PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed with a doctor's prescription only

Gabapentin Teva 300 mg Capsules

Composition
Each capsule contains:
Gabapentin 300 mg

Gabapentin Teva 400 mg Capsules

Composition
Each capsule contains:
Gabapentin 400 mg

For information regarding inactive ingredients and allergens, see section 2 under "Important information about some of the ingredients of the medicine" and section 6 "Additional information".

Read the entire leaflet carefully before using the medicine.
This leaflet contains concise information about the medicine. If you have additional questions, refer to the doctor or the 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.
This medicine is intended for treatment of epilepsy in adults and adolescents above 12 years of age. This medicine is intended for treatment of neuropathic pain in adults from 18 years of age and up.

1. WHAT IS THE MEDICINE INTENDED FOR?

Epilepsy:
As adjunctive therapy in the treatment of partial seizures, with or without secondary generalization, in adults and adolescents (age 12 and above) with epilepsy.
The doctor will prescribe Gabapentin Teva for you to help treat your epilepsy, when the current treatment you are receiving does not enable full control of your condition.
Neuropathic pain:
For the treatment of neuropathic pain in diabetic neuropathy or postherpetic neuropathy (neuralgia) in adults.
Your doctor will prescribe Gabapentin Teva for you to treat neuropathic pain (chronic pain due to nerve damage) following shingles or diabetes in adults.
Pain sensations can be described as:
Heat sensation, burning sensation, throbbing pain, sudden pain, stabbing sensation, sharp pain, cramps, tingling sensation, numbness, "pins and needles" sensation and the like.
Therapeutic class: anticonvulsant.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- You are sensitive (allergic) to the active ingredient (gabapentin) or to any one of the additional components the medicine contains. See section 6.

Special warnings regarding the use of the medicine
Before treatment with Gabapentin Teva, inform the doctor if:
- You are pregnant or breastfeeding. See "Pregnancy, breastfeeding and fertility" under section 2.
- You are suffering from kidney problems. The doctor may change the treatment plan.
- You are being treated with hemodialysis (to remove waste products due to kidney failure). Tell your doctor if you develop muscle pain and/or weakness.
- You develop signs such as persistent abdominal pain, nausea and vomiting. Refer to your doctor immediately, as these may be symptoms of acute pancreatitis.
- You are suffering from a disorder of various types of seizures, including "absence" type seizures.
- You have nervous system disorders, respiratory disorders, or you are over the age of 65. The doctor may prescribe you a different dosing regimen.

Incidents of gabapentin dependence and abuse have been reported in post-marketing studies. Tell the doctor if you have a history of dependence or abuse.
A small number of patients being treated with antiepileptic medicines such as gabapentin had suicidal thoughts or thoughts of harming themselves. Refer to the doctor immediately if you have such thoughts.
Important information regarding possible serious reactions
A small number of patients being treated with gabapentin experience an allergic reaction or a serious skin reaction which may develop into an even 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 Teva.
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 muscle pain, particularly if you concomitantly feel unwell or have a high temperature. These may be signs of an abnormal muscle breakdown which may be life-threatening and lead to kidney problems. In addition, there may be a discoloration of urine and a change in blood test results (increase in blood creatine phosphokinase levels).
Other medicines and Gabapentin Teva
If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or the pharmacist.
In particular if you are taking or have recently taken:
- Medicines for convulsions, sleep disorders, depression, anxiety, or any neurological or psychiatric problems.
- Medicines from the opioid family such as morphine – these may increase the effect of Gabapentin Teva. In addition, combination of Gabapentin Teva and opioids may cause sleepiness, tiredness (sedation), decrease in breathing rate or death.
- Concomitant use of Gabapentin Teva and antacids that contain aluminum and magnesium may reduce the absorption of Gabapentin Teva from the stomach. It is therefore recommended to take Gabapentin Teva at least two hours after taking antacids.

Gabapentin Teva is not expected to influence the effect of other antiepileptic medicines or oral contraceptives.
Gabapentin Teva 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 you are taking.
Use of the medicine and food
The medicine may 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 are planning to become pregnant.
Pregnancy
Gabapentin Teva can be used during the first trimester of pregnancy if necessary.
If you are planning to become pregnant or if you are pregnant or think you are pregnant, talk to your doctor immediately.
If you become pregnant and you have epilepsy, it is important that you do not stop taking the medicine without first consulting your doctor, as this may worsen your condition. Worsening of your epilepsy may put you and your unborn child at risk.
In a study that reviewed data from women from Nordic countries who took gabapentin during the first 3 months of pregnancy, there was no increased risk of congenital malformations or problems in the development of the brain function (neurodevelopmental disorders). However, babies of women who took gabapentin during pregnancy were at increased risk of low birth weight and premature birth.
If used during pregnancy, Gabapentin Teva may lead to withdrawal symptoms in newborn babies. This risk may be increased when gabapentin is taken together with opioid analgesics (medicines for treatment of severe pain).
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 this 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 Teva passes into breast milk. Since its effect on the baby is unknown, breastfeeding while taking Gabapentin Teva is not recommended.
Fertility
In animal studies no effect on fertility was found.
Driving and operating machinery
Use of this medicine may cause dizziness, drowsiness and tiredness.
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 Gabapentin Teva 300 mg contains FD&C Yellow 6 / Sunset Yellow FCF which may cause allergic reactions.

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 how to use the preparation.
The dosage and treatment regimen will be determined only by the doctor.
The usual dosage is:
This medicine should be used at set intervals as determined by the treating doctor.
The dosage determined for you by the doctor will usually be administered gradually. 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 3600 mg, divided into 3 separate doses, that is, once in the morning, once at noon and once in the evening.
This medicine is intended for treatment of epilepsy in adults, adolescents and children above 12 years of age.
This medicine is intended for treatment of 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 you a different dosage and/or dosing regimen.
If you are over 65 years of age
You should take the usual dose of Gabapentin Teva unless you have kidney problems. The doctor may prescribe you a different dosage and/or dosing regimen if you are suffering from kidney problems.
If you think that the effect of the medicine is too strong or too weak, refer to the doctor or pharmacist immediately.
Do not exceed the recommended dose.
Always swallow the capsule whole with a lot of water.
Do not open and scatter the content of the capsule! As the effect of these forms of administration has not been tested.
It is recommended that Gabapentin Teva be taken at least two hours after taking antacids.
Continue taking Gabapentin Teva until the doctor instructs you to stop.
If you accidentally took a higher dosage
If you took an overdose or a child accidentally swallowed this medicine, go to the doctor or a hospital emergency room immediately and take 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 diarrhea.
If you forgot 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. Follow the treatment as recommended by the doctor.
Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor.
Do not stop taking the medicine unless instructed to do so by the doctor. If you are required to stop the treatment it should be done gradually over at least a week. If you stop taking the medicine abruptly or before receiving such an instruction from the doctor, the risk of seizures increases. **Do not take medicines in the dark! Check the label and the dose every time you take a medicine. Wear glasses if you need them.**
If you have any other questions regarding use of the medicine, consult the doctor or the pharmacist.

4. SIDE EFFECTS

As with any medicine, using Gabapentin Teva may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience 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 abdominal pain, nausea and vomiting - as these may be symptoms of acute pancreatitis.
- Breathing problems, which, if severe, may require emergency treatment to continue breathing normally.
- Gabapentin Teva 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 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 Gabapentin Teva. Refer to the doctor immediately if you have 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 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 and decide whether you can continue taking the medicine.
- If you are being treated with hemodialysis, tell the doctor if you develop muscle weakness and/or pain.

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

Common side effects (occur in up to 1 out of 10 people):
- 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 swings, 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 or decreased or absence of reflexes
- Blurry vision, double vision
- Dizziness (vertigo)
- High blood pressure, flushing or dilation of blood vessels
- Breathing difficulties, bronchitis, sore throat, cough, dry nose
- Vomiting, nausea, dental problems, inflamed gums, diarrhea, abdominal pain, indigestion, constipation, dry mouth or throat, flatulence
- Facial swelling, bruises, rash, itch, acne
- Joint pain, muscle pain, back pain, spasms
- Impotence in men
- Swelling in the legs and arms, difficulty walking, weakness, pain, malaise, flu-like symptoms
- Decrease in white blood cell count, weight gain
- Accidental injury, fracture, abrasion

Uncommon side effects (occur in up to 1 out of 100 people):
- Agitation (a state of chronic restlessness and unintentional and purposeless movements)
- Allergic reaction such as hives
- Decreased movement
- Fast heartbeat
- Difficulty swallowing
- Swelling which may include the face, body and limbs
- Abnormal blood test results, indicating problems with the liver
- Mental problems
- Falls
- Increased blood glucose level (most often observed in patients with diabetes)

Rare side effects (occur in up to 1 out of 1,000 people):
- Decreased blood glucose levels (most often observed in patients with diabetes)
- Loss of consciousness
- Difficulty breathing, shallow breaths (respiratory depression)

Side effects reported after the medicine was marketed and whose frequency is unknown:
- Decreased level of blood platelets
- Suicidal thoughts
- Hallucinations
- Abnormal body movements such as writhing, involuntary movements and stiffness
- Ringing in the ears
- A group of side effects that may include swollen lymph nodes, fever, rash and hepatitis occurring together
- Yellowing of the skin and the whites of the eyes (jaundice), hepatitis
- Acute renal failure, incontinence
- Breast tissue enlargement, breast enlargement
- Side effects following an abrupt discontinuation of treatment with Gabapentin Teva (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 achieve a sexual climax, delayed ejaculation
- Low blood sodium level
- Anaphylaxis (a serious and life-threatening allergic reaction, including difficulty breathing, swelling of the lips, throat and tongue, and hypotension requiring emergency treatment)

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 your doctor.
Side effects may be reported to the Ministry of Health by clicking on the link "Report side effects due to medicinal treatment" found on the Ministry of Health website homepage (www.health.gov.il) which will direct you to the online form for reporting side effects, or by clicking on the following link: https://sideeffects.health.gov.il

5. HOW TO STORE THE MEDICINE?

- The medicine should be stored in a dry place under 25°C.
- Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants 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) appearing on the package. The expiry date refers to the last day of that month.

6. ADDITIONAL INFORMATION

In addition to the active ingredient the medicine also contains:
Gabapentin Teva 300 mg:
Talc, pregelatinized starch, FD&C red 3, FD&C yellow 6, titanium dioxide, gelatin, printing ink.
Gabapentin Teva 400 mg:
Talc, pregelatinized starch, red iron oxide, yellow iron oxide, black iron oxide, titanium dioxide, gelatin, printing ink.
What does the medicine look like and what are the contents of the package?
Gabapentin Teva 300 mg: a hard, orange, gelatin capsule filled with creamy-white powder containing small agglomerates. The capsule body and cap are imprinted with: 93 and 39.
Gabapentin Teva 400 mg: a hard, brown, gelatin capsule filled with creamy-white powder containing small agglomerates. The capsule body and cap are imprinted with: 93 and 40.
The medicine is packed in trays (blister) in a package containing 100 capsules.
Name and address of the manufacturer and marketing authorization holder:
Teva Israel Ltd., 124 Dvora HaNevi'a St., Tel Aviv 6944020
The leaflet was revised in July 2024 in accordance with the Ministry of Health guidelines.
Registration numbers of the medicines in the National Drug Registry of the Ministry of Health:
Gabapentin Teva 300 mg: 119-46-29956
Gabapentin Teva 400 mg: 119-47-29937

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