

## PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed with a doctor's prescription only

Name of the medicine, its form and strength

# Gabapentin Inovamed 300 mg

Capsules

Each capsule contains:  
Gabapentin 300 mg

# Gabapentin Inovamed 400 mg

Capsules

Each capsule contains:  
Gabapentin 400 mg

For the list of inactive and allergenic ingredients, see section 6. Also see "Important information about some of the ingredients of the medicine" in section 2 of this leaflet.

**Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.**

- Keep the leaflet; you may need it again.
- This medicine has been prescribed to treat you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

**This medicine is intended for treatment of epilepsy in adults and adolescents above 12 years of age.**

**This medicine is intended to treat neuropathic pain in adults from 18 years of age and up.**

## 1. WHAT IS THE MEDICINE INTENDED FOR?

- For treatment of various forms of epilepsy (seizures that are initially limited to certain parts of the brain, whether or not they have spread to other parts of the brain). The doctor will prescribe Gabapentin Inovamed for you to help treat your epilepsy when the current treatment you are receiving does not enable full control of your condition.
- For treatment of neuropathic pain (chronic pain caused by nerve damage) after herpes or due to diabetes in adults. Pain sensations may be described as:  
Sensation of heat, burning sensation, throbbing pain, shooting sensation, stabbing sensation, sharp pain, cramps, tingling sensation, numbness, sensation of pins and needles, and the like.

**Therapeutic group:** Anticonvulsants.

## 2. BEFORE USING THE MEDICINE

**Do not use the medicine if:**

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

## Special warnings regarding use of the medicine

**Before treatment with Gabapentin Inovamed, tell the doctor:**

- If you are pregnant or breastfeeding. See "Pregnancy, breastfeeding and fertility" under section 2.
- If you are suffering from kidney problems, your doctor may alter the treatment plan.
- If you are being treated with hemodialysis (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, nausea and vomiting, refer to your doctor immediately as these may be symptoms of acute pancreatitis.
- If you are suffering from a disturbance of various types of seizures, including "absence" seizures.
- If you have nervous system disorders, respiratory disorders, or you are over the age of 65, your doctor may prescribe a different dosing regimen for you.

Incidents of Gabapentin Inovamed dependence and abuse have been reported in post-marketing studies. Tell your doctor if you have a history of dependence or abuse. A small number of patients being treated with antiepileptic medicines, such as Gabapentin Inovamed, experienced suicidal thoughts or thoughts of harming themselves. Refer to your doctor immediately if you have such thoughts.

## Important information regarding possible serious reactions

A small number of patients being treated with Gabapentin Inovamed experience an allergic reaction or a serious skin reaction. These may develop into a more serious problem if they are not treated. You need to be familiar with the symptoms in order to recognize them during treatment with Gabapentin Inovamed.

Read the description of these symptoms in section 4 "Side effects" under "Refer to the doctor immediately if you experience one or more of the following symptoms after taking the medicine, as they can be serious:".

Refer to the doctor immediately in cases of muscle weakness, muscle tenderness or pain and particularly if, at the same time, you feel unwell or have a high fever; these may be signs of abnormal muscle breakdown which can be life-threatening and lead to kidney problems. In addition, your urine may be colorless and there may be changes in blood test results (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.**

In particular if you are taking or have recently taken:

- Medicines for convulsions, sleeping disorders, depression, anxiety, or any other neurological or psychiatric problems.
- Medicines from the opiate family such as morphine - these may increase the effect of Gabapentin Inovamed. In addition, the combination of Gabapentin Inovamed and opiates may cause symptoms such as sleepiness and/or a reduced respiratory rate.
- A combination of Gabapentin Inovamed and antacids that contain aluminum and magnesium may cause a decrease in the absorption of Gabapentin Inovamed from the stomach. It is therefore recommended to take Gabapentin Inovamed at least two hours after taking antacids.

Gabapentin Inovamed is not expected to influence the effect of other antiepileptic medicines or oral contraceptives.

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

## Use of the medicine and food

The capsules can be taken with or without food.

## Pregnancy, breastfeeding and fertility

Before taking the medicine, consult with the doctor if you are pregnant or breastfeeding, if you think you may be pregnant or if you are planning to become pregnant.

### Pregnancy

Do not take Gabapentin Inovamed during pregnancy, unless you have been told otherwise by your doctor. Women of child-bearing age must use effective contraceptives during the course of treatment with the medicine. Studies on the use of this medicine by pregnant women have not been conducted. However, an increased risk of harm to the developing baby has been reported upon use of other medicines to treat seizures, especially when taking more than one medicine to treat seizures at the same time. Therefore, if possible, try to take only one medicine for prevention of seizures during pregnancy, and only as advised by your doctor. Refer to the doctor immediately if you become pregnant during treatment with the medicine, if you think you may be pregnant, or if you are planning to become pregnant while taking the medicine. Do not stop treatment with this medicine abruptly, as this may lead to recurrence of seizures, which may have severe consequences on you and your baby.

### Breastfeeding

Gabapentin Inovamed passes into breast milk. Since its effect on the baby is unknown, it is advisable not to breastfeed while taking Gabapentin Inovamed.

### Fertility

In animal studies no effect on fertility was found.

## Driving and operating machinery

Use of this medicine may cause dizziness, drowsiness and tiredness. You should avoid driving, operating machinery or engaging in other activities that may be dangerous until you know how the medicine affects you and your ability to perform these activities.

**Important information about some of the ingredients of the medicine**

The medicine contains lactose monohydrate:

Each Gabapentin Inovamed 300 mg capsule contains 40 mg lactose monohydrate.

Each Gabapentin Inovamed 400 mg capsule contains 53.3 mg lactose monohydrate.

If you have been told by your doctor that you have an intolerance to certain sugars, refer to your doctor before commencing treatment with the medicine.

## 3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.

The dosage and treatment regimen will be determined by the doctor only.

The usual dosage is:

Use this medicine at specified time intervals, as determined by the attending doctor.

The dosage determined by the doctor will usually be administered gradually. The initial dosage is between 300 mg and 900 mg per day. After that, the doctor may instruct you to increase the dosage up to a maximum daily dosage of 3,600 mg, divided into 3 separate doses, that is, once in the morning, once in the afternoon and once in the evening. This medicine is intended to treat epilepsy in adults, adolescents and children above 12 years of age.

This medicine is intended to treat neuropathic pain in adults from 18 years of age and up.

**If you have kidney problems or are being treated with hemodialysis:** The doctor may prescribe a different dosage and/or dosing regimen for you.

**If you are over 65 years of age:** You should take the normal dose of Gabapentin Inovamed unless you have kidney problems. It is possible that the doctor may prescribe a different dosage and/or dosing regimen for you if you are suffering from kidney problems.

If you feel that the effect of the medicine is too strong or too weak, refer to your doctor or pharmacist immediately.

**Do not exceed the recommended dose.**

Always swallow the capsule whole with a lot of water.

Do not open and disperse the contents of the capsule! This is because the effect of these forms of administration have not been tested.

It is recommended to take Gabapentin Inovamed at least two hours after taking antacids.

Continue taking Gabapentin Inovamed until your doctor instructs you to stop.

## If you accidentally took a higher dosage

If you took an overdose, or if a child has accidentally swallowed the medicine, immediately refer to a doctor or proceed to a hospital emergency room and bring the package of medicine with you.

Taking an overdose may cause an increase in side effects including loss of consciousness, dizziness, double vision, unclear speech, drowsiness and diarrhea.

## If you forget to take the medicine

If you forgot to take this medicine at the required time, take a dose as soon as you remember, unless it is time for your next dose. **Never take a double dose** to make up for a forgotten dose.

Adhere to the treatment regimen as recommended by the doctor.

Even if there is an improvement in your health, do not stop the treatment with the medicine without consulting the doctor.

Do not stop taking the medicine unless so instructed by your doctor. If you need to stop treatment, it should be done gradually, over at least one week. If you stop taking the medicine abruptly or before receiving such instructions from the doctor, the risk of seizures increases.

**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 further questions regarding use of the medicine, consult the doctor or pharmacist.**

## 4. SIDE EFFECTS

As with any medicine, use of Gabapentin Inovamed 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.

**Refer to the doctor immediately if you experience one or more of the following symptoms after taking the medicine, as they can be serious:**

- Severe allergic skin reaction requiring immediate treatment, swelling of the lips and face, skin rash and redness and/or hair loss (these may be symptoms of a severe allergic reaction).
- Persistent stomach pain, nausea and vomiting - since they may be symptoms of acute pancreatitis.
- Breathing problems, which, if severe, may require emergency treatment to continue breathing normally.
- Gabapentin Inovamed may cause a serious 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 can occur, or not occur, as a part of this reaction. As a result of this reaction, you may have to be hospitalized or to stop taking Gabapentin Inovamed. Refer to your doctor immediately if you experience any of the following symptoms:
  - skin rash
  - hives
  - fever
  - swollen glands that do not go away
  - swelling of the lips and tongue
  - yellowing of the skin or of the whites of the eyes
  - occurrence of unusual bruising or bleeding
  - severe fatigue or weakness
  - unexpected muscle pain
  - frequent inflammations

These symptoms may be the first signs of a serious reaction. A doctor should examine you and decide whether you can continue taking the medicine.

- If you are being treated with hemodialysis, tell your doctor if you develop muscle pain and/or weakness

### Additional side effects:

**Very common side effects - effects that occur in more than 1 in 10 users:**

- viral infection
- feeling drowsy, dizziness, lack of coordination
- feeling tired, fever

**Common side effects - effects that occur in 1-10 users out of 100:**

- pneumonia, respiratory tract infections, urinary tract infections, inflammation of the ears or other types of infections
- low white blood cell count
- anorexia, increased appetite
- anger towards others, confusion, mood changes, depression, anxiety, nervousness, difficulty thinking
- convulsions, involuntary movements, speech difficulties, memory loss, tremor, sleeping difficulties, headache, sensitive skin, numbness, coordination difficulties, unusual eye movements, increased, decreased or absence of reflexes
- blurred vision, double vision
- dizziness (vertigo)
- high blood pressure, flushing or dilation of blood vessels
- breathing difficulties, bronchitis, sore throat, cough, dryness in the nose
- vomiting, nausea, dental problems, inflamed gums, diarrhea, stomach pain, indigestion, constipation, dry mouth or throat, flatulence
- facial swelling, bruises, rash, itching, acne
- joint pain, muscle pain, back pain, cramps
- impotence in men
- swelling in the legs and arms, walking difficulties, weakness, pain, feeling unwell, flu-like symptoms
- decrease in white blood cells, weight gain
- accidental injury, fracture, abrasion

**Uncommon side effects - effects that occur in 1-10 users out of 1,000:**

- agitation (a state of chronic restlessness and unintentional and purposeless motions)
- allergic reaction such as hives
- decreased movement
- rapid heartbeat
- difficulty swallowing
- swelling which may include the face, body and limbs
- abnormal laboratory test results, indicating problems with the liver
- mental problems
- falls
- increased blood glucose levels (most often observed in patients with diabetes)

**Rare side effects - effects that occur in 1-10 users out of 10,000:**

- decreased blood glucose levels (most often observed in patients with diabetes)
- loss of consciousness
- difficulty in breathing, shallow breaths (respiratory depression)

**Side effects reported since marketing the medicine and whose frequency is unknown:**

- decreased level of blood platelets
- hallucinations
- abnormal body movements such as writhing, involuntary movements and stiffness
- ringing in the ears
- a group of side effects that could include swollen lymph nodes, fever, rash and hepatitis occurring together
- yellowing of the skin and whites of the eyes (jaundice), inflammation of the liver
- acute kidney failure
- incontinence
- increased breast tissue, breast enlargement
- side effects due to abrupt discontinuation of treatment with Gabapentin Inovamed: anxiety, sleeping difficulties, nausea, pain, sweating, chest pain
- breakdown of muscle fibers (rhabdomyolysis)
- change in blood test results (increase in levels of creatine phosphokinase)
- sexual function problems, including inability to reach sexual satisfaction, delayed ejaculation
- low level of sodium in the blood
- anaphylaxis (a serious and life-threatening allergic reaction including breathing difficulties, swelling of the lips, throat, and tongue, and low blood pressure requiring emergency treatment)

**If a side effect occurs, if any of the side effects worsen, or if you are suffering from a side effect not mentioned in the leaflet, consult the doctor.**

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage [www.health.gov.il](http://www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: <https://sideeffects.health.gov.il>

## 5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine should be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.

- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.

- After removing the capsule from the blister, use it immediately.
- Store the medicine at a temperature below 30°C.
- Store in original package to protect from light.

## 6. FURTHER INFORMATION

**In addition to the active ingredient, the medicine also contains:**

Gabapentin Inovamed 300 mg:

Capsule content: lactose monohydrate, maize starch, talc.

Capsule shell: gelatin, titanium dioxide, yellow iron oxide.

Gabapentin Inovamed 400 mg:

Capsule content: lactose monohydrate, maize starch, talc.

Capsule shell: gelatin, titanium dioxide, yellow iron oxide, red iron oxide.

**What the medicine looks like and the contents of the package:**

Gabapentin Inovamed 300 mg: a hard, yellow-colored capsule.

Gabapentin Inovamed 400 mg: a hard, orange-colored capsule.

The capsules are packaged in plastic trays (blisters), which are packaged in carton boxes.

### Package sizes:

The medicine is marketed in packages of 10, 50 and 100 capsules.

The number of capsules in each package appears on the carton package.

Not all package sizes may be marketed.

**Name of Manufacturer and its address:** Pharmaprojects, Barcelona, Spain.

**License Holder and its address:** Inovamed Ltd., P.O.B. 62, Even Yehuda 40500.

Revised in March 2020.

**Registration number of the medicine in the National Drug Registry of the Ministry of Health:**

Gabapentin Inovamed 300 mg: 146 48 33100

Gabapentin Inovamed 400 mg: 146 49 33246