This leaflet format has been determined by the Ministry of Health and the content thereof has been checked and approved

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

The medicine is dispensed with a doctor's prescription only

Levetiracetam Teva® 250 mg
Tablets

The active ingredient and its quantity:
Each tablet contains:
Levetiracetam 250 mg

Levetiracetam Teva® 500 mg
Tablets

The active ingredient and its quantity:
Each tablet contains:
Levetiracetam 500 mg

Levetiracetam Teva® 1000 mg
Tablets

The active ingredient and its quantity:
Each tablet contains:
Levetiracetam 1000 mg

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

Read this leaflet carefully in its entirety before using this 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 for the treatment of your ailment. Do not pass this medicine on to others. It may harm them even if it seems to you that their medical condition is similar.

This medicine is not intended for use in infants and children under 4 years of age.

1. WHAT IS THE MEDICINE INTENDED FOR?

- The medicine is intended:
  1. as a monotherapy for different types of epilepsy in adults over the age of 16 years.
  2. as an adjunctive therapy to other anti-epileptics in adult patients and in children from 4 years of age, presenting certain types of epilepsy.
  3. as a treatment for juvenile myoclonic epilepsy and primary generalized tonic clonic seizures in patients over the age of 12 years.

Therapeutic group:
The active ingredient belongs to the group of anti-convulsants.

2. BEFORE USING THE MEDICINE:

☒ Do not use the medicine if:
- you are sensitive (allergic) to levetiracetam or to other derivatives of pyrrolidone, or to any of the other ingredients in the medicine **(see section 6 below)**.

Special warnings regarding use of the medicine:
- If there is an increase in the severity of seizures (e.g., increase in number) during the course of treatment, refer to the doctor.
- Taking anti-convulsants may increase the risk of suicidal actions or thoughts. You and your family members must pay attention to changes in mood and behavior patterns.
  Monitor signs that indicate a risk of suicide, such as:
  - talking or thinking about wanting to harm yourself
  - introversion and withdrawing from family and friends
  - becoming depressed or worsening of existing depression
  - preoccupation with death
  - abandoning or giving away prized possessions

  If you experience symptoms of depression and/or suicidal thoughts, refer to a doctor.
- During the course of treatment with this medicine, it is recommended that you visit a doctor regularly, particularly in the first months of treatment.
- Inform every doctor (including the dentist) and pharmacist treating you, that you are using this preparation.
- If you are sensitive to any food or medicine, inform the doctor before taking this medicine.
- There is limited experience regarding the long-term effects of this medicine in children. If you notice a slowed growth rate in your child, or premature sexual development, refer to a doctor.

❗ Before treatment with Levetiracetam Teva® tell the doctor if:
If you are suffering, or have suffered in the past, from impaired function of: the liver, kidney/urinary system.

❗ 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:
- Laxatives that contain macrogol. Do not take laxatives that contain macrogol for an hour before or after taking Levetiracetam Teva®.

❗ Use of the medicine and alcohol consumption:
Do not drink wine or alcoholic beverages during the course of treatment with the medicine.

❗ Pregnancy and breastfeeding:
Inform the doctor if you are pregnant or planning to become pregnant. Levetiracetam Teva® is not intended for use during pregnancy, unless the doctor thinks the treatment is essential. The possibility of it causing congenital defects in the unborn baby cannot be ruled out. The risk of congenital defects increases in combined treatment with other anti-epileptics, when compared to monotherapy.
Breastfeeding is not recommended during the course of treatment with this medicine.

❗ Driving and use of machinery:
Use of this medicine may impair alertness, especially at the beginning of treatment or after increasing the dosage. Therefore, caution must be exercised when driving a car, operating dangerous machinery and in any activity that requires alertness. Children should be cautioned against riding bicycles or playing near roads, and the like.

3. HOW SHOULD YOU USE THE MEDICINE?

- Always use according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain.

The dosage and treatment regimen will be determined by the doctor only. The usual dosage is generally:
As monotherapy:
Dosage for adults and adolescents (above 16 years of age):
Between 1000 mg and 3000 mg per day, divided into two doses.
At the beginning of the treatment, the doctor will prescribe a lower dosage for the first two weeks, before you switch to the regular dosage recommended for you.
As a combined therapy with other medicines:
Dosage for adults and adolescents (ages 12-17 years) weighing more than 50 kg:
Between 1000 mg and 3000 mg per day, divided into two doses.
Dosage for children over 4 years of age and for adolescents weighing under 50 kg:
The doctor will prescribe the dosage and route of administration most appropriate for the given age and weight.
The usual dosage is between 20 mg and 60 mg per kg per day, divided into two doses.

Do not exceed the recommended dose.

Instructions for use of the medicine:
Be sure to divide the dosage of the medicine to twice per day, once in the morning and once in the evening. Make an effort to take the medicine at set times.
Do not chew! Swallow the tablets with a glass of water.
The medicine can be taken with or without food.
The tablet has a score line; if necessary, the tablet can be halved.

If you forgot to take this medicine at the scheduled time, refer to a doctor who will instruct you what to do. Never take two doses together.

If you took an overdose, 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.
Possible side effects in the event of overdose are sleepiness, agitation, aggression, decreased alertness, respiratory depression, coma.

Adhere to the treatment as recommended by the doctor.

If you stop treatment with this medicine
Even if there is an improvement in your health condition, do not discontinue treatment with this medicine without consulting the doctor. If the doctor decides to stop treatment with this medicine, he will instruct you how to gradually reduce its use, since abrupt discontinuation of the treatment may cause recurrence or increased frequency 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 further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS:

As with any medicine, use of Levetiracetam 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.
Effects of sleepiness, tiredness and dizziness are more common at the beginning of treatment or when the dosage is increased. These effects are usually reduced with progression of the treatment.

Very common side effects (affect more than 1 patient in 10):
- Nasopharyngitis
- Sleepiness, headache

Common side effects (affect 1 to 10 patients in 100):
- Lack of appetite (anorexia), especially in combination with the medicine topiramate
- Depression, hostility or aggression, anxiety, insomnia, nervousness or restlessness
- Convulsions, balance disorders, dizziness, lethargy (a state of lack of activity and responsiveness), tremor
- Vertigo (sensation of rotation)
- Cough
- Abdominal pain, diarrhea, dyspepsia, vomiting, nausea
- Rash (on the skin)
- Weakness

Uncommon side effects (affect 1 to 10 patients in 1,000):
- Decreased number of blood platelets, decreased number of white blood cells
- Changes in body weight (increase or decrease)
- Suicide attempts and suicidal thoughts, psychotic disturbances, mental disorder, abnormal behavior, hallucinations, anger, confusion, panic attack, mental instability/mood swings, frantic behavior
- Loss of memory, memory impairment (forgetfulness), lack of muscle control (ataxia), tingling sensation, lack of concentration
- Double vision, blurred vision
- Abnormal liver function test
- Hair loss, eczema, skin itching
- Muscle weakness, muscle pains
- Tendency to bruise

Rare side effects (affect 1 to 10 patients in 10,000):
- Infection, decrease in the number of all types of blood cells (e.g., agranulocytosis)
- Increase in the number of white blood cells (eosinophilia), combined with systemic symptoms (DRESS)
- Suicide, personality disorders, thinking disturbances (slow thinking, difficulty concentrating)
- Uncontrollable muscle contractions that affect the head, torso and limbs, difficulty in controlling movements, choreoathetosis (a type of movement disturbances), involuntary movements (dyskinesia), hyperactivity (hyperkinesia)
- Pancreatitis
- Hepatic failure, liver inflammation (hepatitis - yellowing of the eyes and skin, abdominal pain, vomiting, fever, dark urine and loss of appetite)
- Skin rash (erythema multiforme), which may be manifested by blisters that look like small targets (central dark spots surrounded by a pale area), a widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (Stevens–Johnson syndrome), or a more severe form causing skin peeling in more than 30% of the skin surface (toxic epidermal necrolysis)
- Decreased blood sodium concentration

Additional side effects:
Tendency toward intentional self-harm

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

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 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. The expiry date refers to the last day of that month.
- Store in a dry place, below 25°C.
- Do not discard medicines in the waste water or waste bin. Ask the pharmacist how to dispose of medicines that are no longer in use. These measures will help protect the environment.

6. FURTHER INFORMATION

In addition to the active ingredient, Levetiracetam Teva® 250 mg, 500 mg, 1000 mg tablets also contain:
Croscarmellose sodium, starch, povidone, magnesium stearate, hypromellose, titanium dioxide, macrogol/PEG 3350
In addition:
Levetiracetam Teva® 250 mg –
FD&C blue #1, FD&C blue #2
Levetiracetam Teva® 500 mg –
FD&C yellow #5, iron oxide yellow, FD&C blue #2

Each Levetiracetam Teva® 250 mg tablet contains 9.62-14.06 mg sodium
Each Levetiracetam Teva® 500 mg tablet contains 4.81-7.03 mg sodium
Each Levetiracetam Teva® 1000 mg tablet contains 2.41-3.52 mg sodium

What the medicine looks like and the contents of the package:
Levetiracetam Teva® 250 mg – blue, oblong shaped, film-coated tablet, scored on one side and debossed with "9" on one side of the score and with "3" on the other side of the score. Debossed with "7285" on the other side of the tablet.

Levetiracetam Teva® 500 mg – yellow, oblong shaped, film-coated tablet, scored on one side and debossed with "9" on one side of the score and with "3" on the other side of the score. Debossed with "7286" on the other side of the tablet.

Levetiracetam Teva® 1000 mg – white, oblong shaped, film-coated tablet, scored on one side and debossed with "9" on one side of the score and with "3" on the other side of the score. Debossed with "7493" on the other side of the tablet.

The package marketed for each dosage contains 60 tablets.

Manufacturer and address:
Teva Pharmaceutical Industries Ltd., P.O.B. 3190, Petah Tikva

This leaflet was checked and approved by the Ministry of Health in August 2014.

Registration numbers of the medicine in the National Drug Registry of the Ministry of Health:
141.45.31783.00
141.44.31957.00
141.43.31958.00