

# hovid-Levetiracetam Tablets 500 mg

## Levetiracetam Tablet 500 mg

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### What hovid-Levetiracetam Tablets 500 mg is used for

hovid-Levetiracetam Tablets is used on its own in adults and adolescents from 16 years of age with a certain type of newly diagnosed epilepsy. Epilepsy is a condition where the patients have repeated fits (seizures). Levetiracetam is used for the epilepsy form in which the fits initially affect only one side of the brain, but could thereafter extend to larger areas on both sides of the brain (partial onset seizures with or without secondary generalization). hovid-Levetiracetam Tablets has been given to you by your doctor to reduce the number of fits.

hovid-Levetiracetam Tablets is also used as an add-on to other antiepileptic medicines to treat:

- partial onset seizures with or without secondary generalization in adults and children from 4 years of age with epilepsy.
- myoclonic seizures (short, shock-like jerks of a muscle or group of muscles) in adults and adolescents from 12 years of age with juvenile myoclonic epilepsy.
- primary generalized tonic-clonic

seizures (major fits, including loss of consciousness) in adults and children from 12 years of age with Idiopathic Generalized Epilepsy.

### How hovid-Levetiracetam Tablets 500 mg works

hovid-Levetiracetam Tablets contains Levetiracetam as active substance, which treats seizure in epilepsy.

### Before you use hovid-Levetiracetam Tablets 500 mg

#### - When you must not use it

Do not take hovid-Levetiracetam Tablets if you are hypersensitive to levetiracetam or other pyrrolidone derivatives or to any of the excipients in hovid-Levetiracetam Tablets which listed at end of the leaflet.

#### - Before you start to use it

Tell your doctor or pharmacist before taking this medicine if you are:

- Suffer from kidney problems
- Having liver related health issues.
- Having weakness, fever, infection or blood coagulation disorders.
- A small number of people being treated with anti-epileptics have had thoughts of harming or killing themselves. If you have any symptoms of depression and/or suicidal ideation, please contact your doctor.

#### - Taking other medicines

Tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription, as they may interact with hovid-Levetiracetam Tablets.

The following medications may interact with hovid-Levetiracetam Tablets:

- other antiepileptic products (e.g. phenytoin, carbamazepine, valproic acid)

- Probenecid (to increase uric acid excretion in the urine. It is primarily used in treating gout and hyperuricemia)
- Methotrexate (chemotherapy agent and immune system suppressant. It is used to treat cancer, autoimmune diseases, ectopic pregnancy, and for medical abortions)
- Oral contraceptives
- Osmotic laxatives (macrogol)

### How to use hovid-Levetiracetam Tablets 500 mg

#### - How much to use

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

#### ***Monotherapy for adults and adolescents from 16 years old.***

Recommended starting dose is 250mg twice daily. Dose should be increased to a dose of 500mg twice daily after two weeks. Dose can be further increased by 250mg twice daily every two weeks, depending in clinical response. Maximum dose is 1500mg twice daily.

#### ***Add-on therapy for adults (18 years old or more) and adolescents (12 to 17 years old) weighing more than 50kg.***

The initial therapeutic dose is 500 mg twice daily. This dose can be started on the first day of treatment.

Depending upon the clinical response and tolerability, the daily dose can be increased up to 1500 mg twice daily. Dose changes can be made in 500 mg twice daily increases or decreases every two to four weeks.

#### ***Dose in children (4 to 11 years) and adolescents (12 to 17 years) weighing less than 50 kg.***

An oral solution of levetiracetam is preferred. Dosage is based on body weight where 10mg per kg of body

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weight is given twice daily initially, increasing to 30mg per kg of body weight twice daily as decided by your doctor.

Swallow hovid-Levetiracetam tablets with a sufficient quantity of liquid (e.g. a glass of water). You can take hovid-Levetiracetam tablets with or without food. After oral administration the bitter taste of levetiracetam may be experienced.

### **Elderly.**

Your doctor might prescribe you with lower dose if you suffer from kidney problems.

### **Kidney Problems.**

Your doctor might adjust the dose of hovid-Levetiracetam Tablets for you, based on the severity of your kidney problems. If you are on dialysis, your doctor might advise you to take hovid-Levetiracetam Tablets only after dialysis.

### **Liver Problems.**

If you are having a more severe problem on both kidney and liver function, your doctor might reduce your dose of hovid-Levetiracetam Tablets.

The tablet must be taken orally, swallowed with a sufficient quantity of liquid and may be taken with or without food.

### - When to use it

Take hovid-Levetiracetam Tablets as your doctor's or pharmacist's advice.

### - How long to use it

hovid-Levetiracetam Tablets is used as a chronic treatment. You should continue this treatment for as long as your doctor has told you. Do not stop your treatment without your doctor's advice as this could increase your seizures.

### - If you forget to use it

Contact your doctor if you have missed one or more doses. Do not take a double dose to make up for a forgotten tablet.

### - If you use too much (overdose)

The possible side effects of an overdose of Levetiracetam are sleepiness, agitation, aggression, decrease of alertness, inhibition of breathing and coma. Contact your doctor if you took more tablet than you should. Your doctor will establish the best possible treatment of overdose.

### **While you are using it**

#### - Things you must do

Take hovid-Levetiracetam Tablets with the correct dose and at the correct time.

#### - Things you must not do

Do not skip the dose or stop taking this medication as this will increase your seizure attack.

#### - Things to be careful of

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Hovid-Levetiracetam Tablets can be used during pregnancy, only if after careful assessment it is considered necessary by your doctor. You should not stop your treatment without discussing this with your doctor. A risk of birth defects for your unborn child cannot be completely excluded. Breast-feeding is not recommended during treatment.

Levetiracetam has minor or moderate influence on the ability to drive and use machines. Due to possible different individual sensitivity, some patients might feel sleepy or other symptoms, especially at the

beginning of treatment or following a dose increase.

Therefore, caution is recommended in those patients when performing skilled tasks, e.g. driving vehicles or operating machinery. Patients are advised not to drive or use machines until it is established that their ability to perform such activities is not affected.

### **Side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

*Very common:* nasopharyngitis (common cold).

- Somnolence (sleepiness), headache.

*Common:*

- Anorexia (loss of appetite).
- Depression, hostility or aggression, anxiety, insomnia, nervousness or irritability.
- Convulsion, balance disorder (equilibrium disorder), dizziness (sensation of unsteadiness), lethargy (lack of energy and enthusiasm), tremor (involuntary trembling).
- Vertigo (sensation of rotation);
- Cough;
- Abdominal pain, diarrhoea, dyspepsia (indigestion), vomiting, nausea.
- Rash.
- Asthenia/fatigue (tiredness).

*Uncommon:*

- Decreased number of blood platelets, decreased number of white blood cells.
- Weight decrease, weight increase.
- Suicide attempt and suicidal ideation, mental disorder, abnormal behaviour, hallucination, anger, confusion, panic attack, emotional instability/mood swings, agitation.

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- Amnesia (loss of memory), memory impairment (forgetfulness), abnormal coordination/ataxia (impaired coordinated movements), paraesthesia (tingling), disturbance in attention (loss of concentration).
- Diplopia (double vision), vision blurred.
- Elevated/abnormal values in a liver function test.
- Hair loss, eczema, pruritus.
- Muscle weakness, myalgia (muscle pain).
- Injury.

### Rare:

- Infection.
- Decreased number of all blood cell types.
- Severe allergic reactions (DRESS, anaphylactic reaction [severe and important allergic reaction],
- Decreased blood sodium concentration.
- Suicide, personality disorders (behavioural problems), thinking abnormal (slow thinking, unable to concentrate).
- Uncontrollable muscle spasms affecting the head, torso and limbs, difficulty in controlling movements, hyperkinesia (hyperactivity).
- pancreatitis (pancreas inflammation);
- Hepatic failure, hepatitis
- Skin rash, which may form blisters and looks like small targets (central dark spots surrounded by a paler area, with a dark ring around the edge) (erythema multiforme), a widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (Stevens–Johnson syndrome), and a more severe form causing skin peeling in more than 30% of the body surface (toxic epidermal necrolysis).
- Rhabdomyolysis (breakdown of muscle tissue) and associated

blood creatine phosphokinase increase. Prevalence is significantly higher in Japanese patients when compared to non-Japanese patients.

- acute kidney injury
- This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known. Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list. Ask your doctor or pharmacist if you do not understand anything in this list.

Tell your doctor immediately if you notice any of the following:

- Symptoms such as low urine volume, tiredness, nausea, vomiting, confusion and swelling in the legs, ankles or feet, may be a sign of sudden decrease of kidney function.
- Signs or symptoms including muscle ache, feeling of weakness and dark urine may indicate the side effect of rhabdomyolysis (breakdown of muscle tissue).
- If someone around you notices signs of confusion, somnolence (sleepiness), amnesia (loss of memory), memory impairment (forgetfulness), abnormal behaviour or other neurological signs including involuntary or uncontrolled movements, these could be symptoms of an encephalopathy.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website [nprra.gov.my](http://nprra.gov.my) [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

### Storage and Disposal of hovid-Levetiracetam mg

#### - Storage

Store below 30°C.

#### - Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

### Product Description

#### - What it looks like

hovid-Levetiracetam 500 mg Tablet is a yellow coloured, oblong shaped film-coated tablet, with a scoreline on one side and debossed with “500” on the other side of tablet.

#### - Ingredients

Active ingredient(s)

- Levetiracetam

Inactive ingredients

- Povidone
- Croscarmellose Sodium
- Polyethylene Glycol 6000
- Silica, colloidal anhydrous
- Magnesium Stearate
- Polyvinyl Alcohol Partially Hydrolyzed
- Titanium Dioxide
- Macrogol
- Talc
- Iron Oxide Yellow(hovid-Levetiracetam Tablets 500mg)

#### - MAL number:

MALXXXXXXXXXA

### Manufacturer

Jubilant Generics Limited,  
Village- Sikandarpur Bhainswal,  
Roorkee Dehradun Highway,  
Bhagwanpur, Roorkee- 247 661  
Distt. Haridwar (Uttarakhand), India

### Product Registration Holder

Hovid Berhad.,  
121, Jalan Tunku Abdul Rahman  
(Jalan Kuala Kangsar),  
30010 Ipoh, Malaysia

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16/01/2021

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