

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) 1986

This medicine is to be supplied by physician's prescription only

**Inovelon 100 mg, film coated tablets
Inovelon 200 mg, film coated tablets
Inovelon 400 mg, film coated tablets**

Composition

Active ingredients:

Rufinamide 100 mg
Rufinamide 200 mg
Rufinamide 400 mg

For the list of Inactive ingredients: See section "Additional information".

Read the entire leaflet carefully before you start using this medicine. This leaflet contains essential information about this medicine. If you have any further questions, refer to the physician or the pharmacist.

This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their illness is similar.

Inovelon contains Rufinamide; this medicine belongs to the class of anti-epileptic medicines used for the treatment of epileptic seizures related to Lennox–Gastaut syndrome.

Lennox–Gastaut syndrome is characterized by recurrent severe seizures appearing in different variations.

What is this medicine intended for?

Inovelon is administered as an addition to the treatment of seizures related to Lennox–Gastaut syndrome in patients above the age of 4 years.

Therapeutic group: anti-convulsant

Before using this medicine

Do not use this medicine if:

You are sensitive (allergic) to the active ingredient, Rufinamide or to other derivatives of the Triazole group or to any of the other ingredients that this medicine contains (please see 'Additional Information')

PANEL B

Special warnings regarding the use of this medicine

Before using Inovelon, tell your physician if:

- You suffer or have previously suffered from problems with liver function. Since there is little information regarding the use of **Inovelon** in people with liver diseases, the physician may increase the dose more slowly. In severe cases, the physician may decide that treatment with **Inovelon** is not suitable for you.
- You or any of your family members suffer from a congenital syndrome associated with short QT interval in ECG (heart rate disorder). **Inovelon** may lead to exacerbation of this condition.
- You suffer from skin rash or fever. These may be signs of an allergic reaction to **Inovelon**. Contact a physician immediately.
- You suffer from exacerbation of seizures, increased duration of each seizure or more frequent appearance of seizures. Contact a physician immediately.
- You experience difficulties walking, abnormal movements, dizziness or somnolence.

In addition, notify the physician if the above events have occurred during any period in the past.

If you are taking or have recently taken other medicines, including nonprescription medications and food supplements, inform your physician or pharmacist. In particular inform the physician or the pharmacist if you are taking:

- Oral contraceptives – their efficacy may be reduced, therefore it is recommended to use additional contraceptive methods which are not based on oral hormones.

SECOND FOLD

- For children aged 4 years or older weighing less than 30 kg (taking valproate in addition):

Initial dosage of 200 mg per day divided into two doses (100 mg twice a day).

If required, the physician will increase the dosage by 200 mg every two days up to the maximal dosage of 600 mg.

- For children and adults weighing more than 30 kg: Initial dosage of 400 mg per day divided into two doses (200 mg twice a day).

If required, the physician will increase the dosage by 400 mg every two days up to the maximal dosage of 3200 mg (depending on your body weight).

If you experience side effects, the physician may increase your dose at a slower rate.

- Swallow the medicine with a glass of water.
- Take the tablet twice a day, one in the morning and one in the evening.
- If you have difficulties swallowing, you can crush the tablet and mix the powder with about half a glass of water (100 ml) and drink immediately.

If you have accidentally taken a higher dose or if a child has accidentally swallowed the medicine, go immediately to a hospital emergency room and bring the medicine package with you.

If you forget to take the medicine at the scheduled time, take the missed dose immediately, do not take a double dose to make up for the missed dose. If you forgot to take more than one tablet, consult with the attending physician.

If you stop taking the medicine even if there is an improvement in your health, do not stop treatment with this medicine or change the dosage without consulting the physician or the pharmacist.

If the physician decides to stop the treatment with **Inovelon**, he will do it gradually to reduce the risk of increasing the level of seizures.

If you have any other questions regarding the use of the medicine, consult the physician or the pharmacist.

Side effects

As with any medicine, use of **Inovelon** may cause side effects in some users. Do not be alarmed by reading the list of side effects. You may not experience any of them.

The following side effects may be severe:

- Rash and/or fever, these may be signs of an allergic reaction. If you experience these effects, contact a physician or a hospital emergency room immediately.
- Changes in the nature of seizures – increased frequency of seizures and prolonged duration of each seizure. Contact a physician immediately.
- If you have suicidal thoughts or think about hurting yourself, contact a physician immediately.

Very common side effects

- Dizziness and headaches
- Nausea and vomiting
- Somnolence and fatigue

Common side effects

- Disorders of the nervous system: difficulties walking, movement disorders, convulsions / seizures, abnormal eye movements, blurred vision, tremor.
- Gastrointestinal disorders: abdominal pain, constipation, indigestion, diarrhea, loss or change of appetite, weight loss.
- Infections: ear infection, influenza, nasal congestion, chest infections.
- Anxiety, sleeplessness, nose bleeds, acne, rash, back pain, menstrual cycle disorders, trauma and head injuries (due to injury during a seizure).

Uncommon side effects

- Allergic reactions and elevation of liver enzymes.

If any side effect gets worse, or if you suffer from a side effect not mentioned in the leaflet, you should consult the physician.

- Medicines metabolized by the CYP3A4 enzyme in the liver. The physician may need to closely monitor your condition during the first two weeks of treatment with **Inovelon**, after stopping treatment with **Inovelon**, or after changing its dose since the efficacy of other medicines may be reduced.

• Warfarin- an anticoagulant. The physician may need to adjust the dose.

• Digoxin – a medicine for the treatment of heart problems. The physician may need to adjust the dose.

• If the physician recommends or prescribes another treatment for epilepsy (e.g. valproate), you need to inform him that you are treated with **Inovelon**. Dose adjustment may be required.

Children

Do not administer **Inovelon** to children below the age of 4 years since there is no information about the use of **Inovelon** in these ages.

Taking Inovelon and food

Inovelon should be taken with food.

Use of the medicine and alcohol consumption

As a precaution, do not drink alcohol during treatment with **Inovelon**.

Pregnancy and breastfeeding

If you are a woman of childbearing age, you should use contraceptives while being treated with **Inovelon**. If you are using hormonal contraceptives, it is recommended to use an additional contraceptive method as well, since **Inovelon** may reduce the efficacy of hormonal contraceptives.

If you are pregnant, think you may be pregnant or are planning to get pregnant, you should consult a physician before taking **Inovelon**.

It is recommended to avoid breastfeeding during treatment with **Inovelon**, since it is not known whether the active ingredient of the medicine pass through breast milk.

Driving and using machines

If **Inovelon** causes you to experience dizziness, somnolence or blurred vision, do not drive or operate machines. Especially extreme caution is required in the beginning of treatment or after dose elevation.

PANEL C

Important information about some of the medicine's ingredients

Inovelon contains lactose. If you are intolerant to certain sugars, inform the attending physician prior to using this medicine.

How should you use the medicine?

Always use according to the physician's instructions. You should check with the physician or the pharmacist if you are unsure.

- The standard dosage for children aged 4 years or older weighing less than 30 kg (not taking valproate in addition): Initial dosage of 200 mg per day divided into two doses (100 mg twice a day).

If required, the physician will increase the dosage by 200 mg every two days up to the maximal dosage of 1000 mg.

How to store the medicine?

- Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the reach of children and/or infants in order to avoid poisoning. Do not induce vomiting without an explicit instruction from the physician.
- Do not take medicines in the dark! Check the label and the dose each time you take the medicine. Wear glasses if you need them.
- Do not use the medicine after the expiry date (exp. date) appearing on the outer package. The expiry date refers to the last day of that month.
- Do not store at a temperature above 30°C.
- Do not use this medicine if you've noticed a change in the appearance of the tablets.

Additional information

- In addition to the active ingredient (Rufinamide) the medicine also contains: Lactose monohydrate; Cellulose microcrystalline; Maize starch; Croscarmellose sodium; Hypromellose; Magnesium stearate; Sodium laurilsulfate; Silica colloidal anhydrous
Film coating: Hypromellose, Macrogols (8000), Titanium Dioxide (E171), Talc, Ferric Oxide Red (E172)
- What does the medicine look like and what are the contents of the package:
Inovelon 100, 200, 400 mg - Coated pink oval tablets, slightly convex, with a score line on both sides.
Inovelon 100 mg – E261 is embossed on one side, packed in blisters, 10 tablets per pack.
Inovelon 200 mg – E262 is embossed on one side, packed in blisters, 60 tablets per pack.
Inovelon 400 mg – E263 is embossed on one side, packed in blisters, 60 tablets per pack.
- Registration holder and importer: Eisai Israel Ltd, PO Box 8049, Kfar Saba, 4418001, Israel.
- Revised in January 2023 according to MOH guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:

Inovelon 100 mg – 145-35-33202

Inovelon 200 mg – 145-36-33204

Inovelon 400 mg – 145-37-33205