Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) 1986
This medicine is to be supplied by physician's prescription only

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

Composition
Active ingredients:
Rufinamide 100 mg
Rufinamide 200 mg
Rufinamide 400 mg

For the list of Inactive and allergenic 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.

1. What is this medicine intended for?

Inovelon Tablets is administered as an addition to the treatment of seizures related to Lennox–Gastaut syndrome in patients 1 year of age and older..

Therapeutic group: anti- convulsant**.**

Inovelon Tablets 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.

2. 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')

Special warnings regarding the use of this medicine

Before using Inovelon Tablets, tell your physician if:
- You or any of your family members suffer from a congenital syndrome associated with short QT interval in ECG (heart rate disorder). **Inovelon Tablets** may lead to exacerbation of this condition.
- You suffer from problems with liver function. Since there is little information regarding the use of **Inovelon Tablets** in people with liver diseases, the physician may increase the dose more slowly. In severe cases of liver disease, the physician may decide that treatment with **Inovelon Tablets** is not suitable for you.
- Following treatment with **Inovelon Tablets**, you suffer from skin rash or fever. These may be signs of an allergic reaction to **Inovelon Tablets**. Contact a physician immediately because these symptoms can often be severe.
- 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 sleepiness. Contact a physician if you experience any of these effects.
- If after taking this medicine you have suicidal thoughts or think about hurting yourself, **contact your physician or go to the emergency room at the hospital immediately**

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

Children
There is not enough information about the use of this medicine in children under the age of one year.

Hepatic failure
It is recommended to use this medicine carefully during the titration process for patients with mild to moderate hepatic failure. Use of this medicine is not recommended for patients with severe hepatic failure.

Drug interactions:
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:

- Antiepileptic medicines and Inovelon Phenobarbital, Fosphenytoin, Phenytoin, Primidone. The physician may need to closely monitor your condition during the first two weeks of treatment with Inovelon Tablets, after stopping treatment with Inovelon Tablets, or after changing its dose. A change in the dose of the other medicines may be needed as they may become slightly less effective when given with rufinamide.
- If the physician recommends or prescribes another treatment for epilepsy (e.g., a medicine that contains valproic acid), you need to inform him that you are treated with **Inovelon Tablets**. Dose adjustment may be required.
- Oral/ hormonal contraceptives– **Inovelon Tablets** may reduce their efficacy at preventing pregnancy; therefore, it is recommended to use additional contraceptive method (such as a barrier method, e.g., condoms) while taking **Inovelon Tablets**.
- 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.
- Adults and children taking valproate at the same time as rufinamide will result in high levels of rufinamide in the blood. Tell your doctor if you are taking valproate as the dose of Inovelon may need to be reduced by your doctor.

Taking Inovelon Tablets and food
See section 3– 'How should you use the medicine?' for advice on taking **Inovelon Tablets** with food and water.

Use of the medicine and alcohol consumption
There is no information about alcohol consumption during treatment with **Inovelon Tablets**.

Pregnancy, breastfeeding, and fertility
If you are pregnant, think you may be pregnant or are planning to get pregnant, you should consult a physician before taking Inovelon Tablets. You must only take Inovelon during your pregnancy if the doctor tells you to.

It is recommended to avoid breastfeeding during treatment with **Inovelon Tablets**, since it is not known whether the active ingredient of the medicine passes through breast milk.
If you are a woman of childbearing age, you should use contraceptives while being treated with **Inovelon Tablets**.
Ask the doctor or pharmacist for advice before taking any medicine at the same time as Inovelon.

Driving and using machines
Inovelon Tablets may make you feel dizzy, drowsy and affect your vision, particularly at the beginning of treatment or after a dose increase. If this happens to you, do not drive, or operate machines.

Important information about some of the medicine's ingredients
Inovelon Tablets contain lactose. If you are intolerant to certain sugars, inform the attending physician prior to using this medicine.
Inovelon Tablets 100 mg – Contains 20 mg lactose
Inovelon Tablets 200 mg – Contains 40 mg lactose
Inovelon Tablets 400 mg – Contains 80 mg lactose

Inovelon Tablets contain sodium
This medicine contains less than 1 mmol sodium (23 mg) per daily dose, that is to say essentially 'sodium-free'.

3. 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 of the dose and the treatment method for this medicine.

The process of determining the best dose of **Inovelon Tablets** for you could take time. This dose will be calculated for you by the physician and will depend on your age, body weight, and whether you are taking **Inovelon Tablets** with another medicine called valproic acid.

- Children aged 1 to 4 years:
  The recommended initial dose is 10 mg per kg of body weight, each day. This dose is divided into 2, half in the morning and half in the evening. The physician will calculate the dose and may increase it by 10 mg per kg of body weight, at 3-day intervals (the dose will be increased on the third day after the previous increase).

  The maximum daily dose will depend on whether or not the patient is concomitantly taking a medicine that contains valproic acid. The maximum daily dose for patients who are not concomitantly taking a medicine that contains valproic acid is 45 mg per kg of body weight a day.
  As for patients concomitantly taking a medicine that contains valproic acid, the maximum daily dose is 30 mg per kg of body weight a day.
- Children aged 4 years or older weighing less than 30 kg:
  The recommended initial dose is 200 mg per day. This dose is divided into 2, half in the morning and half in the evening. The physician will calculate the dose and will increase it by 200 mg, when necessary, at 3-day intervals.

  The maximum daily dose will depend on whether the patient is concomitantly taking a medicine that contains valproic acid. The maximum daily dose for patients who are not concomitantly taking a medicine that contains valproic acid is 1,000 mg a day. As for patients concomitantly taking valproic acid, the maximum daily dose is 600 mg.
- Children, adolescents, and adults weighing 30 kg or over:
  The recommended initial dose is 400 mg per day. This dose is divided into 2, half in the morning and half in the evening. The physician will calculate the dose and will increase it by 400 mg every other day when necessary.

  The daily dose will depend on whether the patient is concomitantly taking a medicine that contains valproic acid. The maximum daily dose for patients who are not concomitantly taking a medicine that contains valproic acid is 3,200 mg a day (depending on your body weight). As for patients concomitantly taking valproic acid, the maximum daily dose is 2,200 mg (depending on your body weight).

  Some patients may response to lower doses. The physician may adjust the dose depending on the way you respond to the treatment.

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

Do not exceed the recommended dose

Administration method
- Swallow the medicine with water.
- Take the tablet twice a day, one in the morning and one in the evening with food.
- 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. You can also break the tablets into two equal halves and swallow with water.

If you have accidently taken a higher dose or if a child has accidentally swallowed the medicine, tell the doctor or immediately, or 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, continue taking the medicine as normal. 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.
If the physician decides to stop the treatment with **Inovelon Tablets**, follow their instructions concerning the gradual reduction of the medicine to reduce the risk of an increase in seizures.

Do not take medicines in the dark! Inspect the labels and the dose every time you take medicine. Wear glasses if you need them.

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

4. Side effects

As with any medicine, use of **Inovelon Tablets** 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 can be very serious:

- 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 types of seizures – increased frequency of seizures which last a long time (called status epilepticus). Contact a physician immediately.
- A small number of people being treated with antiepileptics such as **Inovelon Tablets** have had thoughts of harming or killing themselves. If at any time you have these thoughts, contact a physician immediately (see section 2- Before using this medicine).

The following side effects may appear during the use of this medicine. Contact your physician if any of the following occurred:

Very common side effects: effects that appear in more than 1 patient of every 10:
- Dizziness and headaches
- Nausea and vomiting
- sleepiness and fatigue

Common side effects; effects that appear in 1-10 patients of every 100:
- 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, flu, nasal congestion, chest infections.
- In addition, patients have experienced: Anxiety, insomnia, nose bleeds, acne, rash, back pain, infrequent periods, trauma and head injuries (as a result of accidental injury during a seizure).

Uncommon side effects; effects that appear in 1-10 patients of every 1000:
- Allergic reactions and an increase in markers of liver function (hepatic enzyme increase).

If any side effect appears, gets worse, or if you suffer from a side effect not mentioned in the leaflet, you should consult the physician.
Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects Following Medicinal Treatment" found on the Ministry of Health homepage (www.health.gov.il), which directs you to the online form for reporting side effects, or by entering the link: *https://sideeffects.health.gov.il/*

5. How to store the medicine?

- Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting without an explicit instruction from the physician.
- 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.

Storage conditions:
- Store at a temperature below 30°C.
- Do not use this medicine if you've noticed a change in the appearance of the tablets.
- Do not throw any medicines into the wastewater or the household waste. Ask the pharmacist how to dispose of medicines you no longer use. These measures will help protect the environment.

6. Additional information

In addition to the active ingredient (Rufinamide) the medicine also contains:

cellulose microcrystalline (E460), Lactose monohydrate; Maize starch; Croscarmellose sodium (E468); Hypromellose (E464); Magnesium stearate (E470b); Silica colloidal anhydrous, Sodium laurilsulfate;

Film coating: Hypromellose (E464), 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 Tablets 100, 200, 400 mg - Coated pink oval tablets, slightly convex, with a score line on both sides.
  Inovelon Tablets 100 mg – E261 is embossed on one side, packed in blisters, 10 tablets per pack.
  Inovelon Tablets 200 mg – E262 is embossed on one side, packed in blisters, 60 tablets per pack.
  Inovelon Tablets 400 mg – E263 is embossed on one side, packed in blisters, 60 tablets per pack.

Registration holder and importer: Eisai Israel ltd, PO Box 3393, Petah Tikva, 4951600, Israel.

Revised in February 2024 according to the directions of the Ministry of Health

Registration number of the medicine in the National Drug Registry of the Ministry of Health:
Inovelon Tablets 100 mg – 145-35-33202
Inovelon Tablets 200 mg – 145-36-33204
Inovelon Tablets 400 mg – 145-37-33205