

IRACET ORAL SOLUTION 100 MG/ML

Levetiracetam (100mg/mL)

What is in this leaflet

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

What *Iracet* is used for

Iracet 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). *Iracet* has been given to you by your doctor to reduce the number of fits.
- 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 *Iracet* works

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

Before you use *Iracet*

When you must not use it

Do not take *Iracet*

- If you are allergic to levetiracetam, pyrrolidone derivatives or any of the other ingredients of this medicine.

Pregnancy and breastfeeding:

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.

Iracet 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. *Iracet* has shown unwanted reproductive effects in animal studies.

Breast-feeding is not recommended during treatment.

Children and adolescents

Iracet is not indicated in children and adolescents before 16 years on its own (monotherapy).

- Before you start to use it

Talk to your doctor before taking *Iracet*

- 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 slowdown in the growth or unexpected puberty development of your child, please contact your doctor.
- A small number of people being treated with anti-epileptics such as *Iracet* have had 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 heart problems, for

example disturbance in heart rhythm (visible on an electrocardiogram) or if you are taking any other medicine that makes you prone to have disturbance in heart rhythm or unusual amount of salt in the body.

- Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

How to use *Iracet*

- How much to use

Always take this medicine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. Take the number of tablets following your doctor's instructions.

Monotherapy:

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

General dose: between 1000 mg and 3,000 mg each day.

When you will first start taking *Iracet*, 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 1,000 mg and 3,000 mg each 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 *Iracet* according to the age, weight and dose.

Iracet 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 measuring cup 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 ml twice daily	3 ml twice daily
15 kg	1.5 ml twice daily	4.5 ml twice daily
20 kg	2 ml twice daily	6 ml twice daily
25 kg	2.5 ml twice daily	7.5 ml twice daily
From 50 kg	5 ml twice daily	15 ml twice daily

Method of administration:

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

- When to use it

Iracet must be taken twice a day, once in the morning and once in the evening, at about the same time each day. You may take *Iracet* with or without food.

- How long to use it

Iracet is used as a chronic treatment. You should continue *Iracet* 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 stopping treatment, *Iracet* should be discontinued gradually to avoid an increase of seizures. Should your doctor decide to stop your *Iracet* treatment, he/she will instruct you about the gradual withdrawal of *Iracet*.

- 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 dose.

- If you use too much (overdose)

The possible side effects of an overdose of *Iracet* are sleepiness, agitation, aggression, decrease of alertness, inhibition of breathing and coma.

Contact your doctor if you took more 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.

Iracet oral solution may be diluted in a glass of water or baby's bottle.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

- Things you must not do

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

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

- Things to be careful of

Iracet contains Sodium Methyl Hydroxybenzoate and Sodium Propyl Hydroxybenzoate, which may cause allergic reactions (possibly delayed).

Iracet contains 300mg sorbitol in each mL. Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine.

Iracet also contains FD&C Red No. 40 and D&C Yellow No. 10 which may cause allergic reactions.

Glycerol: No labelling requirement required as the threshold is 10 g per dose.

This medicine contains 3 mg aspartame in each mL. Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot

remove it properly. Unsuitable for phenylketonurics.

Driving and using machines

Iracet may impair your ability to drive or operate any tools or machinery, as *Iracet* 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.

Your seizures may rarely become worse or happen more often, mainly during the first month after starting the treatment or increase of the dose of *Iracet*. If you notice any of these symptoms while taking *Iracet*, immediately contact your doctor.

Side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The most frequently reported side effects are nasopharyngitis, somnolence (sleepiness), headache, fatigue and dizziness. At the beginning of the treatment or at dose increase side effects like sleepiness, tiredness and dizziness may be more common. These effects should however decrease over time.

Very common:

- nasopharyngitis (common cold)
- somnolence (sleepiness), headache.

Common:

- anorexia (loss 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, diarrhea, 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 behavior, hallucination, anger, confusion, panic attack, emotional instability/mood swings, agitation
- amnesia (loss of memory), memory impairment (forgetfulness), abnormal coordination/ataxia (impaired coordination 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)
- encephalopathy (degenerative disease of the brain);
- seizures may become worse or happen more often;
- disturbance in heart rhythm (electrocardiogram);
- pancreatitis (pancreas inflammation)
- liver failure, hepatitis
- skin rash, which may form blisters and look 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
- limp or difficulty walking

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 (generally occur at the beginning of the treatment, from few days to a few months).

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 [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Iracet®

- Storage

Store below 30°C, protected from light and moisture. Store in original package.

- 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

An orange color solution having sweet orange flavor with slight bitter taste; free from any visible foreign particle. The solution is filled in transparent PET bottle and sealed with white color PP cap overprinted with "SQUARE".

Packaging:

90ml PET bottle filled with 50ml oral solution with plastic closure. 10ml measuring cup and 1.25ml dropper are supplied.

Pack size: 1x50ml and 6x50ml bottles

- Ingredients

- Active ingredient
Levetiracetam

- Inactive ingredients

Glycerol, liquid sorbitol (non crystalizing), sodium methyl hydroxybenzoate, sodium propyl hydroxybenzoate, aspartame, sucralose, sodium citrate, anhydrous citric acid, FD&C Red No. 40, D&C yellow No.10, orange liquid (sweet) essence No 1 NA and purified water q.s.

- MAL number:

MAL23066014AZ

Manufacturer

SQUARE PHARMACEUTICALS PLC
Square Road, Salgaria,
Pabna. 6600, BANGLADESH

Product Registration Holder

Medispec (M) Sdn Bhd
B-1-07, Jalan SS 25/22,
Taman Mayang,
47301 Petaling Jaya, Selangor, Malaysia.

Date of revision

09/07/2026

Serial number

NPRA(R2/1)260511/00062