Pharmacode

Pharmacode

Package leaflet: Information for the patient

Carbamazepine Noumed 200mg Prolonged-release Tablets Carbamazepine Noumed 400mg Prolonged-release Tablets

The name of your medicine is Carbamazepine Noumed 200mg (or) 400 mg Prolonged-release Tablets but will be referred as Carbamazepine Noumed Prolonged-release Tablets throughout the rest of the leaflet.

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 or nurse.
- 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 or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Carbamazepine Noumed Prolonged-release Tablets are and what they are used for
2. What you need to know before you take Carbamazepine Noumed Prolonged-release Tablets
3. How to take Carbamazepine Noumed Prolonged-release Tablets
4. Possible side effects
5. How to store Carbamazepine Noumed Prolonged-release Tablets
6. Contents of the pack and other information

1. What Carbamazepine Noumed Prolonged-release Tablets are and what they are used for

Carbamazepine Noumed Prolonged-release Tablets are specially formulated to release the active ingredient gradually. Carbamazepine, the active ingredient, can affect the body in several different ways. It is an anti-convulsant medicine (prevents fits), it can also modify some types of pain and can control mood disorders.

Carbamazepine Noumed Prolonged-release Tablets are 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 Noumed Prolonged-release Tablets

Some people MUST NOT take Carbamazepine Noumed Prolonged-release Tablets. Talk to your doctor if:
- you think you may be hypersensitive (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). If you are allergic to carbamazepine there is a one in four (25%) chance that you could also have an allergic reaction to oxcarbazepine.
- you think you may be allergic to any of the other ingredients of Carbamazepine Noumed Prolonged-release Tablets (these are listed at the end of the leaflet). Signs of a hypersensitivity reaction include swelling of the face or mouth (angioedema), breathing problems, runny nose, skin rash, blistering or peeling.
- you have any heart problems,
- you have ever had problems with your bone marrow,
- you have a blood disorder called porphyria,
- you have taken drugs called monoamine oxidase inhibitors (MAOIs), used to treat depression, within the last 14 days.
- If any of these apply to you, do not take Carbamazepine Prolonged-release Tablets and tell your doctor.

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 an allergic reaction happens, such as swelling of lips, eyelids, face, throat, mouth, or sudden breathing problems, fever with lymph nodes swelling, rash or skin blistering, tell your doctor immediately or go to the emergency department at your nearest hospital (see "Possible side effects").

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.

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 taking Carbamazepine Noumed Prolonged-release Tablets. If the answer to any of these questions is YES, discuss your treatment with your doctor or pharmacist because Carbamazepine Noumed Prolonged-release Tablets might not be the right medicine for you.

Talk to your doctor or pharmacist before taking **Carbamazepine Noumed Prolonged-release Tablets**:
- 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 if you have difficulty retaining your urine.

Other medicines and Carbamazepine Noumed Prolonged-release Tablets
Because of the way that carbamazepine 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.

There is a risk of harm to the unborn child if Carbamazepine Prolonged-release Tablet is used during pregnancy. Women of childbearing age should use effective contraception during treatment with Carbamazepine Prolonged-release Tablet and for at least two weeks after the last dose (see the information in Section 2 on 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).

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
- Hormone contraceptives, e.g. pills, patches, injections or implants. Carbamazepine may affects how hormonal contraceptive works 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 Prolonged release tablets.
- Hormone Replacement Therapy (HRT). Carbamazepine 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. ciprofloxacillin).
- Antifungals to treat fungal infections.
- Painkillers containing paracetamol, dextropropoxyphene, tramadol, methadone or buprenorphine.
- Other medicines to treat epilepsy (brivaracetam).
- Medicines for high blood pressure or heart problems.
- Antihistamines (medicines to treat allergy such as hayfever, itch, etc).
- 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).

Pregnancy, breast-feeding and fertility

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 Noumed Prolonged-release Tablets. Carbamazepine Noumed Prolonged-release Tablets 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 Noumed Prolonged-release Tablets. If treatment with Carbamazepine Noumed Prolonged-release Tablets 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.

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.

Problems with neurodevelopment (development of the brain) cannot be ruled out in children born to women with epilepsy treated with carbamazepine alone or in combination with other antiepileptic drugs during pregnancy.

Findings from a large, published epidemiology study have shown that the use of carbamazepine may affect the growth of your unborn baby during pregnancy.

If you take Carbamazepine Noumed Prolonged-release Tablets 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.

Breastfeeding
Mothers taking Carbamazepine Noumed Prolonged-release Tablets 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
You should use an effective method of contraception throughout your treatment with Carbamazepine Noumed Prolonged-release Tablets 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 Noumed Prolonged-release Tablets. 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.

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Front Side

Pharmacode

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Driving and using machines
Carbamazepine Noumed Prolonged-release Tablets 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.

Other special warnings
- 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.
- Your doctor may want you to have a number of blood tests before you start taking carbamazepine and from time to time during your treatment. This is quite usual and nothing to worry about.
- Macrogolglycerol hydroxystearate 40 which may cause stomach upset and diarrhoea.

3. How to take Carbamazepine Noumed Prolonged-release Tablets

The doctor will tell you how many Carbamazepine Noumed Prolonged-release Tablets to take and when to take them. Always follow his/her instructions carefully. The dose will be on the pharmacist's label. Check the label carefully. It is important to take the tablets at the right times. If you are not sure, ask your doctor or pharmacist. Keep taking your tablets for as long as you have been told, unless you have any problems. In that case, check with your doctor.

Your doctor will usually start carbamazepine at a fairly low dose which can then be increased to suit you individually. The dose needed varies between patients. You can take Carbamazepine Noumed Prolonged-release Tablets during, after or between meals. **Swallow the tablets with a drink. Do not chew them.** You are usually told to take a dose two or three times a day.If necessary you may break the tablets in half along the scored line.

To treat epilepsy the recommended doses are:
Adults: 800–1,200 mg a day, although higher doses may be necessary. If you are elderly you might require a lower dose.
Children:
Aged 5–10 years: 400–600 mg a day.
Aged 10–15 years: 600–1,000 mg a day.

Carbamazepine Noumed Prolonged-release Tablets are not recommended for children under 5.

To treat trigeminal neuralgia the recommended dose is:
600–800 mg a day. The maximum dose is 1200 mg a day. If you are elderly you might require a lower dose.

To treat mood swings the recommended dose is:
400–600 mg a day

If you forget to take Carbamazepine Noumed Prolonged-release Tablets
If you forget to take a dose, take one as soon as you remember. If it is nearly time for your next dose, though, just take the next dose and forget about the one you missed.

If you take more Carbamazepine Noumed Prolonged-release Tablets than you should
If you accidentally take too many Carbamazepine Noumed Prolonged-release Tablets, tell your doctor or your nearest hospital casualty department. Take your medicine pack with you so that people can see what you have taken.

4. Possible side effects

Carbamazepine Noumed Prolonged-release Tablets do not usually cause problems, but like all medicines, they can sometimes cause side effects.

Some side effects can be serious
Stop taking Carbamazepine Noumed Prolonged-release Tablets 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 multiorgan 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.
Very Common (may affect more than 1 in 10 people)
- 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.

Common (may affect up to 1 in 10 people)
- 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.

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
- a generalised allergic reaction including rash
- joint pain
- fever
- problems with the 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.

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

Not known (frequency cannot be estimated from available data)
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 take Carbamazepine Noumed Prolonged-release Tablets 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 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 Noumed Prolonged-release Tablets

- Store in the original package.
- 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 blister strip. The expiry date refers to the last day of that month.
- Do not use this medicine if you notice any discoloration or visible signs of deterioration.
- 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 to protect the environment.

6. Contents of the pack and other information

What Carbamazepine Noumed Prolonged-release Tablets contains
The active substance is carbamazepine.
200 mg: Each tablet contains 200 mg of carbamazepine.
400 mg: Each tablet contains 400 mg of carbamazepine.

The other ingredients are: Povidone, Colloidal anhydrous silica (E551), Polyacrylate Dispersion 30 percent, Ethylcellulose aqueous dispersion, Microcrystalline cellulose (E460), Croscarmellose sodium (E 468), Talc, Magnesium stearate (E572).

Film coating ingredients are Hypromellose, Macrogolglycerol hydroxystearate 40, Titanium dioxide (E171), Talc, Iron oxide red (E172), Iron oxide yellow (E172).

What Carbamazepine Noumed Prolonged-release Tablets looks like and contents of the pack
Carbamazepine Noumed 200 mg Prolonged-release Tablets are Yellowish orange, oval shaped, slightly biconvex, coated tablets with a score line on each side.
Carbamazepine Noumed 400 mg Prolonged-release Tablets are Brownish orange, oval shaped, slightly biconvex, coated tablets with a score line on each side.

Carbamazepine Noumed Prolonged-release Tablets are supplied in blister packs of 56 and 100 Tablets.
Not all pack sizes may be marketed.

This leaflet was last revised in February 2026.

Marketing Authorisation Holder and Manufacturer:
NOUMED LIFE SCIENCES LIMITED
Noumed House, Shoppenhangers Road,
Maidenhead, Berkshire, SL6 2RB, United Kingdom.

Other sources of information:
To listen to or request a copy of this leaflet in braille, large print or audio please call, 020 33998960 (UK only). Please be ready to give the following information:

Product name:
Carbamazepine Noumed 200 mg Prolonged-release Tablets
Reference number: PL 44041/0130

Product name:
Carbamazepine Noumed 400 mg Prolonged-release Tablets
Reference number: PL 44041/0131

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Signature of Author:	
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			Title: Art Work Approval Form		
Product	Carbamazepine Noumed 200mg/400mg Tablets Combined PIL		Specification:		
Customer	**NOUMED LIFE SCIENCES LIMITED, UK**				
Reason for Issue	Content Update		Colours:	Refer to colour list	
			Dimensions:	580 x 180mm	
Related FG Codes	LCAR05/03	Pharmacode No.	No. of Folds (only for PIL)		
Item Code		Layout No.:			