

INTIRACETAM Oral Solution

Levetiracetam 100mg/ml

What is in this leaflet

1. What INTIRACETAM is used for
2. How INTIRACETAM works
3. Before you use INTIRACETAM
4. How to use INTIRACETAM
5. While you are using it
6. Side effects
7. Storage and Disposal of INTIRACETAM
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision

What INTIRACETAM is used for

INTIRACETAM is used:

- on its own in patients from 16 years of age with newly diagnosed epilepsy, to treat partial onset seizures with or without secondary generalization.
- as an add-on to other antiepileptic medicines to treat:
 - partial onset seizures with or without secondary generalisation 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 generalised tonic-clonic seizures (major fits, including loss of consciousness) in adults and children from 12 years of age with idiopathic generalised epilepsy

How INTIRACETAM works

INTIRACETAM is an antiepileptic medicine (a medicine used to treat seizures in epilepsy).

Before you use INTIRACETAM

-When you must not use it

Do not take INTIRACETAM

- If you are allergic (hypersensitive) to levetiracetam or any of the other ingredients of this medicine (listed in Product Description).

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

If you are pregnant or if you think you may be pregnant, please inform your doctor. INTIRACETAM should not be used during pregnancy unless clearly necessary. The potential risk to your unborn child is unknown.

Breast-feeding is not recommended during treatment.

Children and adolescent

INTIRACETAM is not indicated in children and adolescent below 16 years on its own (monotherapy)

-Before you start to use it

Talk to your doctor before taking INTIRACETAM

- If you suffer from kidney problems, follow your doctor's instructions. He/she may decide if your dose should be adjusted.
- If you notice any slow down in the growth or unexpected puberty development of your child, please contact your doctor.

- If you notice an increase in seizure severity (e.g. increased number), please contact your doctor.
- People being treated with anti-epileptics such as levetiracetam has potential of having thoughts of harming or killing themselves. If you have any symptoms of depression and/or suicidal ideation, please contact your doctor.
- If you notice any abnormal and aggressive behaviours, or if you or your family and friends notice important changes in mood or behaviour, immediately contact your doctor.
- If you have a family or medical history of irregular heart rhythm (visible on an electrocardiogram), or if you have a disease and/or take a treatment that make(s) you prone to heartbeat irregularities or salt imbalances.

-Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

INTIRACETAM with food, drink and alcohol

You may take INTIRACETAM with or without food. As a safety precaution, do not take INTIRACETAM with alcohol.

INTIRACETAM oral solution contains methyl parahydroxybenzoate which may cause allergic reactions (possibly delayed).

INTIRACETAM Oral Solution

Levetiracetam 100mg/ml

INTIRACETAM oral solution also contains maltitol. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

How to use INTIRACETAM

-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:

Dose in adults and adolescents (from 16 years of age):

General dose: between 10 ml (1,000 mg) and 30 ml (3,000 mg) each day, divided in 2 intakes per day. When you will first start taking INTIRACETAM, your doctor will prescribe you a lower dose during 2 weeks before giving you the lowest general dose.

Add-on therapy:

Dose in adults and adolescents (12 to 17 years) weighing 50 kg or more:

General dose: between 10 ml (1,000 mg) and 30 ml (3,000 mg) each day, divided in 2 intakes per day.

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

Your doctor will prescribe the most appropriate pharmaceutical form of INTIRACETAM according to the age, weight and dose.

INTIRACETAM 100 mg/ml oral solution is a presentation more appropriate to children under the age of 6 years and to children

and adolescent (from 6 to 17 years) weighing less than 25kg and when tablets don't allow accurate dosage.

The exact quantity of oral solution formulation should be delivered using the syringe provided in the cardboard box.

Weight	Starting dose: 0.1 ml/kg twice daily	Maximum dose: 0.3 ml/kg twice daily
10 kg ⁽¹⁾	1 ml twice daily	3 ml twice daily
15 kg ⁽¹⁾	1.5 ml twice daily	4.5 ml twice daily
20 kg ⁽¹⁾	2 ml twice daily	6 ml twice daily
25 kg	2.5 ml twice daily	7.5 ml twice daily
From 50 kg ⁽²⁾	5 ml twice daily	15 ml twice daily

⁽¹⁾ Children 25 kg or less should preferably start the treatment with levetiracetam 100 mg/ml oral solution

⁽²⁾ Dose in children and adolescents 50 kg or more is the same as in adults

INTIRACETAM oral solution may be diluted in a glass of water. You may take INTIRACETAM with or without food. After oral administration the bitter taste of levetiracetam may be experienced.

-When to use it

INTIRACETAM must be taken twice a day, once in the morning and once in the evening, at about the same time each day.

-How long to use it

INTIRACETAM is used as a chronic treatment. You should continue INTIRACETAM

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.

Should your doctor decide to stop your INTIRACETAM treatment, he/she will instruct you about the gradual withdrawal of INTIRACETAM.

-If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it. Do not take a double dose to make up for the missed dose.

-If you use too much (overdose)

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

While you are using it

-Things you must do

Take your medicine exactly as your doctor has told you.

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

Tell your doctor immediately if you become pregnant while taking this medication.

-Things you must not do

Do not stop taking the medicine unless advised by your doctor.

INTIRACETAM Oral Solution

Levetiracetam 100mg/ml

Do not take any new medicines without consulting your doctor.

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

-Things to be careful of

Driving and using machines
INTIRACETAM may impair your ability to drive or operate any tools or machinery, as INTIRACETAM may make you sleepy. This is more likely at the beginning of treatment or after an increase in the dose. You should not drive or use machines until it is established that your ability to perform such activities is not affected.

If stopping treatment, as with other antiepileptic medicines, INTIRACETAM should be discontinued gradually to avoid an increase of seizures. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

Side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Some of the side effects like sleepiness, tiredness and dizziness may be more common at the beginning of the treatment or at dose increase. These effects should however decrease over time.

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, 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
- 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], angioedema [swelling of the face, lips, tongue and throat])
- 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
- acute kidney injury
- 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

INTIRACETAM Oral Solution

Levetiracetam 100mg/ml

compared to non-Japanese patients

- encephalopathy (brain disorder)
- seizures may become worse or happen more often
- change of the heart rhythm (Electrocardiogram)
- limp or difficulty walking

If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

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 muscleache, 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 npa.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of INTIRACETAM

-Storage

Do not store above 30°C. Store in the original container to protect from light.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date stated on the cardboard box and bottle. The expiry date refers to the last day of the month.

-Disposal

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Product Description

-What it looks like

INTIRACETAM 100mg/ml oral solution is a clear, colourless liquid with sweet fruity odour and bitter raspberry flavor.

-Ingredients

-Active ingredients

The active substance is called levetiracetam. Each ml contains 100 mg of levetiracetam.

-Inactive ingredients

Sodium citrate, citric acid, methyl parahydroxybenzoate, glycerol, acesulfame potassium, liquid maltitol, raspberry liquid, purified water.

-MAL number

MAL22016016ACZ

Manufacturer

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Product Registration Holder

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