Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a doctor's prescription only

Neurontin® 300 mg Capsules

Composition
Each capsule contains:
gabapentin 300 mg

Neurontin® 400 mg Capsules

Composition
Each capsule contains:
gabapentin 400 mg

Inactive ingredients and allergens: see section 2 under 'Important information about some of this medicine's ingredients' and section 6 'Further information'.

Read the entire leaflet carefully before using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

This medicine is indicated for the treatment of epilepsy in adults and adolescents over 12 years of age. This medicine is indicated for the treatment of neuropathic pain in adults over 18 years of age.

1. WHAT IS THIS MEDICINE INTENDED FOR?

- **Epilepsy:**
  As adjunctive therapy in the treatment of partial seizures, with and without secondary generalization, in adults and adolescents (age 12 and up) with epilepsy.
- **Neuropathic pain:**
  For the treatment of neuropathic pain in diabetic neuropathy or postherpetic neuropathy (neuralgia) in adults.

Therapeutic group:
Anticonvulsant.

- Your doctor will prescribe Neurontin® for you to help treat epilepsy when the current treatment is not fully controlling your condition.
- Your doctor will prescribe Neurontin® to treat neuropathic pain (chronic pain due to damage to the nerves) following shingles or diabetes in adults.
  Pain sensations may be described as:
  hot, burning, throbbing, shooting, stabbing, sharp, cramping, tingling, numbness, pins and needles, etc.

2. BEFORE USING THIS MEDICINE

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient (gabapentin) or to any of the other ingredients in this medicine (see section 6).

Special warnings regarding use of the medicine

Before treatment with Neurontin®, tell your doctor if:
- You are pregnant or breastfeeding. See 'Pregnancy, breastfeeding and fertility' under section 2.
- You suffer from kidney problems, your doctor may prescribe a different dosing schedule.
- You are on haemodialysis (to remove waste products because of kidney failure). Tell your doctor if you develop muscle pain and/or weakness.
- 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.
- You suffer from a disturbance of various types of seizures, including "absence" seizures.
- 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 Neurontin® in post-marketing studies. 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 Neurontin® have had thoughts of harming or killing themselves. If 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 serious skin reaction, which may develop into a more serious problem if they are not treated. You need to know the symptoms so that you can recognize them while you are being treated with Neurontin®.

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

Contact your doctor immediately in case of muscle weakness, tenderness or pain and particularly, if at the same time, you feel unwell or have a high temperature. These may be signs of abnormal muscle breakdown which can be life-threatening and lead to kidney problems. You may also have discoloration of your urine and a change in blood test results (increase in blood creatine phosphokinase levels).

Other medicines and Neurontin®
If you are taking or have recently taken other medicines, including nonprescription medicines and dietary supplements, tell your doctor or pharmacist.
Particularly if you are taking or have been recently taking:
- any medicines for convulsions, sleeping disorders, depression, anxiety, or any neurological or psychiatric problems.
- Opioid medicines such as morphine - they may increase the effect of Neurontin®. In addition, combination of Neurontin® with opioids may cause sleepiness, sedation, decrease in breathing rate, or death.
- Neurontin® and antacids containing aluminium and magnesium taken at the same time, may reduce absorption of Neurontin® from the stomach. It is therefore recommended that Neurontin® is taken at the earliest two hours after taking antacids.

Neurontin® is not expected to affect the action of other antiepileptic medicines or oral contraceptive pills.
Neurontin® may interfere with the results of certain laboratory tests. If you need to provide a urine test, tell your doctor or the medical staff what medicines you are taking.

Using this medicine and food

The medicine may be used with or without food.

Pregnancy, breastfeeding and fertility
Before taking this medicine, consult your doctor if you are pregnant or breastfeeding, think you may be pregnant or are planning to become pregnant.

Pregnancy
Do not take Neurontin® during pregnancy, unless you are told otherwise by your doctor. Effective contraception must be used by women of child-bearing potential while being treated with this medicine.

There have been no studies on the use of the medicine in pregnant women. However, when other medications have been used to treat seizures, an increased risk of harm to the developing baby have been reported, 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 this medicine. 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.

Breastfeeding
Neurontin® is passed on through human milk. Because its effect on the baby is unknown, it is not recommended to breastfeed while taking Neurontin®.

Fertility
No effect on fertility was found in animal studies.

Driving and using machines
Use of this medicine may produce dizziness, drowsiness and tiredness. You should not drive, operate machinery or take part in other potentially hazardous activities until you know how this medicine affects you and your ability to perform these activities.

Important information about some of this medicine's ingredients
This medicine contains 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 medicine.
This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say it is considered sodium free.

3. HOW TO USE THIS MEDICINE?
Always use this medicine according to your doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the medicine.
The dosage and treatment regimen will be determined by your doctor only.
The standard dosage is:
Take this medicine at set times, as determined by your doctor.
The dosage determined for you by your doctor will generally be built up gradually. The starting dosage is between 300 mg and 900 mg each day. Thereafter, the dosage may be increased as instructed by your doctor, up to a maximum daily dosage of 3600 mg, divided into in 3 separate doses, i.e. once in the morning, once in the afternoon and once in the evening.

This medicine is indicated for the treatment of epilepsy in adults, adolescents and children over 12 years of age.
This medicine is indicated for the treatment of neuropathic pain in adults over 18 years of age.

If you have kidney problems or are receiving haemodialysis

Your doctor may prescribe a different dosage and/or dosing schedule.

If you are over 65 years of age
You should take the standard dosage of Neurontin® unless you have problems with your kidneys. Your doctor may prescribe you a different dosage and/or dosing schedule if you have kidney problems.

If you have the impression that the effect of the medicine is too strong or too weak, contact your doctor or pharmacist immediately.

Do not exceed the recommended dose.
Always swallow the tablets whole with plenty of water.
Do not open and sprinkle the content of the capsule, because the effect of these forms of administration has not been tested.
It recommended that Neurontin® be taken at the earliest two hours after taking antacids.

Continue taking Neurontin® until your doctor tells you to stop.

If you have accidentally taken a higher dosage
If you have taken an overdose, or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.
Taking an overdose may cause an increase in side effects, including loss of consciousness, dizziness, double vision, slurred speech, drowsiness and diarrhoea.

If you forget to take the medicine
If you forget to take this medicine at the schedule time, take a dose as soon as you remember unless it is time for your next dose. Under no circumstances should you take a double dose to make up for the forgotten dose.

Adhere to the treatment as recommended by your doctor.

Even if your health improves, do not stop taking this medicine without consulting your doctor.

Do not stop taking this medicine unless your doctor tells you to. If you are required to stop the treatment, it should be done gradually over a minimum of one week. If you stop taking this medicine suddenly or before being instructed to do so by your doctor, there is an increased risk of seizures.

Do not take medicines in the dark! Check the label and dose each time you take medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. SIDE EFFECTS
As with any medicine, use of Neurontin® may cause side effects in some users. Do not be alarmed by this list of side effects. You may not experience any of them.

Contact your doctor immediately if you experience any of the following symptoms after taking this medicine as they can be serious:
- Severe allergic skin reaction that requires immediate treatment, 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.

- Breathing problems, which if severe you may need emergency treatment 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. A rash may or may not appear as part of this reaction. You may need to be hospitalized or stop taking Neurontin® as a result of this reaction. 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 lips and tongue
    - Yellowing of your skin or the whites of the eyes
    - Appearance of 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 can continue taking the medicine.
- If you are on haemodialysis, tell your doctor if you develop muscle pain and/or weakness.

Additional side effects:

Very common side effects (affect more than 1 in 10 people):
- Viral infection
- Feeling drowsy, dizziness, lack of coordination
- Feeling tired, fever

Common side effects (affect up to 1 in 10 people):
- Pneumonia, respiratory infections, urinary tract infections, 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, numbness, difficulty with coordination, unusual eye movements, increased, decreased or absent reflexes
- Blurred vision, double vision
- Dizziness (vertigo)
- High blood pressure, flushing or dilation of blood vessels
- Difficulty breathing, bronchitis, sore throat, cough, dry nose
- Vomiting, nausea, 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
- Impotence in men
- 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

Uncommon side effects (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 indicating problems with the liver
- Mental impairment
- Falls
- Increase in blood glucose level (most often observed in patients with diabetes)

Rare side effects (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)

Side effects reported after marketing of the medicine and the frequency of which is unknown

- Decreased platelet level
- 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, 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
- Side effects following the abrupt discontinuation of treatment with Neurontin® (anxiety, difficulty sleeping, feeling sick, pain, sweating), chest pain
- Breakdown of muscle fibers (rhabdomyolysis)
- Change in blood test results (creatine phosphokinase levels increased)
- Problems with sexual functioning including inability to achieve a sexual climax, delayed ejaculation
- Low blood sodium level
- Anaphylaxis (serious and life-threatening allergic reaction, including difficulty breathing, swelling of the lips, throat, and tongue, and hypotension requiring emergency treatment)

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the link ‘Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects or by using the link:
https://sideeffects.health.gov.il

5. HOW TO STORE THE MEDICINE?

- Store the medicine in a dry place, below 25ºC.
- Prevent poisoning! This and any other medicine should be kept in a closed place, out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.

6. FURTHER INFORMATION

In addition to the active ingredient, this medicine also contains:
Neurontin® 300 mg:
Capsule content: lactose monohydrate, maize corn starch, talc.
Capsule shell: gelatin, water, titanium dioxide (E171), yellow iron oxide (E172), sodium lauryl sulphate.
Printing Ink: shellac, titanium dioxide (E171), indigocarmine aluminium salt (E132).

Neurontin® 400 mg:
Capsule content: lactose monohydrate, maize corn starch, talc.
Capsule shell: gelatin, water, titanium dioxide (E171), yellow iron oxide (E172), red iron oxide (E172), sodium lauryl sulphate.
Printing Ink: shellac, titanium dioxide (E171), indigocarmine aluminium salt (E132).

The medicine contains lactose monohydrate:
Neurontin® 300 mg: 42.75 mg
Neurontin® 400 mg: 57 mg

What the medicine looks like and contents of the pack:
Neurontin® 300 mg: a yellow capsule with “Neurontin 300” imprinted on the upper part and “PD” on the lower part.
Neurontin® 400 mg: an orange capsule with “Neurontin 400” imprinted on the upper part and “PD” on the lower part.

The medicine is marketed in packages of 10, 50 and 100 capsules. Not all pack sizes may be marketed.

Registration holder and address: Pfizer PFE Pharmaceuticals Israel Ltd., 9 Shenkar St., Herzliya Pituach 46725.

Registration number of the medicine in the Ministry of Health’s National Drug Registry:
Neurontin® 300 mg: 125.05.30497
Neurontin® 400 mg: 125.06.30498

Revised in 08/2021 according to MOH guidelines.