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

Levetiracetam Dexcel
250, 500, 750, 1000, tablets

Each tablet contains Levetiracetam 250, 500, 750 or 1000 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 to treat your illness. Do not pass it on to others. It may harm them, even if you think that their medical condition is similar to yours.

1. What is the medicine intended for?

- As single treatment of various types of epilepsy in patients over 16 years of age.
- As adjunctive treatment with other antiepileptic drugs in:
  - Adult patients and children over 4 years of age, who have certain types of epilepsy.
  - Adult patients and adolescents over 12 years of age who suffer from Juvenile Myoclonic Epilepsy or Idiopathic generalised epilepsy.

Therapeutic group: the active ingredient belongs to an anticonvulsant group of medicines.

2. Before using the medicine

Do not use the medicine if:

- You are hypersensitive (allergic) to the active ingredient (levetiracetam) or to other Pyrrolidone derivatives or to any of the other ingredients this medicine contains (see section 6).

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

- You suffer from impaired kidney function. The doctor may adjust the dosage of the medicine.
- You have noticed any slowdown in the growth or unexpected puberty development of your child, please refer to your doctor.
- You experience symptoms of depression and/or suicidal thoughts. A small number of people being treated with anti-epileptic medicines such as Levetiracetam have experienced self - destructive or suicidal thoughts.

Taking anticonvulsants may increase the risk of suicidal actions or thoughts.
You and your family should pay attention to mood and behavior patterns changes.
You should monitor signs of a suicide risk, such as talking or thinking about wanting to harm yourself, gathering into yourself and distancing from family and friends, depression

or worsening of existing depression, preoccupation with death, abandoning or giving away valuable assets.

- You or someone in your family has a history of irregular heart beat (according to EKG test) or if you have an illness or you are taking medicines that can cause irregularity in heart beat or a disturbance of the salt balance.
- One of the following side effects worsens or persists for more than a few days:
  - Unusual thoughts, irritability or more aggressive reactions than usual, or if you or your family and people around you observe significant changes in your mood or behavior.
  - Worsening of epilepsy: Rarely, you may experience a worsening in seizures or increase in their frequency, mainly during the first month after starting treatment or increasing dosage. If during treatment there is an increase in the frequency of seizures (such as an increase in their number) or in their severity, refer to the attending doctor as soon as possible. In a very rare form of early-onset epilepsy (epilepsy associated with SCN8A mutations) that causes multiple types of seizures and impairs skills, the seizures may persist or worsen during the treatment.

If one or more of these signs or any other alarming behavior pattern occurs - contact the doctor immediately!

Children and adolescents

Levetiracetam Dexcel is not intended as a monotherapy for children and adolescents under 16 years of age.

Drug interactions

If you are taking, or have recently taken other medicines, including non-prescription medicines and nutrition supplements, tell the doctor or pharmacist. Especially if you are taking:

- Macrogol (laxative medicine). Do not take Macrogol for an hour before or an hour after taking **Levetiracetam Dexcel**, as this may cause it to lose its effect.
- Temozolomide. Liver function tests should be performed before the beginning of combined treatment of Temozolomide with **Levetiracetam Dexcel**. If combined treatment was decided, liver function tests should be performed regularly during concomitant treatment and termination of the combined treatment should be considered if required.

Use of the medicine and food

The tablets should be swallowed with sufficient amount of liquid (glass of water).
You may take the medicine with or without food.
After taking the medicine, you may experience a bitter taste.

Use of the medicine and alcohol consumption

There is no information regarding interaction of the medicine with alcohol.

Pregnancy and breastfeeding

If you are pregnant, think you may be pregnant or are planning to become pregnant, consult a doctor before taking this medicine.

Levetiracetam Dexcel can be used during pregnancy, if after careful assessment it is considered necessary by your doctor. Do not stop treatment without consulting with your doctor. A risk of birth defects for the unborn child cannot be completely excluded.
There are two studies that do not suggest an increased risk of autism or intellectual disability in children of mothers who have taken levetiracetam during pregnancy. Nevertheless, limited evidence is available on the neural development of children exposed to levetiracetam.
Breastfeeding is not recommended during treatment with **Levetiracetam Dexcel**.

Driving and using machines

Levetiracetam Dexcel may impair your ability to drive or operate dangerous machines, because you may feel sleepy. This occurs mainly at the beginning of the treatment and after a dose increase. Do not drive or operate dangerous machinery until you feel able to perform such activities.
As for children, they should be warned about riding a bicycle or playing near roads etc.

Important information about some of the ingredients of the medicine
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say, essentially "sodium free".
Levetiracetam Dexcel 750 contains the substance Sunset Yellow (E110), which may cause allergic reactions.

3. How to use this 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 dosage is:
Monotherapy for adults and adolescents over the age of 16:
The recommended starting dose is 250 mg twice daily which should be increased to an initial therapeutic dosage of 500 mg twice daily after two weeks. The dosage can be increased by 250 mg twice daily every two weeks, depending on the clinical response. The maximum dosage is 1500 mg twice daily.
Adjunctive therapy for adults (18 years and above) and adolescents (12 to 17 years) weighing 50 kg or more:
The initial therapeutic dosage is 500 mg twice daily. This dosage can be started on the first day of treatment.
Depending on the clinical response and tolerance, the daily dosage can be increased up to 1500 mg twice daily. The dosage can be increased or decreased by increments of 500 mg twice daily, every 2-4 weeks.

Special populations:
The elderly, patients with impaired kidney/liver function: dosage adjustment will be done by the attending doctor.
Children: the doctor will determine the form of administration according to the age, weight and dosage.

Do not exceed the recommended dose.

Method of administration

The tablets should be swallowed with sufficient amount of liquid (glass of water).
Divide the daily dosage to 2 identical doses, and take one in the morning and one in the evening.
This medicine must be taken at regular intervals.
For patients who have swallowing difficulties, an oral solution formulation is available.
The tablets can be halved. There is no information regarding crushing or chewing.

Duration of treatment

- **Levetiracetam Dexcel** is used for chronic treatment. Continue treatment with **Levetiracetam Dexcel** as long as the doctor has told you.
- Do not stop the treatment without a doctor's instruction as this could increase your seizures.

If you have accidentally taken a higher dosage

If you have 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.
Possible side effects in case of an overdose are: sleepiness, agitation, aggression, decrease of alertness, inhibition of breathing and coma.

If you forgot to take the medicine

If you forgot to take this medicine at the designated time, do not take a double dose.
Contact your doctor who will instruct you what to do.
Continue with the treatment as recommended by the doctor.

If you stop taking the medicine

If stopping treatment, you should discontinue taking **Levetiracetam Dexcel** gradually (e.g., in adults and adolescents weighing more than 50 kg: reducing the dosage by 500 mg twice daily every 2-4 weeks; in children and adolescents weighing less than 50 kg: dosage reduction should not exceed 10 mg/kg twice daily every two weeks) in order to avoid an increase of seizures.
If the doctor decides to stop the treatment with this medicine, he will instruct you how to reduce the use gradually.

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 regarding the use of this medicine, consult the doctor or pharmacist.

4. Side effects

Like any medicine, the use of **Levetiracetam Dexcel** 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 a doctor or to a nearest hospital emergency room immediately if you experience:

- Weakness, feeling dizzy or difficulty breathing, as these may be signs of a serious allergic (anaphylactic) reaction.
- Swelling of the face, lips, tongue and throat (Quincke's oedema).
- Flu-like symptoms and a rash on the face followed by an extended rash with a high temperature, increased levels of liver enzymes and an increase in a type of white blood cell (eosinophilia) in blood tests, enlarged lymph nodes and the involvement of other body organs (DRESS syndrome).
- Low urine volume, tiredness, nausea, vomiting, confusion and swelling in the legs, ankles and feet, as these may be signs of sudden decrease in kidney function.
- A skin rash which may form blisters and look like small targets (dark spots surrounded by a paler area, surrounded by a dark ring) (erythema multiforme).
- A widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (Stevens-Johnson syndrome).
- A more severe form of rash causing skin peeling in more than 30% of the body surface (toxic epidermal necrolysis).
- Signs of serious mental changes or if someone around you notices signs of confusion, sleepiness, loss of memory (amnesia), memory impairment (forgetfulness), abnormal behavior or other neurological signs including involuntary or uncontrolled movements. These could be symptoms of an encephalopathy.

The most common side effects are nasopharyngitis, sleepiness, headache, fatigue and dizziness. Side effects like sleepiness, fatigue and dizziness, may be more common at the beginning of the treatment or when the dose is increased. These effects usually decrease as the treatment progresses.

Very common side effects (effects that occur in more than 1 in 10 users):

- Nasopharyngitis
- Sleepiness, headache

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

- Loss of appetite (anorexia)
- Depression, hostility or aggression, anxiety, insomnia, nervousness or irritability
- Convulsions, balance disorder, dizziness, lethargy (lack of energy and enthusiasm), tremor
- Vertigo (sensation of rotation)
- Cough
- Abdominal pain, diarrhoea, indigestion, vomiting, nausea
- Rash
- Asthenia and fatigue

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

- Decreased number of blood platelets, decreased number of white blood cells
- Decrease or increase in body weight

- Suicide attempt and suicidal thoughts, mental disorder, abnormal behaviour, hallucinations, anger, confusion, panic attack, mental instability or mood swings, agitation
- Loss of memory, memory impairment (forgetfulness), impaired coordination/ataxia, tingling (paraesthesia), lack of concentration
- Double vision, blurred vision
- Abnormal / elevated values in liver function test
- Hair loss, eczema, pruritus
- Muscle pain, muscle weakness
- Proneness to injury

Rare side effects (effects that occur in 1-10 out of 10,000 users):
- Infection
- Decreased number of all blood cell types
- Severe allergic reactions (DRESS, anaphylactic reaction [severe allergic reaction], Quincke's oedema [swelling of the face, lips, tongue and throat])
- Decreased blood sodium concentration
- Suicide, personality disorders, thinking disorders (slow thinking, inability to concentrate)
- Delirium
- Encephalopathy (see subsection "Refer to a doctor or to a nearest hospital emergency room immediately if you experience" for detailed description of the symptoms)
- Worsening of seizures or an increase in their frequency
- Uncontrollable muscle spasms affecting the head, torso and limbs, difficulty in controlling movements, excessive movements (hyperkinesia)
- Change in heart beat (EKG)
- Pancreatitis
- Liver failure, hepatitis
- Sudden decrease in kidney function
- Skin rash, which may form blisters and look like small targets (dark spots surrounded by a paler area, surrounded by a dark ring) (erythema multiforme), 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 body surface (toxic epidermal necrolysis)
- Rhabdomyolysis (breakdown of muscle tissue) and blood creatine phosphokinase increase. The frequency of this effect is higher in patients of Japanese origin compared to non-Japanese patients
- Limp or difficulty walking
- A combination of fever, muscle stiffness, unstable blood pressure and heart rate, confusion, decreased level of consciousness (possible signs of a disorder called malignant neuroleptic syndrome). This effect is more common in Japanese than non-Japanese patients.

Vary rare side effects (effects that occur in less than one in 10,000 users):
- Repetitive and uncontrollable thoughts or sensations or an urge to do something over and over again (obsessive compulsive disorder).

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 via the link "דיווח על תופעות לוואי עקב טיפול תרופתי" found on the homepage 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 stated on the package. The expiry (תאריך תפוגה) date refers to the last day of that month.
- **Storage conditions:** Store below 25°C.

6. Additional information

In addition to the active ingredient, this medicine also contains:
Croscarmellose sodium, microcrystalline cellulose, povidone, glyceryl behenate, polyvinyl alcohol partially hydrolyzed, titanium dioxide (E171), macrogol 3350, talc, silica colloidal anhydrous, carnauba wax.
Levetiracetam Dexcel 250 also contains Indigo carmine lake (E132).
Levetiracetam Dexcel 500 also contains Yellow iron oxide (E172).
Levetiracetam Dexcel 750 also contains Sunset yellow (E110), Red iron oxide (E172).

What the medicine looks like and what the package contains:
Levetiracetam Dexcel 250: blue, oblong, biconvex tablets, scored on one side.
Levetiracetam Dexcel 500: yellow, oblong, biconvex tablets, scored on one side.
Levetiracetam Dexcel 750: orange, oblong, biconvex tablets, scored on one side.
Levetiracetam Dexcel 1000: white, oblong, biconvex tablets, scored on one side.
Approved pack size: 60 tablets.

Manufacturer name and address: Dexcel Ltd., 1 Dexcel St., Or Akiva 3060000, Israel

Revised in December 2025 according to MOH guidelines.

Drug registration number at the national drug registry of the Ministry of Health:
Levetiracetam Dexcel 250: 149-63-33519-00
Levetiracetam Dexcel 500: 149-64-33518-00
Levetiracetam Dexcel 750: 149-65-33520-00
Levetiracetam Dexcel 1000: 149-66-33514-00

Registration holder: Dexcel Pharma Technologies Ltd., 10 Hakidma St., Yokneam Illit 2069200, Israel