

# LEVAUR 250 (Levetiracetam Tablets 250mg)

# LEVAUR 500 (Levetiracetam Tablets 500mg)

Levetiracetam (250mg, 500mg)

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## What is LEVAUR used for

LEVAUR is used to control epilepsy. Epilepsy is a condition where you have repeated seizures (fits). There are many different kinds of seizures that can be mild or severe in nature.

LEVAUR can be used alone or in combination with other medicines to treat your condition.

LEVAUR is used in patients who are already taking other anti-epileptic medicines:

- For treating partial seizures in adults and children from 4 years of age.
- For treating myoclonic seizures in adults and adolescents from 12 years of age with Juvenile Myoclonic Epilepsy.
- For treating primary generalized tonic-clonic seizures in adults and adolescents from 12 years of age with Idiopathic Generalized Epilepsy.

## How LEVAUR works

LEVAUR contains the active ingredient levetiracetam, which belongs to a group of medicines called anti-epileptics. It is thought to control brain chemicals which send signals to nerves, so that seizures do not occur.

## Before you use LEVAUR

### -When you must not use it

Do not use LEVAUR if you are allergic to:

- Any medicine containing levetiracetam.
- Medicines derived from a chemical called pyrrolidine (e.g. piracetam) or any of the ingredients that are listed here.

If you are unsure about the use of LEVAUR, please consult your doctor or pharmacist for further advice.

### -Before you start to use it

Inform your doctor if you have any known allergies.

It is important to inform your doctor if:

- You suffer from any kidney or liver related health issues. Your doctor will adjust the dose of this medication for you accordingly.
- You have any blood related disorders (such as issues with your blood cells).
- You are suffering from mental health issues such as depression or thoughts of suicide.

Currently there are no known impact on growth and puberty in children who have taken levetiracetam however, long term effects are still unknown.

There are no studies on the effects of levetiracetam on ability to drive and use machines. In any case, if you feel drowsy or lethargic while on this medication, it is advisable not to drive or operate machinery.

Pregnancy and breastfeeding: tell your doctor if you are pregnant, planning to become pregnant or are

currently breast-feeding. Your doctor will determine if it is alright for you to take LEVAUR during pregnancy as it may affect the developing foetus. Levetiracetam is known to pass through breast-milk. Therefore, speak to your doctor if you are breastfeeding or plan to breastfeed your child while on LEVAUR.

### -Taking other medications

Inform your doctor if you are on any other medications prior to taking LEVAUR, including medicines you buy without a prescription from the pharmacy, supermarket or a health food shop.

Your doctor or pharmacist will advise you accordingly if you are on other medications before starting LEVAUR.

## How to use LEVAUR

### -How much to use

Follow all instructions given by your doctor or pharmacist carefully as they may differ from instructions in this leaflet.

Ask for help if you do not understand the instructions written on the medicine box.

If you are taking LEVAUR for epilepsy, adults & adolescents from 16 years of age onwards: take the number of recommended tablets by your doctor. The usual starting dose is 250mg tablet to be taken twice a day. It may be increased by 250mg twice daily at 2 weeks interval to a maximum dose of 1500mg twice a day.

If you are taking other medicines for epilepsy along with LEVAUR, adults ( $\geq 18$  years) and adolescents (12 to 17 years) weighing 50kg or more: take the number of tablets as recommended by your doctor. The usual starting dose is 500mg tablet to be taken twice daily. The dose may be increased by 500mg twice daily at 2 weeks or monthly interval to a

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maximum dose of 1500mg twice a day.

Dosage in children aged 4 to 11 years and adolescents (12 to 17 years) weighing less than 50kg: give to your child the number of tablets as recommended by your doctor. The general starting dose is 10mg/kg twice daily, which may be increased to a maximum of 30mg/kg twice daily.

LEVAUR may not be suitable for all dosages. Therefore, other suitable available strengths and/or dosage forms of levetiracetam should be used in such cases.

Dosage in the elderly (65 years and older): dose adjustment is required if you have kidney problems. Your doctor will adjust the dose for you accordingly.

Dosage in patients with kidney problems: dosage will be adjusted accordingly by your doctor according to your kidney test results.

Dosage in patients with liver problems: dosage will be adjusted accordingly by your doctor according to your liver test results.

### -When to use it

LEVAUR must be taken twice a day, preferably once in the morning and once in the evening at the same time every day.

LEVAUR can be taken before or after food.

### -How long to use it

Continue taking LEVAUR for as long as your doctor recommends it. It helps to control your epilepsy, thus you must take it every day.

### -If you forget to use it

Take the forgotten dose as soon as you remember. If it is already time for your next dose, skip the forgotten dose and take your next dose as

usual. Do not double the dose to replace the missed dose.

If you are still unsure, please contact your doctor or pharmacist for advice.

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

Contact your doctor for advice immediately if you have taken too much of this medicine. Alternatively, you may visit the emergency department of the nearest hospital. Do this even if you do not experience any signs of over dosage, you may need medical attention.

Some common symptoms of over dosage are sleepiness, agitation, aggression, difficulty in breathing, depressed level of consciousness and coma.

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

#### -Things you must do

Take LEVAUR everyday as instructed by your doctor even if you have no seizures (fits). Inform your doctor immediately if you still notice increase in seizures.

If you are about to be started on other medications, please inform your doctor or pharmacist that you are taking LEVAUR.

Please inform your doctor if you notice changes in behaviour (e.g. anxiety, depression, mood swings, suicidal thoughts and irritability)

#### -Things you must not do

Do not share your medication with anyone else although they are experiencing the same symptoms as you.

Do not stop taking your medicine just because you feel better unless advised by your doctor. Levetiracetam should be discontinued gradually by your doctor to avoid an increase of seizures.

### -Things to be careful of

Levetiracetam may cause drowsiness, this is more frequent at the beginning of treatment or a dosage increase.

If you become drowsy while on LEVAUR, please do not drive or operate any machinery.

### **Side effects**

Like all medicines, LEVAUR can cause side effects although not everyone will experience them.

If you do not feel well while on LEVAUR, please inform your doctor.

Some very common and common side effects while on LEVAUR are listed below:

Very common: nose and throat inflammation, depressed mood and headache.

Common: loss of appetite, depression, aggressive behaviour, unable to sleep well, nervousness, dizziness, lethargy, diarrhoea, nausea and vomiting and rashes.

Please inform your doctor if you experience any of the side effects listed below:

- Thoughts of suicide
- Emotional instability
- Hallucination
- Blistering of skin
- Bleeding or bruising easily
- Severe stomach pain
- Frequent infections

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.

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- 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.

Other side effects not listed above may also occur in some people. Ask your doctor or pharmacist

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

## Storage and Disposal of LEVAUR

### -Storage

Do not store above 30°C. Keep all medicines out of reach of children.

### -Disposal

Do not dispose unwanted or expired medicine via household waste or sewage system. Return them to your doctor or pharmacist for safe disposal. These measures can help protect the environment from pollution.

## Product Description

### -What it looks like

LEVAUR 250: blue oval shaped biconvex film coated tablets with a deep break line separating 'E' and '10' on one side and plain on the other side.

LEVAUR 500: Yellow oval shaped biconvex film coated tablets debossed with a deep break line separating 'E' and '11' on one side and plain on the other side.

### -Ingredients

- Active ingredient(s)

Levetiracetam

- Inactive ingredient(s)

Colloidal anhydrous silica, povidone k30, maize starch, talc, magnesium stearate, opadry blue (OY-S-30913), opadry yellow (05F82840), purified water

### -MAL number

LEVAUR 250 (Levetiracetam Tablets 250 mg): MAL18056071AZ

LEVAUR 500 (Levetiracetam Tablets 500 mg): MAL18056070AZ

## Manufacturer

Aurobindo Pharma Limited  
Unit-XV, Plot No.17 A, E- Bonangi Village, Jawaharlal Nehru Pharma City, Parawada Mandal, Anakapalli District, Andhra Pradesh - 531021, India

## Product Registration Holder

Healol Pharmaceuticals Sdn Bhd  
74-3, Jalan Wangsa Delima 6, KLSC Wangsa Maju, 53300 Kuala Lumpur, Malaysia

## Date of revision

-11/06/2024

## Serial Number

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