Package leaflet: Information for the patient

Larofec 250 mg film-coated granules in sachet
Larofec 500 mg film-coated granules in sachet
Larofec 750 mg film-coated granules in sachet
Larofec 1000 mg film-coated granules in sachet

levetiracetam

Read all of this leaflet carefully before you or your child start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Larofec is and what it is used for

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

Larofec is used
- on its own in adults and adolescents from 16 years of age with newly diagnosed epilepsy, to treat a certain form of 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 seizure with or without secondary generalisation). Levetiracetam 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 generalization in adults, adolescents, children and infants from one month of age
  - myoclonic seizures (short, shock-like jerks of a muscle group or 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 adolescents from 12 years of age with Idiopathic Generalised Epilepsy (the type of epilepsy that is thought to have a genetic cause).

2. What you need to know before you take Larofec

Do not take Larofec
- If you are allergic to levetiracetam, pyrrolidone derivatives or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor before taking Larofec
- 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 levetiracetam 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 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.

Tell your doctor or pharmacist if any of the following side effects gets serious or last longer than a few days:
- Abnormal thoughts, feeling irritable or reacting more aggressively than usually, or if you or your family and friends notice important changes in mood or behaviour.
- Aggravation of epilepsy
  Your seizures may rarely become worse or happen more often, mainly during the first month after the start of the treatment or increase of the dose. In a very rare form of early-onset epilepsy (epilepsy associated with SCN8A mutations) that causes multiple types of seizures and loss of skills you may notice that the seizures remain present or are becoming worse during your treatment. If you experience any of these new symptoms while taking Larofec, see a doctor as soon as possible.

Children and adolescents

Larofec film-coated granules are not indicated in children and adolescents below 16 years on its own (monotherapy), and are not recommended, in children under the age of 6 years as well as in the initial treatment of children weighing less than 25 kg.

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

Do not take macrogol (a drug used as laxative) for one hour before and one hour after taking levetiracetam as this may result in a loss of its effect.

Pregnancy and breast-feeding
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. Levetiracetam 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. Two studies do not suggest an increased risk of autism or intellectual disability in children born to mothers treated with levetiracetam during pregnancy. However, the available data regarding the impact of levetiracetam on neurodevelopment in children is limited.
Breast-feeding is not recommended during treatment.

Driving and using machines
Larofec may impair your ability to drive or operate any tools or machinery, as it may make you feel 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.

3. How to take Larofec

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

Take the number of sachets following your doctor's instructions.
Larofec must be taken twice a day, once in the morning and once in the evening, at about the same time each day.

Adjunctive therapy and monotherapy (from 16 years of age)

Adults (≥18 years) and adolescents (12 to 17 years) weighing 50 kg or more:

- Recommended dose: between 1,000 mg and 3,000 mg each day.

When you will first start taking Larofec, your doctor will prescribe you a lower dose during 2 weeks before giving you the lowest daily dose.

Example: if your daily dose is intended to be 1,000 mg, your reduced starting dose is 1 sachet of 250 mg in the morning and 1 sachet of 250 mg in the evening, and the dose will be gradually incremented to reach 1,000 mg daily after 2 weeks.

Adolescents (12 to 17 years) weighing 50 kg or less

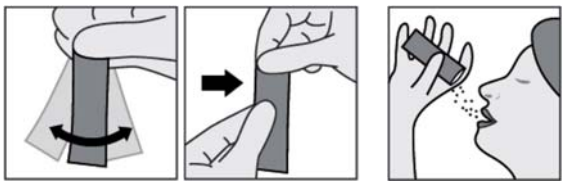
Your doctor will prescribe the most appropriate pharmaceutical form of Larofec according to weight and dose.

Dose in infants (1 month to 23 months) and children (2 to 11 years) weighing less than 50 kg

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

- Levetiracetam oral solution is a formulation more appropriate to infants and children under the age of 6 years and to children and adolescent (from 6 to 17 years) weighing less than 50 kg and when sachets don't allow accurate dosage.

Method of administration



1. 2. 3.

1. Hold sachet above arrow and shake content downwards.

2. Tear off at incision (arrowhead) or cut off at dotted line.

3. Pour content directly into the mouth and swallow the granules immediately without chewing and with a sufficient quantity of liquid (e.g. a glass of water). Do not chew the film-coated granules, as they may be of bitter taste. You may take Larofec with or without food.

Each sachet is for single use only.

Duration of treatment

- Larofec is used as chronic treatment. You should continue Larofec 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 take more Larofec than you should

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

If you forget to take Larofec

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 stop taking Larofec

If stopping treatment, Larofec should be discontinued gradually to avoid an increase of seizures. Should your doctor decide to stop your Larofec treatment, he/she will instruct you about the gradual withdrawal of Larofec.

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

4. Possible side effects

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

Tell your doctor immediately, or go to your nearest emergency department, if you experience:

- weakness, feel light-headed or dizzy or have difficulty breathing, as these may be signs of a serious allergic (anaphylactic) reaction
- swelling of the face, lips, tongue and throat (Quincke's oedema)
- flu-like symptoms and a rash on the face followed by an extended rash with a high temperature, increased levels of liver enzymes seen in blood tests and an increase in a type of white blood cell (eosinophilia), enlarged lymph nodes and the involvement of other body organs (Drug Reaction with Eosinophilia and Systemic Symptoms [DRESS])
- symptoms such as low urine volume, tiredness, nausea, vomiting, confusion and swelling in the legs, ankles or feet, as this may be a sign of sudden decrease of kidney function
- a 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)*
- a more severe form of rash causing skin peeling in more than 30% of the body surface *(toxic epidermal necrolysis)*
- signs of serious mental changes or 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.

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: may affect more than 1 in 10 people
- nasopharyngitis (nose or throat inflammation);
- somnolence (sleepiness), headache.

Common: may affect up to 1 in 10 people
- 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: may affect up to 1 in 100 people
- 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: may affect up to 1 in 1,000 people
- infection;
- decreased number of certain types of white blood cells (e.g. neutrophil granulocytes), or decreased number of all types of blood cells;
- severe allergic reactions (DRESS, anaphylactic reaction [severe and important allergic reaction], Quincke's oedema [swelling of the face, lips, tongue and throat]);
- decreased blood sodium concentration;
- suicide, personality disorders (behavioural problems), thinking abnormal (slow thinking, unable to concentrate);
- delirium;
- encephalopathy (see sub-section "Tell your doctor immediately" for a detailed description of symptoms);
- seizures may become worse or happen more often;
- uncontrollable muscle spasms affecting the head, torso and limbs, difficulty in controlling movements, hyperkinesia (hyperactivity);
- change of the heart rhythm (Electrocardiogram);
- pancreatitis;
- liver failure, hepatitis;
- sudden decrease in kidney function;
- 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;
- limp or difficulty walking;
- combination of fever, muscle stiffness, unstable blood pressure and heart rate, confusion, low level of consciousness (may be signs of a disorder called *neuroleptic malignant syndrome*). Prevalence is significantly higher in Japanese patients when compared to non-Japanese patients.

Very rare: may affect up to 1 in 10,000 people
- repeated unwanted thoughts or sensations or the urge to do something over and over again (Obsessive Compulsive Disorder).

Reporting of side effects
If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Website: www.hpra.ie
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Larofec

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

Do not use this medicine after the expiry date which is stated on the carton and sachet after EXP:. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

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.

6. Contents of the pack and other information

What Larofec contains

The active substance is levetiracetam. Each sachet contains 250 mg or 500 mg or 750 mg or 1000 mg of levetiracetam.

The other ingredients are:
Povidone
Cellulose, microcrystalline
Silica, colloidal anhydrous
Magnesium stearate
Poly(vinyl alcohol)
Titanium dioxide (E171)
Macrogol
Talc

What Larofec looks like and contents of the pack

Film-coated granules in sachets; the film-coated granules are white or almost white and round (diameter approx. 2 mm).

Larofec 250 mg film-coated granules in sachet
Pack size of 30, 50, 60, 100 sachets
Larofec 500 mg film-coated granules in sachet
Pack size of 30, 50, 60, 100 sachets
Larofec 750 mg film-coated granules in sachet
Pack size of 30, 50, 60, 100 sachets
Larofec 1000 mg film-coated granules in sachet
Pack size of 30, 50, 60, 100 sachets

Not all pack sizes may be marketed.

Marketing Authorisation Holder

C4 health GmbH
Wildstr. 20
89522 Heidenheim a. d. Brenz
Germany

Manufacturer

Desitin Arzneimittel GmbH
Weg beim Jaeger 214
22335 Hamburg
Germany

This medicine is authorised in the Member States of the European Economic Area under the following names:

Member State	Name
Belgium	Larofec 250/500/750/1000 mg filmomhuld granulaat in sachet / Larofec 250/500/750/1000 mg filmüberzogenes Granulat im Beutel / Larofec 250/500/750/1000 mg granulés pelliculés en sachet

Italy	Larofec 250/500/750/1000 mg granulato rivestito con film in bustina
Ireland	Larofec 250/500/750/1000 mg film-coated granules in sachet
Luxembourg	Larofec 250/500/750/1000 mg granulés pelliculés en sachet
The Netherlands	Larofec 250/500/750/1000 mg filmomhuld granulaat in sachet
Norway	Larofec
Finland	Larofec 250/500/750/1000 mg kalvopäällysteiset rakeet, annospussi

This leaflet was last revised in 12/2025.