

**PATIENT PACKAGE INSERT IN
ACCORDANCE WITH THE PHARMACISTS’
REGULATIONS (PREPARATIONS) - 1986**

The medicine is dispensed with
a doctor's prescription only

Gabapentin Teva® 600 mg

Tablets

The active ingredient and its quantity:

Each tablet contains:
Gabapentin 600 mg

Gabapentin Teva® 800 mg

Tablets

The active ingredient and its quantity:

Each tablet contains:
Gabapentin 800 mg

For the list of inactive ingredients, please see section 6.

Read this 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.

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 above.

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 they spread to other parts of the brain or not). The doctor will prescribe gabapentin for you to help treat your epilepsy when your current treatment does not provide full control of your condition.
- For treatment of neuropathic pain (prolonged pain caused by nerve damage) after herpes or due to diabetes. Pain sensations may be described as hot, burning, throbbing, shooting, stabbing, sharp, cramping, tingling, numbing, pins and needles and the like.

Therapeutic group:

Anticonvulsants.

2. BEFORE USING THE MEDICINE:

- ☒ **Do not use the medicine if:**
- There is a known sensitivity to gabapentin or to any of the other ingredients (see section 6: “Further Information”).

Special warnings regarding use of the medicine:

- A small number of people being treated with anti-epileptics, such as gabapentin, had suicidal thoughts or thoughts of harming themselves. You and your family members must pay attention to changes in mood and behavior patterns. Monitor signs that indicate risk of suicide, such as:
 - Talking or thinking about wanting to harm yourself.
 - Introversion and withdrawal from family and friends.
 - Depression or worsening of existing depression.
 - Preoccupation with death.
 - Relinquishing or giving away prized possessions.

In the event of appearance of one or more of these signs, or any other worrisome behavior pattern – refer to the doctor immediately!

- A small number of people taking gabapentin suffer from an allergic reaction or serious skin reaction, which may develop into more serious problems if they are not treated. You need to pay attention to all of the symptoms detailed below and inform the doctor immediately upon their appearance:

Muscle weakness, tenderness or pain and particularly, if at the same time, you feel unwell or have a high fever that may be caused by abnormal muscle breakdown, which can be life-threatening and lead to kidney problems. There may also be a discoloration of your urine, and a change in blood test results (mainly increased blood creatine phosphokinase levels).

☒ Before treatment with Gabapentin Teva®, tell the doctor if:

- You are pregnant, planning a pregnancy or are breastfeeding.
- You are suffering, or have suffered in the past, from impaired kidney function. The doctor may prescribe a different dosage regimen for you.
- You are being treated with hemodialysis. Tell your doctor if you develop muscle pain and/or weakness.
- You develop symptoms such as persistent abdominal pains, nausea and vomiting, contact your doctor immediately, as these symptoms may indicate acute pancreatitis.
- You are suffering from a disturbance of various types of seizures, including “absence” seizures.

From the experience gained since marketing this preparation, incidents of gabapentin abuse and dependence have been reported. Inform the attending doctor if you have a history of abuse or dependence.

☒ If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.

In particular, inform the doctor or pharmacist if you are taking:

- Medicines containing opioids, such as morphine. Morphine may increase the effect of gabapentin. In addition, the combination of gabapentin with opioids may cause symptoms such as sleepiness and/or respiratory depression.
- Antacids for digestion problems. When taking gabapentin concomitantly with antacids containing aluminum and magnesium, absorption of gabapentin from the stomach may be reduced. Therefore, it is recommended that gabapentin be taken at least two hours after taking an antacid.
- Gabapentin is not expected to interact with other anti-epileptics or with oral contraceptive pills.
- Gabapentin can interfere with the results of some laboratory tests. If you have to undergo a urine test, tell your doctor that you are taking this medicine.

☒ Use of the medicine and food:

The tablets can be taken with or without food.

☒ Use of the medicine and alcohol consumption:

Do not drink wines or alcoholic beverages during the course of treatment with the medicine.

☒ Pregnancy and breastfeeding:

It is not recommended to take the medicine during pregnancy, unless your doctor has determined that it can be taken. Women of child-bearing age must use effective contraceptives during the course of treatment with the medicine.

Studies on use of this medicine in pregnant women have not been conducted; however, an increased risk of harm to the developing baby has been observed upon use of other medicines to treat seizures in pregnant women, especially if more than one medicine to prevent seizures was used at the same time. Therefore, if possible, try to take only one medicine to prevent seizures during pregnancy, and only as advised by your doctor.

Refer to the doctor immediately if you are pregnant, think you may be pregnant or are planning to become pregnant while taking the preparation. Do not stop taking the medicine suddenly, as discontinuing use of the medicine may lead to an epileptic attack, which may have severe consequences on your health and on the health of the unborn baby.

Gabapentin, the active ingredient in the medicine, passes through breast milk. Since the effect on the baby is unknown, it is not recommended to breastfeed while using the medicine.

☒ Driving and use of machinery:

Use of this medicine may impair alertness and cause dizziness and tiredness; therefore, do not drive a vehicle, operate dangerous machinery or engage in any dangerous activities until you know whether this medicine affects your ability to perform these activities.

3. HOW SHOULD YOU USE THE MEDICINE?

- Always use according to the doctor's instructions. If the effect of gabapentin is too strong or too weak or if you are uncertain, check, as soon as possible, with the doctor or pharmacist.
- The dosage and treatment regimen will be determined by the doctor only.
Do not exceed the recommended dose.
- This medicine is intended to treat 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 above.
- The attending doctor will usually increase the dosage gradually.
- The starting dosage will usually be between 300 mg and 900 mg per day.
- After that, the dose can be increased as per the doctor's instructions, up to the maximum daily dosage of 3600 mg, and the doctor will instruct you to take it in 3 separate doses, i.e., once in the morning, once at noon and once in the evening.
- Use this medicine at specified time intervals, as determined by the attending doctor.
- Do not chew! Swallow the tablets with a lot of water.
The tablets can not be halved. If necessary to ease swallowing, the tablet can be split into smaller pieces, but they must all be swallowed at the same time.
- It is recommended that Gabapentin Teva® be taken at least two hours after taking antacids.
- Continue taking the preparation until the doctor tells you to stop.
- If you are suffering from kidney problems or are being treated with hemodialysis, the doctor may prescribe a different dosage regimen or dose for you.
- If you are over the age of 65, take a regular dose of gabapentin, unless you are suffering from kidney problems. The doctor may prescribe you a different dosage regimen or dose if you are suffering from kidney problems.

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

An overdose may cause an increase in side effects, including: loss of consciousness, dizziness, double vision, unclear speech, drowsiness and diarrhea. Do not induce vomiting without explicit instruction from a doctor!

If you forgot to take this medicine at the scheduled time, take a dose as soon as you remember, unless it is time for the next dose. Never take two doses together to compensate for a forgotten dose!

Adhere to the treatment as recommended by the doctor.

If you stop taking the medicine suddenly or without consulting the doctor, there is an increased risk of seizures. Do not stop treatment with the medicine without consulting the doctor. Discontinuation of treatment, lowering the treatment dosage or switching this medicine for another medicine should be done gradually, over at least one week, as per the doctor's instructions. (See section 4 in this leaflet – Side effects due to sudden discontinuation of treatment).

- 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 Teva® 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.

Side effects that require special attention; if the following effects occur, refer to the doctor immediately:

- Severe skin reactions, including signs such as: itching, skin rash, redness and/or hair loss, swelling of the lips and face, may be symptoms of a serious allergic reaction
- Persistent stomach pain, nausea and vomiting, may be symptoms of acute pancreatitis
- Gabapentin 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. You may have a rash as part of this reaction. The serious reaction may cause you to be hospitalized or you may be forced to stop taking gabapentin (at the doctor's discretion). Contact your doctor immediately if you have any of the following symptoms:
 - skin rash
 - urticaria
 - fever
 - swollen glands that do not go away (e.g., lymph nodes)
 - 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 infections
- If you are being treated with hemodialysis, refer to the doctor upon occurrence of muscle pain and/or weakness
- Muscle weakness, tenderness or pain, especially if accompanied by an unwell feeling or fever; these may be signs of unusual muscle breakdown that 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) – refer to the doctor immediately!
- Worsened seizures – refer to the doctor immediately!
- Involuntary movements, mainly of the face, tongue or limbs – refer to the doctor immediately!

Very common side effects (may occur in more than 1 in 10 patients):

- Viral infection
- Drowsiness, lack of coordination (ataxia), dizziness
- Fatigue, fever

Common side effects (may occur in more than 1 in 100 patients):

- Pneumonia, respiratory tract infections, urinary tract infections, inflammation of the ears or other types of infections
- Low white blood cell count
- Anorexia, increased appetite
- Confusion, difficulty thinking, mood changes, depression, anxiety, nervousness, anger towards others – refer to the doctor immediately! (See “Special warnings regarding use of the medicine” in section 2 of this leaflet)
- Convulsions, spastic movements (jerky movements), difficulty with speech, memory loss, tremor, difficulty sleeping, headache, skin sensitivity, decreased sensation (numbness), difficulty with coordination, unusual eye movements, increased, decreased or absence of reflexes – refer to the doctor immediately! Forgetfulness, reduced sensitivity to touch (dullness)
- Blurred vision or double vision – refer to the doctor immediately!
- Dizziness/vertigo – refer to the doctor immediately!
- Hypertension, flushing or dilation of blood vessels
- Breathing difficulties – refer to the doctor immediately! Bronchitis (inflammation of the pharynx or bronchi). Sore throat – refer to the doctor immediately! Cough, dry nose
- Vomiting, nausea – refer to the doctor immediately! Problems with teeth, inflamed gums
- Diarrhea, stomach pain, indigestion, constipation, flatulence. Dry throat or mouth
- Facial swelling, bruises, rash, itch, acne, stinging
- Joint pain, muscle pain – refer to the doctor immediately! 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 cell count, increase in weight
- Accidental injury, fracture, abrasion/erosion
- Additionally, in clinical studies in children, reports of aggressive behavior and jerky movements were common

Uncommon side effects (may occur in more than 1 in 1,000 patients):

- Allergic reaction such as hives
- Decreased movement
- Rapid heartbeat – refer to the doctor immediately!
- Abnormal laboratory test results, indicating problems with the liver
- Mental impairments
- Falls
- Increased blood sugar levels (generally observed in patients with diabetes)

Rare side effects (may occur in more than 1 in 10,000 patients):

- Loss of consciousness
- Decreased blood sugar levels (generally observed in patients with diabetes)

Since introduction of gabapentin to the market, the following side effects have been reported:

- Decreased level of blood platelets (which help with clotting)
- Hallucinations - refer to the doctor immediately!
- Problems of abnormal movements such as writhing, jerky 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
- Jaundice (yellowing of the skin and eyes), inflammation of the liver
- Acute kidney failure, urinary incontinence
- Increased breast tissue, breast enlargement
- Side effects due to sudden discontinuation of treatment: anxiety, difficulty sleeping, nausea, pain, sweating, chest pain – refer to the doctor immediately!
- Blood glucose level fluctuations in patients with diabetes
- Signs of breakdown of muscle fibers (rhabdomyolysis) – sudden muscle pains, muscle tenderness or weakness. Refer to the doctor immediately!
- Change in blood test results – increase in blood levels of CPK (creatine phosphokinase), an enzyme released as a result of muscle injury or damage – refer to the doctor immediately!
- Stevens-Johnson syndrome (may be manifested by blistering, peeling or bleeding of the skin around the lips, eyes, mouth, nose and genitals, flu-like symptoms and high fever) – refer to the doctor immediately!
- Sexual function problems, including inability to reach orgasm, delayed ejaculation
- Decrease in blood sodium level

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) that directs you to the online form for reporting side effects, or by entering the link:

<https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il>

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine must 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 explicit instruction from the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package/blister. The expiry date refers to the last day of that month. In any case of doubt, consult the pharmacist who dispensed the medicine to you.
- Store this medicine in a dry and dark place, below 25°C. Keep in the original package.

6. FURTHER INFORMATION

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

Microcrystalline cellulose, povidone, hydrogenated vegetable oil type 1, talc, croscopovidone, HPMC 2910/hypromellose, titanium dioxide, Macrogol/PEG 400.

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

Gabapentin Teva® 600 mg

A white to off-white, oval-shaped tablet. One side of the tablet has “93” debossed on it and the other side has “7173” debossed on it.

Gabapentin Teva® 800 mg

A white to off-white, oval-shaped tablet. One side of the tablet has “93” debossed on it and the other side has “7174” debossed on it.

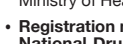
The medicine is packaged in trays (blister), in the following possible package sizes: 10, 30, 50, 60, 90, 100, 200 tablets. Not all package sizes may be marketed.

- **License Holder and its Address, Name of Manufacturer and its Address:** Teva Pharmaceutical Industries Ltd., P.O.B. 3190, Petach-Tikva

- This leaflet was checked and approved by the Ministry of Health in 12.2016

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

Gabapentin Teva® 600 mg: 146.53.32979
Gabapentin Teva® 800 mg: 146.54.32980



GABA TAB PL SH 251216