

Package leaflet: Information for the user

Inovelon 40 mg/ml oral suspension Rufinamide

Read all of this leaflet carefully before you 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 the 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 the doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Inovelon is and what it is used for
2. What you need to know before you take Inovelon
3. How to use Inovelon
4. Possible side effects
5. How to store Inovelon
6. Contents of the pack and other information

1. What Inovelon is and what it is used for

Inovelon contains a medicine called rufinamide. It belongs to a group of medicines called antiepileptics, which are used to treat epilepsy (a condition where someone has seizures or fits).

Inovelon is used with other medicines to treat seizures associated with Lennox-Gastaut syndrome in adults, adolescents and children from 1 year of age. Lennox-Gastaut syndrome is the name given to a group of severe epilepsies in which you may experience repeated seizures of various types.

Inovelon has been given to you by your doctor to reduce the number of your seizures or fits.

2. What you need to know before you take Inovelon

Do not take Inovelon:

- if you are allergic to rufinamide or triazole derivatives or any of the other ingredients of Inovelon (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist if:

- you have Congenital Short QT Syndrome or a family history of such a syndrome (electrical disturbance of the heart), as taking rufinamide could make it worse.
- you suffer from liver problems. There is limited information on the use of rufinamide in this group, so the dose of your medicine may need to be increased more slowly. If your liver disease is severe the doctor may decide Inovelon is not recommended for you.
- you get a skin rash or fever. These could be signs of an allergic reaction. See the doctor immediately as very occasionally this may become serious.
- you suffer an increase in the number or severity or duration of your seizures, you should contact the doctor immediately if this happens.
- you experience difficulty walking, abnormal movement, dizziness or sleepiness inform the doctor, if any of these happen.

- if you take this medicine and have thoughts of harming or killing yourself at any time, **contact your doctor or go to a hospital straight away** (see section 4).

Consult the doctor, even if these events occurred at any time in the past.

Children

Inovelon should not be given to children younger than 1 year of age since there is not enough information on its use in this age group.

Other medicines and Inovelon

Tell the doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. If you are taking the following medicines: phenobarbital, fosphenytoin, phenytoin or primidone, you may need to be carefully monitored for two weeks at the start of, or after the end of treatment with rufinamide, or after any marked change in the dose. A change in the dose of the other medicines may be needed as they may become slightly less effective when given with rufinamide.

Antiepileptic medicines and Inovelon

If the doctor prescribes or recommends an additional treatment for epilepsy (e.g., valproate) you must tell the doctor you are taking Inovelon as the dose may need adjusting.

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.

Tell the doctor if you are taking hormonal/oral contraceptives, e.g., “The pill”. Inovelon may make the pill not effective at preventing pregnancy. Therefore, it is recommended that you use an additional safe and effective contraceptive method (such as a barrier method, e.g., condoms) when taking Inovelon.

Tell the doctor if you are taking the blood thinner – warfarin. The doctor may need to adjust the dose.

Tell the doctor if you are taking digoxin (a medicine used to treat heart conditions). The doctor may need to adjust the dose.

Inovelon with food and drink

See section 3 – ‘How to use Inovelon’ for advice on taking Inovelon with food and drink.

Pregnancy, breast-feeding and fertility

If you are pregnant, or think you might be pregnant, or are planning to get pregnant, ask the doctor or pharmacist for advice before taking Inovelon. You must only take Inovelon during your pregnancy if the doctor tells you to.

You are advised not to breast-feed while taking Inovelon, as it is not known if rufinamide will be present in breast milk.

If you are a woman of childbearing age, you must use contraceptive measures while taking Inovelon.

Ask the doctor or pharmacist for advice before taking any medicine at the same time as Inovelon.

Driving and using machines

Inovelon 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 machinery.

Inovelon contains sorbitol

Patients with rare, hereditary problems of fructose intolerance should not take this medicine.

Inovelon contains methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216)

These ingredients may cause allergic reactions (possibly delayed).

3. How to use Inovelon

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

It may take a while to find the best dose of Inovelon for you. The dose will be calculated for you by the doctor and will depend on your age, weight and whether you are taking Inovelon with another medicine called valproate.

Children aged between 1 and 4 years of age

The recommended starting dose is 10 mg (0.25 ml) for each kilogram of body weight, each day. Taken in two equal doses, half in the morning and the other half in the evening. The dose will be calculated for you by the doctor and may be increased by 10 mg (0.25 ml) for each kilogram of body weight, every third day.

The maximum daily dose will depend on whether or not you are also taking valproate. Maximum daily dose not taking valproate is 45 mg (1.125 ml) for each kilogram of body weight, each day. Maximum daily dose taking valproate is 30 mg (0.75 ml) for each kilogram of body weight, each day.

Children 4 years of age or older weighing less than 30 kg

The recommended starting dose is 200 mg (5 ml) a day. Taken in two equal doses, half in the morning and the other half in the evening. The dose will be calculated for you by the doctor and may be increased by 200 mg (5 ml) every third day.

The maximum daily dose will depend on whether or not you are also taking valproate. Maximum daily dose not taking valproate is 1,000 mg (25 ml) each day. Maximum daily dose taking valproate is 600 mg (15 ml) each day.

Adults, adolescents and children weighing 30 kg or over

The recommended starting dose is 400 mg (10 ml) a day. Taken in two equal doses, half in the morning and the other half in the evening. The dose will be calculated for you by the doctor and may be increased by 400 mg (10 ml) every other day.

The maximum daily dose will depend on whether or not you are also taking valproate. Maximum daily dose not taking valproate is no more than 3,200 mg (80 ml), depending on body weight. Maximum daily dose taking valproate is no more than 2,200 mg (55 ml), depending on body weight.

Some patients may respond to lower doses and your doctor may adjust the dose depending on how you respond to the treatment.

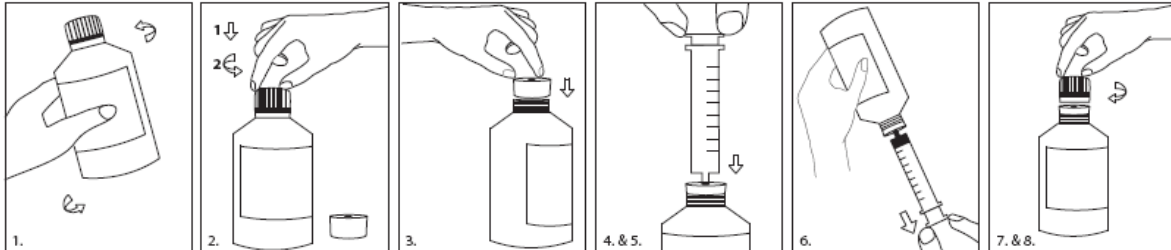
If you experience side effects, your doctor may increase the dose more slowly.

Inovelon oral suspension must be taken twice every day, once in the morning and once in the evening. Inovelon should be taken with food.

Method of administration

For dosing, please use the syringe and adaptor provided.

Instructions on how to use the syringe and adaptor are provided below:



Shake well before use.

1. Push down and turn cap to open bottle
2. Insert adaptor into the neck of the bottle until a tight seal is made
3. Push plunger of syringe completely down
4. Insert the syringe into the opening of the adaptor as far as possible.
5. Turn upside down and withdraw the prescribed amount of Inovelon from the bottle.
6. Turn upright and remove the syringe
7. Leave the adaptor in place and replace cap on bottle. Wash the syringe with clean water and dry thoroughly.

Do not reduce the dose or stop this medicine unless the doctor tells you to.

If you take more Inovelon than you should

If you may have taken more Inovelon than you should, tell the doctor or pharmacist immediately, or contact your nearest hospital casualty department, taking the medicine with you.

If you forget to take Inovelon

If you forget to take a dose, continue taking the medicine as normal. Do not take a double dose to make up for forgotten dose. If you miss taking more than one dose, seek advice from the doctor.

If you stop taking Inovelon

If the doctor advises stopping treatment, follow their instructions concerning the gradual reduction of Inovelon in order to lower the risk of an increase in seizures.

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

4. Possible side effects

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

The following side effects can be very serious:

Rash and/or fever. These could be signs of an allergic reaction. If they happen to you tell your doctor or go to a hospital immediately:

Change in the types of seizures you experience/more frequent seizures which last a long time (called status epilepticus). Tell your doctor immediately.

A small number of people being treated with antiepileptics such as Inovelon have had thoughts of harming or killing themselves. If at any time you have these thoughts contact your doctor immediately (see section 2).

You may experience the following side effects with this medicine. Tell the doctor if you have any of the following:

Very common (more than 1 in 10 patients) side effects of Inovelon are:

Dizziness, headache, nausea, vomiting, sleepiness, fatigue.

Common (more than 1 in a 100 patients) side effects of Inovelon are:

Problems associated with nerves including: difficulty walking, abnormal movement, convulsions/seizures, unusual eye movements, blurred vision, trembling.

Problems associated with the stomach including: stomach pain, constipation, indigestion, loose stools (diarrhoea), loss or change in appetite, weight loss.

Infections: ear infection, flu, nasal congestion, chest infection.

In addition, patients have experienced: anxiety, insomnia, nose bleeds, acne, rash, back pain, infrequent periods, bruising, head injury (as a result of accidental injury during a seizure).

Uncommon (between 1 in a 100 and 1 in a 1000 patients) side effects of Inovelon are:

Allergic reactions and an increase in markers of liver function (hepatic enzyme increase).

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 the Yellow Card Scheme: <https://yellowcard.mhra.gov.uk/> or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Inovelon

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 bottle label and carton. The expiry date refers to the last day of that month.

If you have any suspension left in the bottle more than 90 days after it was first opened, do not use it.

Do not use the suspension if you notice that the appearance or smell of your medicine has changed. Return the medicine to the pharmacist.

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 to protect the environment.

6. Contents of the pack and other information

What Inovelon contains

- The active substance is rufinamide. Each millilitre contains 40 mg of rufinamide. 5 ml contains 200 mg rufinamide.
- The other ingredients are microcrystalline cellulose and carmellose sodium, anhydrous citric acid, simeticone emulsion 30% (containing benzoic acid, cyclotetrasiloxane, dimethicone, glycol stearate and glyceryl distearate, methylcellulose, PEG-40 stearate [polyethylene glycol stearate], polysorbate 65, silica gel, sorbic acid, sulphuric acid and water), poloxamer 188, hydroxyethylcellulose, methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216), potassium sorbate, propylene glycol (E1520), sorbitol, liquid (non-crystallising), orange flavour and water.

What Inovelon looks like and contents of the pack

- Inovelon is a white slightly viscous suspension. It comes in a bottle of 460 ml with two identical syringes and a push in bottle adaptor (PIBA). The syringes are graduated in 0.5 ml increments.

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Detailed information on this product is available on the European Medicines Agency website
<http://www.ema.europa.eu>