

JUBLEVET

Levetiracetam Tablets 500mg

Levetiracetam (500mg)

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What is JUBLEVET used for

JUBLEVET 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.

JUBLEVET can be used alone or in combination with other medicines to treat your condition. Alone, JUBLEVET is used in treatment of newly diagnosed epilepsy in patients from 16 years and older.

JUBLEVET 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 JUBLEVET works

JUBLEVET 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 JUBLEVET

-When you must not use it

Do not use JUBLEVET 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 JUBLEVET, please consult your doctor or pharmacist for further advice.

Pregnancy and lactation

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 JUBLEVET 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 JUBLEVET.

-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.

-Taking other medications

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Inform your doctor if you are taking a medicine called methotrexate (a medicine used in chemotherapy) if you are being prescribed JUBLEVET.

If you are on the gout medication called probenecid or are on any kind of oral contraceptive (medicine to prevent pregnancy), please inform your doctor before consuming JUBLEVET.

If you are on a macrogol laxative, inform your doctor before you take JUBLEVET

The medications mentioned above do affect the way JUBLEVET is metabolised in your body. Therefore, it is important that you inform your doctor.

How to use JUBLEVET

-How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

If you are taking JUBLEVET for epilepsy, adults & adolescents from 16 years of age onwards: Take the

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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 JUBLEVET, adults (≥ 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 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 as add on therapy: An oral solution of levetiracetam is preferred. Dosage is based on bodyweight where 10mg per kg of body weight is given twice daily initially, increasing to 30mg per kg of bodyweight twice daily as decided by your doctor.

Dose in children 50kg or greater is the same as in adults.

JUBLEVET 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

Use as directed by your doctor or pharmacist.

JUBLEVET must be taken twice a day, preferably once in the morning and once in the evening at the same time every day. It can be taken before or after food.

-How long to use it

Continue taking JUBLEVET 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

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

-If you use too much (overdose)

Consult your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Symptoms of overdose include drowsiness, agitation, aggression, depressed level of consciousness or breathing difficulties.

While you are using it

-Things you must do

Take your medicine everyday exactly as your doctor has told you even if there are no more seizures. Inform your doctor immediately if you observe any seizures happening

Tell all the doctors, dentists and pharmacists treating you that you are taking JUBLEVET.

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 stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor or pharmacist.

Do not give JUBLEVET to anyone else, even if they have the same symptoms or condition as you.

-Things to be careful of

Driving and using machines

This medicine may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machine and contact your doctor immediately.

Side effects

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

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

Some common and serious side effects while on JUBLEVET are listed below:

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

Serious: blurred vision, suicidal thoughts, serious drug reactions, muscular pain and inflammation of the pancreas.

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

- Thoughts of suicide
- Emotional instability

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- 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.
- Signs or symptoms including muscle ache, feeling or 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 reaction directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.moh.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of product name

-Storage

Store below 30°C. Keep out of reach of children.

-Disposal

Medicines should not be disposed of via wastewater of 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

Yellow coloured, oblong shaped, film coated tablets, with a score line on one side and debossed with “500” on the other side of the tablet.

-Ingredients

- Active ingredient(s)

Levetiracetam

- Inactive ingredient(s)

Povidone, Purified water, Croscarmellose sodium, Polyethylene glycol 6000, Colloidal anhydrous silica, Magnesium stearate & Opadry II Yellow 85F32004

-MAL number

MAL19116035AZ

Manufacturer

Jubilant Generics Limited.
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Product Registration Holder

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