burning, shooting or stabbing pain; 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 or confused); changes to heart beat; high white blood cell count (shown in a blood test).

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

Porphyria; swelling of the breasts and discharge of milk which may occur in both males and females; abnormal thyroid function tests; osteomalacia (softening of the bones, which may be noticed as pain on walking and bowing of the long bones in the legs); osteopenia or osteoporosis (thinning of the bones, which may lead to increased fractures); increased blood fat or cholesterol 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 such as a blood clot in the lung or pneumonia; sore mouth or tongue; increased sensitivity of the skin to sunlight; alterations in skin pigmentation; acne; excessive sweating; hair loss; increased hair growth; muscle pain or spasm; sexual difficulties which may include reduced male fertility, loss of libido or impotence; kidney problems; blood spots in the urine; increased or decreased desire to pass urine or difficulty in passing urine; low red blood cell count (anaemia) or low level of all blood cells (shown in blood tests).

Not known: frequency cannot be estimated from the available data

Feeling drowsy; memory loss; purple or reddish-purple bumps on your skin that may be itchy; complete loss of your nails; reactivation of herpes virus infection (which can be serious when the immune system is depressed).

High levels of ammonia in the blood (hyperammonaemia). The symptoms of hyperammonaemia may include irritability, confusion, vomiting, loss of appetite, and sleepiness.

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 HPRA Pharmacovigilance, Website: www.hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Carbamazepine Essential Pharma Suppositories

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 foil after “EXP”. The expiry date refers to the last day of that month.

Do not store above 30°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 Carbamazepine Essential Pharma Suppositories contain**

- The active substance is carbamazepine. Each suppository contains either 125 mg or 250 mg carbamazepine.
- The other ingredients are hypromellose and hard fat.

What Carbamazepine Essential Pharma Suppositories look like and contents of the pack

Carbamazepine Essential Pharma 125 mg Suppositories are white to off-white torpedo shaped with a fatty smell. They weigh about 1 gram.

Carbamazepine Essential Pharma 250 mg Suppositories are white to off-white torpedo shaped with a fatty smell. They weigh about 2 grams.

Both come in packs of 5.

Marketing Authorisation Holder

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