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

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
A small number of people taking Neurontin get an allergic reaction or potentially serious skin reaction, which may develop into more serious problems if they are not treated. You need to know the symptoms to look out for while you are taking Neurontin.

Read the description of these 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 discolouration 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 breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy
Neurontin 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.

There have been no studies specifically looking at the use of gabapentin in pregnant women, but other medications used to treat seizures have reported an increased risk of harm to the developing baby, particularly when more than one seizure medication is taken at the same time. Therefore, whenever possible you should try to take only one seizure medication during pregnancy and only under the advice of your doctor.
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.

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.

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 stop taking Neurontin unless your doctor tells you to. If your treatment is stopped it should be done gradually over a minimum of 1 week. If you stop taking Neurontin suddenly or before your doctor tells you, there is an increased risk of seizures.

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.

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

- **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)**
- **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 hospitalised or to stop Neurontin. 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 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)
– Hallucinations
– Problems with abnormal movements such as writhing, jerking movements and stiffness
– Ringing in the ears
– A group of side effects that could include swollen lymph nodes (isolated small raised lumps under the skin), fever, rash, and inflammation of liver occurring together
– 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)

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 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 and blister after ΛΗΞΗ or EXP or CAD. The expiry date refers to the last day of that month.

Do not store Neurontin hard capsules above 25 °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 100 mg hard capsules are Capsule contents: lactose monohydrate, maize starch, talc. Capsule shell: gelatin, sodium laurilsulfate, titanium dioxide (E171). Printing ink: shellac, titanium dioxide (E171), indigo carmine (E132).
The other ingredients in Neurontin 300 mg hard capsules are lactose monohydrate, maize starch, talc, gelatin, titanium dioxide (E171) and yellow iron oxide (E172). Product imported from the United Kingdom and Spain also contains sodium laurilsulfate, water, shellac and indigo carmine.
The other ingredients in Neurontin 400 mg hard capsules for product imported from Greece and the United Kingdom are lactose monohydrate, maize starch, talc, gelatin, titanium dioxide (E171), yellow iron oxide (E172), red iron oxide (E172). Product imported from the United Kingdom also contains sodium laurilsulfate, shellac and indigo carmine.
The other ingredients in product imported from Spain are lactose monohydrate, maize starch and talc.

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.

Film-coating: Opadry white YS-1-18111 (hydroxypropylcellulose, talc)

Polishing agent: candelilla wax

What Neurontin looks like and contents of the pack

Hard capsules
Neurontin 100 mg hard capsules – white hard capsules, marked with ‘Neurontin 100mg’ and ‘PD’.
Neurontin 300 mg hard capsules - yellow hard capsules marked with ‘Neurontin 300mg’ And ‘PD’.
Neurontin 400 mg hard capsules – orange hard capsules, marked with ‘Neurontin 400mg’ and ‘PD’.

Film-coated tablets

Neurontin 600 mg film-coated tablets – white, elliptical film-coated tablets with a bisecting score on both sides and debossed with “NT” and “16” on one side. The tablets can be divided into equal doses.
Neurontin 800 mg film-coated tablets - white, elliptical film-coated tablets with a bisecting score on both sides and debossed with “NT” and “26” on one side.
Pack size: Neurontin 100 mg hard capsules are available in blisters of 90 and 100 hard capsules. Neurontin 300 mg and 400 mg hard capsules are available in blisters of 50, 90 and 100 hard capsules. Neurontin 600 mg and 800 mg film-coated tablets are available in blisters of 90 and 100 film-coated tablets. Not all pack sizes may be marketed.
Product procured from within the EU, repackaged and distributed by the parallel product authorisation holder who is: PCO Manufacturing Ltd., Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath, Ireland.

Manufacturer

Neurontin 100 mg, 400 mg hard capsules and 600 mg and 800 mg film-coated tablets: Pfizer Manufacturing Deutschland GmbH, Betriebsstätte Freiburg, Mooswaldallee 1,

D-79090, Freiburg Germany.

Neurontin 300 mg hard capsules and 600 mg film-coated tablets: Gödecke GmbH or Pfizer Manufacturing Deutschland GmbH, Betriebsstätte Freiburg, Mooswaldallee 1,

D-79090, Freiburg, Germany.

Product Authorisation Number:
Neurontin 100 mg hard capsules: PPA 465/97/3
Neurontin 300 mg hard capsules: PPA 465/97/1
Neurontin 400 mg hard capsules: PPA 465/97/2
Neurontin 600 mg film-coated tablets: PPA 465/97/4
Neurontin 800 mg film-coated tablets: PPA 465/97/5

Neurontin is a registered trademark of Warner-Lambert Company LLC.

Neurontin hard capsules and film-coated tablets are authorised in the following Member States of the EEA under the trade name Neurontin:

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

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