Patient package insert according to Pharmacists' Regulations (Preparations) - 1986
This medicine can be sold with a physician's prescription only

Neurontin® 300, 400 mg, Capsules

Each capsule contains gabapentin 300 or 400 mg respectively.

Inactive ingredients and allergens in the medicine - see section 6 "Additional information" and in section 2 "Important information about some of the ingredients of the medicine".

Read this entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have any further questions, ask the doctor or pharmacist.
This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if you think that their medical condition is similar to yours.

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

1. What is the medicine intended for?

Epilepsy: For adjunctive therapy in the treatment of partial seizures, with or without secondary generalization, in adults and adolescents (aged 12 and up) with epilepsy.
Neuropathic pain: For the treatment of neuropathic pain in diabetic neuropathy or postherpetic neuropathy (neuralgia) in adults.
Therapeutic group: Belongs to a group of medicines used to treat epilepsy and peripheral neuropathic pain (prolonged pain caused by damage to the nerves).
The doctor will prescribe you **Neurontin** to help treat epilepsy when your current treatment does not allow full control of your condition.

The doctor will prescribe you **Neurontin** to treat neuropathic pain (chronic pain caused by damage to the nerves) after shingles or diabetes in adults.
Pain sensations can be described as a sensation of heat, a burning sensation, throbbing pain, sudden pain, a stabbing sensation, sharp pain, cramps, a tingling sensation, numbness, a "pins and needles" sensation, etc.

2. Before using the medicine

Do not use the medicine if:

You are hypersensitive (allergic) to the active ingredient (gabapentin), or to any of the other ingredients this medicine contains (see section 6).

Special warnings regarding the use of the medicine
Before treatment with Neurontin, tell the doctor if:

- You suffer from kidney problems, the doctor may change the treatment plan.
- You are treated with haemodialysis (to remove waste products due to kidney failure). Tell the doctor if you develop pain and/or muscle weakness.
- You develop symptoms such as persistent abdominal pain, nausea and vomiting. Refer to a doctor immediately, as these may be symptoms of acute pancreatitis.
- You have nervous system disorders, respiratory disorders, or you are over 65 years of age. Your doctor may prescribe you a different dosage regimen.
- You have ever abused or had a dependence on alcohol, prescription medications or illegal drugs; you may have an increased risk of developing a dependence on **Neurontin**.

Medicine dependence
Some people may develop a dependence on **Neurontin** (a need to keep taking the medicine). Withdrawal symptoms may appear when the medicine is discontinued (see Section 3 – "How to use the medicine" in the section "If you stop taking the medicine").
If you have concerns about the possibility of developing **Neurontin** dependence, it is important that you consult a doctor.
If you notice any of the following symptoms during treatment, you may have developed a dependence on the drug:
- You feel the need to take the medicine for longer than recommended by the doctor.
- You feel the need to take a higher dosage than recommended.
- You are using the medicine for purposes other than those prescribed for you.
- You have tried unsuccessfully to stop using the medicine or to control the dosage.
- You feel ill when you stop taking the medicine, and feel better when you start taking it again.

If you notice any of these signs - contact the doctor to discuss appropriate treatment options, including when and how to stop the treatment safely.

A small number of patients treated with anti-epileptic drugs such as **Neurontin** have experienced suicidal thoughts or thoughts of harming themselves. Contact the doctor immediately if you have such thoughts.

Important information about potentially serious reactions

There have been reports of severe skin rashes, including Stevens-Johnson Syndrome, Toxic Epidermal Necrolysis and Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) in association of gabapentin. Stop the use of gabapentin and immediately seek medical attention if you notice any of the symptoms related to the severe skin reactions described in section 4.

Read the description of severe symptoms in section 4 in the subsection "Refer to a doctor immediately if you experience any of the following symptoms after taking the medicine as they may be severe".

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

Drug Interactions
If you are taking or have recently taken other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. Especially if you are taking or have recently taken:
- Medicines for seizures, sleep disorders, depression, anxiety or any other neurological or psychiatric problems.
- Opioid medicines such as morphine – these may increase the effect of **Neurontin**. In addition, combination of **Neurontin** with opioids may cause drowsiness, fatigue (sedation), decreased breathing rate, or death.
- Antacids containing aluminium and magnesium - taken at the same time with **Neurontin,** may reduce absorption of **Neurontin** from the stomach. It is therefore recommended that **Neurontin** is taken at least two hours after taking antacids.

Neurontin is not expected to affect the action of other anti-epileptic medicines or oral contraceptive pills.

Neurontin may affect the results of certain laboratory tests. If you are required to provide a urine test, tell
the doctor or medical staff about the medicines you are taking.

Use of the medicine and food
The medicine can be taken with or without food.

Pregnancy, breastfeeding and fertility
- If you are pregnant or think you may be pregnant, contact the doctor immediately and discuss the potential risks that the medication might pose to the foetus.
- Do not stop the treatment without consulting a doctor.
- If you are planning to become pregnant, you should consult your doctor as early as possible before you become pregnant.
- If you are breastfeeding or are planning to breastfeed, consult your doctor before taking this medicine.

Pregnancy
Neurontin may be used during the first trimester of pregnancy if necessary.
If you are planning to become pregnant, if you are pregnant or think you may be pregnant, speak with your doctor immediately.
If you become pregnant and have epilepsy, it is important that you do not stop taking the medicine without first consulting your doctor, as this may worsen your disease and lead to a renewed outbreak of seizures. Worsening of your epilepsy may put you and your foetus at risk.

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

When used during pregnancy, **g**abapentin may lead to withdrawal symptoms in newborn babies. This risk may increase when gabapentin is taken together with opioid painkillers (medicines for treatment of severe pain).

Breastfeeding
Gabapentin, the active ingredient in **Neurontin**, passes into breast milk. Because its effect on the baby is unknown, it is recommended not to breastfeed while taking the medicine.

Fertility
Animal studies have not found any effect on fertility.

Driving and using machines
Use of this medicine may cause dizziness, drowsiness and fatigue. You should avoid driving, using machines, or engaging in other potentially hazardous activities until you know how the medicine affects you and your ability to perform these activities.
As for children, they should be warned against riding bicycles or playing near the road, etc.

Important information about some of the ingredients of the medicine
Neurontin contains lactose. If you have been told by the doctor that you have an intolerance to certain sugars, consult the doctor before taking this medicine.
This medicine contains less than 1 millimole of sodium (23 mg) per capsule, that is to say, essentially "sodium-free".

3. How to use the medicine?

Always use the medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are not sure about the dosage and the manner of treatment with the medicine.
The dosage and manner of treatment will be determined by the doctor only.

The usual recommended dosage is:
Use this medicine at regular intervals as prescribed by the doctor.
The dosage determined for you by the doctor will usually be given gradually. The initial dosage is between 300 mg and 900 mg per day. Thereafter, the doctor may instruct you to increase the dosage, up to a maximum daily dose of 3600 mg, divided into 3 separate doses, i.e., once in the morning, once in the afternoon and once in the evening.

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

If you suffer from kidney problems or are treated with haemodialysis
Your doctor may prescribe you a different dosage and/or a different dosage regimen.

If you are over 65 years old
You should take the standard dosage of **Neurontin** unless you suffer from kidney problems. Your doctor may prescribe you a different dosage and/or different dosage regimen if you suffer from 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.

Method of administration
The capsule should always be swallowed whole with plenty of water.
Do not open and sprinkle the content of the capsule, because the effect of this form of administration has not been tested.
It is recommended that **Neurontin** be taken at least two hours after taking antacids.

Continue taking **Neurontin** until your doctor instructs you to stop.

If you have accidentally taken a higher dosage
If you have accidentally taken an overdose or if a child has accidentally swallowed the medicine, proceed immediately to a doctor or a hospital emergency room and bring the package of the medicine 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 forgot to take the medicine
If you forgot to take this medicine at the designated time, take a dose as soon as you remember, unless it is time for the next dose. Under no circumstances should you take a double dose to make up for a forgotten dose.

Continue with the treatment as recommended by the doctor.

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

If you stop taking the medicine

Do not stop taking the medicine unless instructed by your doctor. If you are required to stop the treatment, it should be done gradually over at least one week. If you stop taking the medicine suddenly or before being instructed to do so by your doctor, the risk of seizures increases. After stopping short or long-term treatment with **Neurontin**, you may experience certain side effects, called withdrawal effects. These effects may include seizures, anxiety, difficulty sleeping, nausea, pain, sweating, tremor, headache, depression, feeling odd, dizziness, and a general sense of being ill. These effects usually appear within 48 hours after stopping the medicine. If you experience withdrawal symptoms, you should contact your doctor.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.
If you have further questions on the use of this medicine, consult a doctor or pharmacist.

4. Side effects

Like any medicine, the use of **Neurontin** may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Stop taking this medicine and refer to the doctor immediately if you experience any of the following symptoms:

- **Non-elevated, target-like or circular reddish patches on the trunk, often with central blisters, skin peeling, ulcers of the mouth, throat, nose, genitals, and eyes. These severe 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 - drug hypersensitivity syndrome).**

Refer to a doctor immediately if you experience any of the following symptoms after taking the medicine, as they may be severe:

- **Persistent abdominal pain, nausea and vomiting - as these may be symptoms of acute pancreatitis.**
- **Breathing problems, in severe cases you may need emergency treatment to continue breathing normally.**
- **Neurontin may cause a severe or life-threatening allergic reaction that may affect the skin or other parts of the body, such as the liver or blood cells. A rash may or may not appear as part of this reaction. As a result of this reaction, you may have to be hospitalized or stop taking Neurontin. Contact your doctor immediately if you experience any of the following symptoms:**
  - **Skin rash and redness and/or hair loss**
  - **Urticaria**
  - **Fever**
  - **Swelling of the glands that does not go away**
  - **Swelling of the lips, face, and tongue**
  - **Yellowing of the 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 severe reaction. A doctor should examine you and 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 (effects that occur in more than one in ten users):
- Viral infection
- Feeling drowsy, dizziness, lack of coordination
- Feeling tired, fever

Common side effects (effects that occur in 1-10 out of 100 users):
- Pneumonia, respiratory tract infections, urinary tract infections, ear infections, or other infections
- Low white blood cell count
- Anorexia, increased appetite
- Anger towards others, confusion, mood changes, depression, anxiety, irritability, difficulty thinking
- Seizures, involuntary movements, difficulty speaking, memory loss, tremor, difficulty sleeping, headache, sensitive skin, numbness, coordination difficulties, 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, dental problems, inflamed gums, diarrhoea, abdominal pain, indigestion, constipation, dry mouth or throat, flatulence
- Facial swelling, bruising, rash, itching, acne
- Joint pain, muscle pain, back pain, cramps
- Impotence in men
- Swelling of the legs and arms, difficulty walking, weakness, pain, feeling ill, flu-like symptoms
- Decreased white blood cell count, weight gain
- Accidental injury, fracture, abrasion
- In clinical studies in children, aggressive behaviour and jerky movements have been reported

Uncommon side effects (effects that occur in 1-10 out of 1,000 users):
- Agitation (a state of chronic restlessness and unintentional, aimless movements)
- Allergic reaction such as urticaria
- Decreased movement
- Rapid pulse
- Difficulty swallowing
- Swelling that may involve the face, body and limbs
- Abnormal blood test results indicating liver problems
- Mental problems
- Falls
- Increase in blood glucose levels (usually observed in patients with diabetes)

Rare side effects (effects that occur in 1-10 out of 10,000 users):
- Decrease in blood glucose levels (usually observed in patients with diabetes)
- Loss of consciousness
- Difficulty breathing, shallow breathing (respiratory depression)

Side effects reported after marketing of the medicine, frequency of which is unknown (effects for which a frequency has not yet been determined):
- Decrease in blood platelet levels
- Suicidal thoughts, hallucinations

- Abnormal body movements such as writhing, involuntary movements, and rigidity
- Ringing in the ears
- Yellowing of the skin and the whites of the eyes (jaundice), hepatitis
- Acute renal failure, urinary incontinence
- Breast tissue enlargement, breast enlargement
- Side effects following abrupt discontinuation of gabapentin (anxiety, difficulty sleeping, nausea, pain, sweating), chest pain
- Breakdown of muscle fibers (rhabdomyolysis)
- Changes in blood test results (increased creatine phosphokinase levels)
- Sexual dysfunction including inability to reach sexual climax, delayed ejaculation
- Low blood sodium level
- Anaphylaxis (a severe, life-threatening allergic reaction, which includes difficulty breathing, swelling of the lips, throat, and tongue, and low blood pressure that requires emergency treatment)
- Developing dependence on **Neurontin** (medicine dependence)

After stopping short or long-term treatment with **Neurontin**, you may experience certain side effects, called withdrawal effects (see "If you stop taking the medicine").

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in this leaflet, consult the doctor.

Side effects can be reported to the Ministry of Health by clicking the link "דיווח על תופעות לוואי עקב טיפול תרופתי" found on the home page of the Ministry of Health website (www.health.gov.il) directing to the online form for reporting side effects, or via the link: https://sideeffects.health.gov.il

5. How to store the medicine?

- Avoid poisoning! This medicine and any other medicine must be stored 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 the doctor.
- Do not use the medicine after the expiry date (Exp.) stated on the package. The expiry date refers to the last day of that month.
- **Storage conditions**: The medicine should be stored in a dry place, below 25ºC.
- Do not throw away any medicines via wastewater or household waste. Ask the pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Additional information

In addition to the active ingredient, the medicine also contains:
Gelatin, lactose monohydrate, maize starch, talc, water, titanium dioxide (E171), yellow iron oxide (E172), sodium lauryl sulphate, shellac, indigocarmine aluminium salt (E132).

Neurontin 400 mg capsules also contain: Red iron oxide (E172)

What the medicine looks like and what the package contains:
Neurontin 300 mg: Yellow coloured capsule with "Neurontin 300" printed on the upper part and "VLE" on the lower part.
Neurontin 400 mg: Orange coloured capsule with "Neurontin 400" printed on the upper part and "VLE" on the lower part.
Approved package sizes: 10, 50 and 100 capsules. Not all package sizes may be marketed.

Revised in July 2025 according to MOH guidelines.

Drug registration number at the national drug registry of the Ministry of Health:
Neurontin 300 mg: 125-05-30497-00
Neurontin 400 mg: 125-06-30498-00

Manufacturer and Registration Holder: Dexcel Ltd., 1 Dexcel St., Or Akiva 3060000, Israel