Package leaflet: Information for the user

Neurontin®

100 mg, 300 mg & 400 mg hard capsules

600 mg & 800 mg film-coated tablets

Gabapentin

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 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 Neurontin is and what it is used for

Neurontin belongs to a group of medicines used to treat epilepsy and peripheral neuropathic pain (long lasting pain caused by damage to the nerves).

The active substance in Neurontin is gabapentin.

Neurontin 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 Neurontin to help treat epilepsy when the current treatment is not fully controlling the condition. You or your child 6 years of age and older should take Neurontin in addition to the current treatment unless told otherwise. Neurontin 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 Neurontin

Do not take Neurontin:

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

Warnings and precautions

Talk to your doctor or pharmacist before taking Neurontin

- if you suffer from kidney problems your doctor may prescribe a different dosing schedule
- 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)
- 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
- 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 Neurontin

Dependence
Some people may become dependent on Neurontin (a need to keep taking the medicine). They may have withdrawal effects when they stop using Neurontin (see section 3, "How to take Neurontin" and "If you stop taking Neurontin"). If you have concerns that you may become dependent on Neurontin, it is important that you consult your doctor.
If you notice any of the following signs whilst taking Neurontin, 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.

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 Neurontin

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 Neurontin. In addition, combination of Neurontin with opioids may cause sleepiness, sedation, decrease in breathing, or death.

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

Neurontin
- 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.

Neurontin with food

Neurontin 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
Neurontin can be used during the first trimester of pregnancy if needed.

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.

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.

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 Neurontin. 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 Neurontin, is passed on through human milk. Because the effect on the baby is unknown, it is not recommended to breast-feed while using Neurontin.

Fertility
There is no effect on fertility in animal studies.

Driving and using machines

Neurontin 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.

Neurontin contains lactose

Neurontin hard capsules contain lactose (a type of sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Neurontin contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per 100 mg, 300 mg and 400 mg hard capsules, that is to say essentially 'sodium-free'.

3. How to take Neurontin

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 or tablets 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 per day. It is usually given in 3 separate doses, by taking the capsule(s) or tablet(s) each day, usually once in the morning, once in the afternoon and once in the evening.

Neurontin 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 or tablets 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 Neurontin 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 Neurontin is too strong or too weak, talk to your doctor or pharmacist as soon as possible.

Method of administration

Neurontin is for oral use. Always swallow the capsules or tablets with plenty of water.

The tablet can be divided into equal halves.

Continue taking Neurontin until your doctor tells you to stop.

If you take more Neurontin 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 Neurontin than your doctor prescribed. Take along any capsules or tablets 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 Neurontin

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 Neurontin

Do not suddenly stop taking Neurontin. If you want to stop taking Neurontin, discuss this with your doctor first. They will tell you how to do this. If your treatment is stopped it should be done gradually over a minimum of 1 week. After stopping a short or long-term treatment with Neurontin, you need to know that you may experience certain side effects, so-called withdrawal effects. These effects can include seizures, anxiety, difficulty sleeping, feeling sick (nausea), pain, sweating, shaking, headache, depression, feeling abnormal, dizziness, and feeling generally unwell. These effects usually occur within 48 hours after stopping Neurontin. 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

Like all medicines, this medicine can cause side effects, although not everybody gets them.
Stop using Neurontin 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-Johnson-syndrome, toxic epidermal necrolysis).**
- **Widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome).**

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

- **persistent stomach pain, feeling sick and being sick as these may be symptoms of acute pancreatitis (an inflamed pancreas)**
- **breathing problems, which if severe you may need emergency and intensive care to continue breathing normally**
- **Neurontin 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 Neurontin. Call your doctor right away if you have any of the following symptoms:**
    - **skin rash and redness and/or hair loss**
    - **hives**
    - **fever**
    - **swollen glands that do not go away**
    - **swelling of your lip, face 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 Neurontin.

- 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)

- Agitation (a state of chronic restlessness and unintentional and purposeless motions)
- Allergic reaction such as hives
- Decreased movement
- Racing heartbeat
- Difficulty swallowing
- 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)

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

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

After marketing Neurontin the following side effects have been reported:

- Decreased platelets (blood clotting cells)
- Suicidal thoughts, 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
- Anaphylaxis (serious, potentially life threatening allergic reaction including difficulty breathing, swelling of the lips, throat, and tongue, and hypotension requiring emergency treatment)
- Becoming dependent on Neurontin ('drug dependence')

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

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 Neurontin

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. The expiry date refers to the last day of that month.

Do not store Neurontin hard capsules above 30°C.
Do not store Neurontin film-coated tablets above 25°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 Neurontin contains

Neurontin hard capsules

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

The other ingredients in Neurontin capsules are:
Capsule contents: lactose monohydrate, maize starch, and talc.
Capsule shell: gelatin, purified water and sodium laurilsulfate.

The 100 mg capsules contain the colouring E171 (titanium dioxide), the 300 mg capsules contain the colourings E171 (titanium dioxide) and E172 (yellow iron oxide) and the 400 mg capsules contain the colourings E171 (titanium dioxide) and E172 (red and yellow iron oxide). The printing ink used on all capsules contains shellac, E171 (titanium dioxide) and E132 (indigocarmine aluminium salt).

Neurontin film-coated tablets
The active substance is gabapentin. Each film-coated tablet contains either 600 mg or 800 mg gabapentin.

The other ingredients in Neurontin film-coated tablets are:
Poloxamer 407 (ethylene oxide and propylene oxide), copovidone, maize starch and magnesium stearate.
Fim-coating: Opadry white YS-1-18111 (hydroxypropylcellulose, talc)
Polishing agent: candelilla wax

What Neurontin looks like and contents of the pack

The 100 mg capsules are white hard capsules marked with "Neurontin 100mg" and “PD”.
The 300 mg capsules are yellow hard capsules marked with "Neurontin 300mg" and “PD”.
The 400 mg capsules are orange hard capsules marked with "Neurontin 400mg" and “PD”

Supplied in PVC/PVDC/aluminium foil blister packs of 20, 30, 50, 60, 84, 90, 98, 100, 200, 500, 1000 capsules.

Not all pack sizes may be marketed.

The 600 mg tablets are white, elliptical film-coated tablets with a bisecting score on both sides and debossed with “NT” and “16” on one side.

The 800 mg tablets are white, elliptical film-coated tablets with a bisecting score on both sides and debossed with “NT” and “26” on one side.

Supplied in PVC/PE/PVDC/aluminium foil blister packs or PVC/PVDC/aluminium foil blister packs of 20, 30, 45, 50, 60, 84, 90, 100, 200, 500 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Upjohn EESV
Rivium Westlaan 142
2909 LD Capelle aan den IJssel
Netherlands

Manufacturer
Pfizer Manufacturing Deutschland GmbH
Betriebsstätte Freiburg
Mooswaldallee 1
D-79090 Freiburg
Germany

Neurontin hard capsules are authorised in the following Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the trade name Neurontin:

Austria, Belgium/Luxembourg, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Netherlands, Norway, Poland, Portugal, Slovenia, Spain, Sweden, United Kingdom (Northern Ireland)

Neurontin film-coated tablets are authorised in the following Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the trade name Neurontin:

Austria, Belgium/Luxembourg, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Latvia, Netherlands, Norway, Poland, Portugal, Slovenia, Spain, Sweden, United Kingdom (Northern Ireland)

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