Package leaflet: Information for the user

GABAPENTIN BROWN & BURK 100MG CAPSULES, HARD
GABAPENTIN BROWN & BURK 300MG CAPSULES, HARD
GABAPENTIN BROWN & BURK 400MG CAPSULES, HARD

Gabapentin

This medicine contains gabapentin, which can cause dependence, tolerance and addiction. You can get withdrawal symptoms if you stop taking it or reduce the dose suddenly. If this medicines is being used for the treatment of epilepsy you must continue to take this medicines as instructed by your doctor.

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.
- 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 of the 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 Gabapentin Brown & Burk is and what it is used for
2. What you need to know before you take Gabapentin Brown & Burk
3. How to take Gabapentin Brown & Burk
4. Possible side effects
5. How to store Gabapentin Brown & Burk
6. Contents of the pack and other information

1. What Gabapentin Brown & Burk is and what it is used for

This medicine has been prescribed for you for the treatment of epilepsy and peripheral neuropathic pain (long lasting pain caused by damage to the nerves).

It contains the gabapentin which belongs to a class of medicines called Gabapentinoids.

This medicine has been <prescribed> to you and should not be given to anyone else.

Gabapentinoids can cause dependence, tolerance and addiction, and you may get withdrawal symptoms if you stop taking it or reduce the dose suddenly. Your prescriber should have explained how long you will be taking it for and, when it is appropriate to stop, how to do this safely. When your treatment is stopped, it is usually done gradually over a period which is specific to you and may occur over a period of weeks to months. If this medicine is being used for the treatment of epilepsy you must continue to take it as prescribed by your doctor.

Gabapentin Brown & Burk is used to treat:

- Various forms of epilepsy (seizures that are initially limited to certain parts of the brain, whether the seizure spreads to other parts of the brain or not). The doctor treating you or your child 6 years of age and older will prescribe Gabapentin Brown & Burk for you to help treat your epilepsy when your current treatment is not fully controlling your condition. You or your child 6 years of age or older should take Gabapentin Brown & Burk in addition to your current treatment unless

told otherwise. Gabapentin Brown & Burk can also be used on its own to treat adults and children over 12 years of age.

- Peripheral neuropathic pain (long lasting pain caused by damage to the nerves).
  A variety of different diseases can cause peripheral neuropathic pain (primarily occurring in the legs and/or arms), such as diabetes or shingles. Pain sensations may be described as hot, burning, throbbing, shooting, stabbing, sharp, cramping, aching, tingling, numbness, pins and needles etc.

2. What you need to know before you take Gabapentin Brown & Burk

Do not take Gabapentin Brown & Burk:

- if you are allergic (hypersensitive) to gabapentin or any of the other ingredients of this medicines (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before taking Gabapentin Brown & Burk

- if you suffer from kidney problems your doctor may prescribe a different dosing schedule
- if you have nervous system disorders, respiratory disorders, or you are more than 65 years old, your doctor may prescribe you a different dosing regimen;
- if you are on haemodialysis (to remove waste products because of kidney failure), tell your doctor if you develop muscle pain and/or weakness;
- if you develop signs such as persistent stomach pain, feeling sick and being sick contact your doctor immediately as these may be symptoms of acute pancreatitis (an inflamed pancreas).
- Before taking this medicine, tell your doctor if you have ever abused or been dependent on alcohol, prescription medicines or illegal drugs; it may mean you have a greater risk of becoming dependent on Gabapentin.
- If you have myasthenia gravis (a disease causing muscle weakness) because this medicine may make your symptoms worse.
- are or have ever been addicted to opioids, alcohol, prescription medicines, or illegal drugs, or if you have ever had a history of struggling to control your alcohol or drug intake.
- have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating, when you have stopped taking alcohol or drugs.
- feel you need to take more of Gabapentin Brown and Burk to get the same level of symptom control, this may mean you are developing tolerance to the effects of this medicine or are becoming addicted to it. Speak to your prescriber who will discuss your treatment and may change your dose or switch you to an alternative medication.

Taking this medicine regularly, particularly for a long time, can lead to physical dependence and addiction. Your prescriber should have explained how long you will be taking it for and, when it is appropriate to stop, how to do this safely. When your treatment is stopped, it is usually done gradually over a period which is specific to you and may occur over a period of weeks to months.

Physical dependence and addiction can cause withdrawal symptoms when you stop taking this medicine. Withdrawal symptoms can include:

Trouble sleeping, headache, nausea, feeling anxious, diarrhoea, flu-like symptoms, convulsions, nervousness, depression, thoughts of harming or killing yourself, pain, sweating, and dizziness.

Your prescriber will discuss with you how to gradually reduce your dose before stopping the medicine. It is important that you do not stop taking the medicine suddenly as you will be more likely to experience withdrawal symptoms. Your prescriber will ensure that your plan for stopping treatment

is tailored to you and can be adapted according to your needs and experience of any withdrawal symptoms.

Gabapentinoids should only be used by those they are prescribed for. Do not give your medicine to anyone else. Taking higher doses or more frequent doses of gabapentinoids, may increase the risk of addiction. Overuse and misuse can lead to overdose and/or death.

Dependence

Some people may become dependent on Gabapentin (a need to keep taking the medicine).
They may have withdrawal effects when they stop using Gabapentin or reduce the dose (see section 3, "How to take Gabapentin" and "If you stop taking Gabapentin"). If you have concerns that you may become dependent on Gabapentin, it is important that you consult your doctor.

If you notice any of the following signs whilst taking Gabapentin, it could be a sign that you have become dependent.
- You feel you need to take the medicine for longer than advised by your prescriber
- You feel you need to take more than the recommended dose
You are using the medicine for reasons other than prescribed
- You have made repeated, unsuccessful attempts to quit or control the use of the medicine
- When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again
If you notice any of these, speak to your doctor to discuss the best treatment pathway for you, including when it is appropriate to stop and how to do this safely.

Cases of abuse and dependence have been reported for Gabapentin from the post-marketing experience. Talk to your doctor if you have a history of abuse or dependence.

A small number of people being treated with anti-epileptics such as Gabapentin have had thoughts of harming or killing themselves. If at any time you have these thoughts, immediately contact your doctor.

Important information about potentially serious reactions

Serious skin rashes including Stevens-Johnson syndrome, toxic epidermal necrolysis and drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported in association with gabapentin. Stop using gabapentin and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

Read the description of serious symptoms in section 4 of this leaflet under '*Contact your doctor immediately if you experience any of the following symptoms after taking this medicine as they can be serious'*

Muscle weakness, tenderness or pain and particularly, if at the same time, you feel unwell or have a high temperature it may be caused by an abnormal muscle breakdown which can be life-threatening and lead to kidney problems. You may also experience discoloration of your urine, and a change in blood test results (notably blood creatine phosphokinase increased). If you experience any of these signs or symptoms, please contact your doctor immediately.

Other medicines and Gabapentin Brown & Burk Capsules

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. In particular, tell your doctor (or pharmacist) if you are taking or have been recently taking any medicines for convulsions, sleeping disorders, depression, anxiety, or any other neurological or psychiatric problems.

Medicines containing opioids such as morphine

If you are taking any medicines containing opioids (such as morphine), please tell your doctor or pharmacist as opioids may increase the effect of Gabapentin Brown & Burk. In addition, combination of Gabapentin Brown and Burk with opioids may cause sleepiness, sedation decrease in breathing, or death.

Antacids for indigestion

If Gabapentin Brown & Burk and antacids containing aluminium and magnesium are taken at the same time, absorption of Gabapentin Brown & Burk from the stomach may be reduced. It is therefore recommended that Gabapentin Brown & Burk is taken at the earliest two hours after taking an antacid.

Gabapentin Brown & Burk:

- is not expected to interact with other antiepileptic drugs or the oral contraceptive pill;
- may interfere with some laboratory tests, if you require a urine test tell your doctor or hospital what you are taking;

Gabapentin Brown & Burk with food

Gabapentin Brown & Burk can be taken with or without food.

Pregnancy, breast-feeding and fertility

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

You should not stop your treatment without discussing this with your doctor.

If you are planning to become pregnant you should discuss your treatment with your doctor <or pharmacist> as early as possible before you become pregnant.

If you are breastfeeding or planning to breastfeed, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

Gabapentin Brown & Burk should not be taken during pregnancy, unless you are told otherwise by your doctor. Effective contraception must be used by women of child-bearing potential.

If you plan to become pregnant or if you are pregnant or think you may be pregnant, talk to your doctor straight away. If you have become pregnant and you have epilepsy, it is important that you do not stop taking your medicine without first consulting your doctor, as this may worsen your illness. Worsening of your epilepsy may put you and your unborn child at risk.

There have been very few studies specifically looking at the use of gabapentin in pregnant women. More research is needed to better understand about the safety of use of gabapentin during pregnancy and whether it is associated with an increased risk of harm to the unborn child.

In a study reviewing data from women in Nordic countries who took gabapentin in the first 3 months of pregnancy, there was no increased risk of birth defects or problems with the development of brain function (neurodevelopment disorders). However, babies of women who took gabapentin during pregnancy had an increased risk of low birth weight and preterm birth.

Some medicines used to treat epilepsy have reported an increased risk of harm to the developing baby, particularly when more than one seizure medication is taken at the same time. This means that where

possible, your doctor should consider using one epilepsy medicine to control your epilepsy.

If used during pregnancy, gabapentin may lead to withdrawal symptoms in newborn infants. This risk might be increased when gabapentin is taken together with opioid analgesics (drugs for treatment of severe pain).

Contact your doctor immediately if you become pregnant, think you might be pregnant or are planning to become pregnant while taking Gabapentin Brown & Burk. Do not suddenly discontinue taking this medicine as this may lead to a breakthrough seizure, which could have serious consequences for you and your baby.

Breast-feeding

Gabapentin, the active substance of Gabapentin Brown & Burk, is passed on through human milk. Because the effect on the baby is unknown, it is not recommended to breast-feed while using Gabapentin Brown & Burk.

Fertility

There is no effect on fertility in animal studies.

Driving and using machines

Gabapentin Brown & Burk may produce dizziness, drowsiness and tiredness. You should not drive, operate complex machinery or take part in other potentially hazardous activities until you know whether this medication affects your ability to perform these activities.

This medication contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per Capsule, that is to say essentially 'sodium-free'.

3. How to take Gabapentin Brown & Burk

Your prescriber should have discussed with you how long the course of tablet will last. They will arrange a plan for stopping treatment. This will outline how to gradually reduce the dose and stop taking the medicine. Your prescriber will ensure that your plan for stopping treatment is tailored to you and can be adapted according to your needs and experience of any withdrawal symptoms.

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

Your doctor will determine what dose is appropriate for you.

Epilepsy, the recommended dose is:

Adults and adolescents:
Take the number of capsules as instructed. Your doctor will usually build up your dose gradually. The starting dose will generally be between 300 mg and 900 mg each day. Thereafter, the dose may be increased as instructed by your doctor, up to a maximum of 3600 mg each day and your doctor will tell you to take this in 3 separate doses, i.e. once in the morning, once in the afternoon and once in the evening.

Children aged 6 years and above:
The dose to be given to your child will be decided by your doctor as it is calculated against your child's weight. The treatment is started with a low initial dose which is gradually increased over a

period of approximately 3 days. The usual dose to control epilepsy is 25-35 mg per kg of body weight per day. It is usually given in 3 separate doses, by taking the capsule(s) each day, usually once in the morning, once in the afternoon and once in the evening.

Gabapentin Brown & Burk is not recommended for use in children below 6 years of age.

Peripheral Neuropathic Pain, the recommended dose is:

Adults:
Take the number of capsules as instructed by your doctor. Your doctor will usually build up your dose gradually. The starting dose will generally be between 300 mg and 900 mg each day. Thereafter, the dose may be increased as instructed by your doctor, up to a maximum of 3600 mg each day and your doctor will tell you to take this in 3 separate doses, i.e. once in the morning, once in the afternoon and once in the evening.

If you have kidney problems or are receiving haemodialysis
Your doctor may prescribe a different dosing schedule and/or dose if you have problems with your kidneys or are undergoing haemodialysis.

If you are an elderly patient (over 65 years of age),
you should take the normal dose of Gabapentin Brown & Burk unless you have problems with your kidneys. Your doctor may prescribe a different dosing schedule and/or dose if you have problems with your kidneys.

If you have the impression that the effect of Gabapentin Brown & Burk is too strong or too weak, talk to your doctor or pharmacist as soon as possible.

Method of administration

Gabapentin Brown & Burk is for oral use. Always swallow the capsules with plenty of water.

Continue taking Gabapentin Brown & Burk until your doctor tells you to stop.

If you take more Gabapentin Brown & Burk than you should

Higher than recommended doses may result in an increase in side effects including loss of consciousness, dizziness, double vision, slurred speech, drowsiness and diarrhoea. Call your doctor or go to the nearest hospital emergency unit immediately if you take more Gabapentin Brown & Burk than your doctor prescribed. Take along any capsules that you have not taken, together with the container and the label so that the hospital can easily tell what medicine you have taken.

If you forget to take Gabapentin Brown & Burk

If you forget to take a dose, take it as soon as you remember unless it is time for your next dose. Do not take a double dose to make up for a forgotten dose.

If you stop taking Gabapentin Brown & Burk

Do not suddenly stop taking Gabapentin or reduce your dose. If you want to stop taking Gabapentin or reduce your dose, discuss this with your doctor first. They will tell you how to do this, usually by reducing the dose gradually so that any unpleasant withdrawal effects are kept to a minimum. This may occur over a period of weeks to months. Your prescriber will ensure that your plan for stopping treatment is tailored to you and can be adapted according to your needs and experience of any withdrawal symptoms.

Withdrawal symptoms such as: trouble sleeping, headache, nausea, feeling anxious, diarrhoea, flu-like symptoms, convulsions, nervousness, depression, thoughts of harming or killing yourself, pain, sweating, and dizziness.

These effects usually occur within 48 hours after stopping Gabapentin or reducing your dose. If you experience withdrawal effects, you should contact your doctor.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Stop using Gabapentin and seek medical attention immediately if you notice any of the following symptoms:

- reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms (Stevens-Johnsonsyndrome, toxic epidermal necrolysis).
- Widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome).

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

Contact your doctor immediately if you experience any of the following symptoms after taking this medicine as they can be serious:

- anaphylaxis (serious, potentially life threatening allergic reaction including difficulty breathing, swelling of the lips, throat, and tongue, and hypotension requiring emergency treatment)
- severe skin reactions that require immediate attention, swelling of the lips and face, skin rash and redness and/or hair loss (these may be symptoms of a serious allergic reaction);
- persistent stomach pain, feeling sick and being sick as these may be symptoms of acute pancreatitis (an inflamed pancreas).
- Gabapentin Brown & Burk may cause a serious or life-threatening allergic reaction that may affect your skin or other parts of your body such as your liver or blood cells. You may or may not have rash when you get this type of reaction. It may cause you to be hospitalized or to stop Gabapentin Brown & Burk.
- breathing problems, which if severe you may need emergency and intensive care to continue breathing normally.
- suicidal thoughts

Call your doctor right away if you have any of the following symptoms:

- skin rash
- hives
- fever
- swollen glands that do not go away
- swelling of your lip and tongue
- yellowing of your skin or of the whites of the eyes
- unusual bruising or bleeding
- severe fatigue or weakness
- unexpected muscle pain
- frequent infections

These symptoms may be the first signs of a serious reaction. A doctor should examine you to decide if you should continue taking Gabapentin Brown & Burk.

If you are on haemodialysis, tell your doctor if you develop muscle pain and/or weakness.

Other side effects include:

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

- Viral infection.
- Feeling drowsy, dizziness, lack of coordination.
- Feeling tired, fever.

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

- Pneumonia, respiratory infections, urinary tract infection, inflammation of the ear or other infections.
- Low white blood cell counts.
- Anorexia, increased appetite.
- Anger towards others, confusion, mood changes, depression, anxiety, nervousness, difficulty with thinking.
- Convulsions, jerky movements, difficulty with speaking, loss of memory, tremor, difficulty sleeping, headache, sensitive skin, decreased sensation (numbness), difficulty with coordination, unusual eye movement, increased, decreased or absent reflexes.
- Blurred vision, double vision.
- Vertigo.
- High blood pressure, flushing or dilation of blood vessels.
- Difficulty breathing, bronchitis, sore throat, cough, dry nose.
- Vomiting (being sick), nausea (feeling sick), problems with teeth, inflamed gums, diarrhoea, stomach pain, indigestion, constipation, dry mouth or throat, flatulence.
- Facial swelling, bruises, rash, itch, acne.
- Joint pain, muscle pain, back pain, twitching.
- Difficulties with erection (impotence).
- Swelling in the legs and arms, difficulty with walking, weakness, pain, feeling unwell, flu-like symptoms.
- Decrease in white blood cells, increase in weight.
- Accidental injury, fracture, abrasion.

Additionally in clinical studies in children, aggressive behaviour and jerky movements were reported commonly.

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

- Allergic reactions such as hives.
- Decreased movement.
- Racing heartbeat.
- Swelling that may involve the face, trunk and limbs.
- Abnormal blood test results suggesting problems with the liver.
- Mental impairment
- Fall
- Increase in blood glucose levels (most often observed in patients with diabetes)
- Agitation (a state of chronic restlessness and unintentional and purposeless motions)
- Difficulty swallowing

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

- Loss of consciousness
- Decrease in blood glucose levels (most often observed in patients with diabetes)
- Trouble breathing, shallow breaths (respiratory depression)

Not known: frequency cannot be estimated from the available data

- Dependence and addiction (see section "How do I know if I am tolerant or addicted?")

After stopping a short or long-term treatment with Gabapentin or after reducing your dose, you need to know that you may experience certain side effects, so-called withdrawal effects (see "If you stop taking Gabapentin").

After marketing Gabapentin the following side effects have been reported:

- Decreased platelets (blood clotting cells).
- Hallucinations.
- Problems with abnormal movements such as writhing, jerking movements and stiffness.
- Ringing in the ears.
- Yellowing of the skin and eyes (jaundice), inflammation of the liver.
- Acute kidney failure, incontinence.
- Increased breast tissue, breast enlargement.
- Adverse events following the abrupt discontinuation of Gabapentin (anxiety, difficulty sleeping, feeling sick, pain, sweating), chest pain
- Breakdown of muscle fibers (rhabdomyolysis)
- Change in blood test results (creatine phosphokinase increased)
- Problems with sexual functioning including inability to achieve a sexual climax, delayed ejaculation
- Low blood sodium level

Not known: frequency cannot be estimated from the available data

- Worsening of myasthenia gravis (a disease causing muscle weakness)

Drug withdrawal

When you stop taking gabapentin, you may experience drug withdrawal symptoms, which include: trouble sleeping, headache, nausea, feeling anxious, diarrhoea, flu-like symptoms, convulsions, nervousness, depression, thoughts of harming or killing yourself, pain, sweating, and dizziness.

How do I know if I am tolerant or addicted?

If you notice any of the following signs whilst taking Gabapentin, it could be a sign that you have become addicted.

- You may feel the need to keep taking the medication for longer than your doctor recommended
- You feel you need to use more than the recommended dose
- You are using the medicine for reasons other than prescribed
- When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again

If you notice any of these signs, it is important you talk to your prescriber.

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 Yellow Card Scheme at 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 Gabapentin Brown & Burk

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 pack 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 Gabapentin Brown & Burk Capsules contains

The active substance is gabapentin.
Each hard-capsule, contains either 100 mg, 300 mg or 400 mg of gabapentin.

The other ingredients are:

Capsule contents:
Maize starch
Talc

Capsule shell:
Gelatin
Sodium laurilsulfate
100 mg capsules: Titanium dioxide (E171)
300 mg capsules: Titanium dioxide (E171), yellow iron oxide (E172)
400 mg capsules: Titanium dioxide (E171), red and yellow iron oxide (E172)

What Gabapentin Brown & Burk Capsules looks like and contents of the pack

The 100 mg capsules are white hard capsules containing a white crystalline powder. The capsule length is 15.70 mm.

The 300 mg capsules are yellow hard capsules containing a white crystalline powder. The capsule length is 19.00 mm.

The 400 mg capsules are orange hard capsules containing a white crystalline powder. The capsule length is 21.20 mm.

Supplied in blister packs of 10, 20, 28, 30, 50, 60, 84, 90, 98, 100, 200, 500, 1000 capsules.

Also supplied in plastic containers of 300, 400 or 500 capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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