

Inovelon®

Rufinamide film-coated tablets

(ru-fin-a-mide)

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Inovelon.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking this medicine against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.
Keep this leaflet with the medicine.

You may need to read it again.

WHAT INOVELON IS USED FOR

Inovelon is used with other medicines to treat seizures associated with Lennox-Gastaut syndrome in adults, adolescents and children from 4 years 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.

It contains the active ingredient rufinamide. Rufinamide belongs to a group of medicines called anti epileptics.

It works by reducing the number of fits that you have.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is available only with a doctor's prescription.

BEFORE YOU TAKE INOVELON

When you must not take it

Do not take this medicine if you have an allergy to:

- Rufinamide, the active ingredient, or to any of the other ingredients listed at the end of this leaflet under Product Description

Inovelon tablets contain lactose.

If you have been told by your doctor that you have intolerance to some sugars, tell your doctor before taking Inovelon.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- congenital Short QT Syndrome or a family history of such a syndrome (electrical disturbance of the heart),
- heart problems,
- liver problems,
- have or have had suicidal thoughts or actions,

depression or mood problems.

Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding. You must only take Inovelon during your pregnancy if the doctor tells you to.

You must use a reliable method of contraception to avoid becoming pregnant while you are being treated with Inovelon.

You should continue doing this for one month after stopping treatment.

Tell your doctor if you are taking hormonal contraceptives. Inovelon may make certain hormonal contraceptives less effective.

You should use other forms of safe and effective contraception (such as a condom or coil) when taking Inovelon. You should also do this for one month after stopping treatment. Discuss with your doctor what may be appropriate contraception for you.

It is not known whether the ingredients of Inovelon can pass into breast milk.

The doctor will weigh up the benefit and risks to your baby of taking Inovelon while you are breastfeeding.

If you have not told your doctor about any of the above, tell him/her before you start taking Inovelon.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

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.

Taking high doses of valproate at the same time as Inovelon will result in high levels of rufinamide in the blood, therefore the dose of Inovelon may need adjusting in adults and children.

Some medicines and Inovelon may interfere with each other. These include:

- carbamazepine
- phenobarbital
- phenytoin
- vigabatrin
- primidone

These medicines may be affected by Inovelon or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

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. Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

HOW TO TAKE INOVELON

Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet.

Your total daily dose of INOVELON should be taken in two equally divided doses. Take one half of your total daily dose in the morning and one half of your total daily dose in the evening.

If you do not understand the instructions, ask your doctor or pharmacist for help.

How much to take

Children 4 years and older and weighing less than 30 kg and not taking valproate

The recommended total daily starting dose is 200 mg taken in two equal doses.

The dose will be adjusted for you by the doctor and may be increased by up to 200 mg/day at intervals of at least three days, up to a total daily dose of no more than the maximum recommended total daily dose of 1000 mg/day.

Children 4 years and older weighing less than 30 kg and taking valproate

The recommended total daily starting dose is 200 mg taken in two equal doses.

The dose will be adjusted for you by the doctor and may be increased by up to 200 mg/day at intervals of at least two days, up to a total daily dose of no more than the maximum

recommended total daily dose of 600 mg/day.

Adults, adolescents and children weighing 30 kg or more and not taking valproate

The recommended total daily starting dose is 400 mg taken in two equal doses.

The dose will be adjusted for you by the doctor and may be increased by up to 400 mg/day at intervals of at least two days, up to a total daily dose of no more than the maximum recommended total daily dose of 3200 mg, depending upon your weight.

Adults, adolescents and children weighing 30 kg or more and taking valproate

The usual total daily starting dose is 400 mg taken in two equal doses.

The dose will be adjusted for you by the doctor and may be increased by up to 400 mg/day at intervals of at least two days, up to a total daily dose of no more than the maximum recommended total daily dose of 2200 mg, depending upon your weight.

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

Your doctor may have prescribed a different dose.

Ask your doctor or pharmacist if you are unsure of the correct dose for you.

They will tell you exactly how much to take.

Follow the instructions they give you.

If you take the wrong dose, Inovelon may not work as well and your problem may not improve.

How to take it

Inovelon tablets must be taken with food twice daily, in the morning and evening.

If you have difficulty swallowing the tablet whole, you can crush the tablet, then mix the powder in about half a glass (100 ml) of water and drink immediately.

When to take Inovelon

Take your medicine with food at about the same time each day in the morning and evening.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

How long to take Inovelon

Continue taking your medicine for as long as your doctor tells you. Do not stop unless your doctor advises you to.

Your doctor may reduce your dose slowly to avoid your fits (seizures) coming back or getting worse.

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

If you forget to take it

Wait until your next dose, and then continue to take it as you would normally.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

If you have missed more than 1 dose of treatment with Inovelon, talk to your doctor immediately.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 0800 764 766) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Inovelon. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

WHILE YOU ARE TAKING INOVELON

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Inovelon.

Tell any other doctors, dentists and pharmacists who treat you that you are taking Inovelon.

If you are going to have surgery, tell the surgeon or

anaesthetist that you are taking Inovelon.

It may affect other medicines used during surgery.

If you become pregnant while taking Inovelon, tell your doctor immediately. Do not stop treatment without first discussing it with your doctor.

If you are about to have any blood tests, tell your doctor that you are taking Inovelon. It may interfere with the results of some tests.

Keep all of your doctor's appointments so that your progress can be checked.

Things you must not do

Do not take Inovelon to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or lower the dosage without checking with your doctor.

Things to be careful of

Do not drive or operating machinery until you know how Inovelon affects you.

You must talk to your doctor about the effect of your epilepsy on 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 use any tools or machines.

Avoid alcohol while taking Inovelon as it may make these effects worse.

SIDE EFFECTS

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Inovelon

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

A small number of people being treated with anti-epileptics have had thoughts of harming or killing themselves. If at any time you have these thoughts, contact your doctor or go to accident & emergency straight away.

The following side effects can be very serious and you should tell your doctor immediately or go to a hospital if you experience any of them:

- Rash and/or fever. These could be signs of an allergic reaction.
- Change in the types of seizures you experience or if you experience more frequent seizures which last a long time (called status epilepticus).

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

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

- dizziness,
- headache,
- nausea,
- vomiting,
- sleepiness,
- fatigue.

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

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

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

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).

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

Other side effects not listed above may also occur in some people.

AFTER TAKING INOVELON

Storage

Keep your medicine in the original container.

If you take it out of its original container it may not keep well.

Keep your medicine in a cool dry place where the temperature stays below 30°C.

Do not store Inovelon or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

PRODUCT DESCRIPTION

What it looks like

Inovelon 100 mg film coated tablets are pink, oval, slightly convex film-coated tablets, scored on both sides, embossed 'C261' on one side and blank on the other side.

They are available as blister packs of 10, 30, 50, 60 and 100 film-coated tablets.

Inovelon 200 mg film coated tablets are pink, oval, slightly convex film-coated tablets, scored on both sides, embossed 'C262' on one side and blank on the other side.

They are available as blister packs of 10, 30, 50, 60 and 100 film-coated tablets.

Inovelon 400 mg film coated tablets are pink, oval, slightly convex film-coated tablets, scored on both sides, embossed 'C263' on one side and blank on the other side.

They are available as blister packs of 10, 30, 50, 60 and 100 film-coated tablets.

Not all pack sizes may be marketed.

Ingredients

Active ingredient:

- Rufinamide

Excipient Ingredients:

- sodium lauryl sulfate
- maize starch,
- hypromellose,
- lactose monohydrate,
- microcrystalline cellulose,
- croscarmellose sodium,
- colloidal anhydrous silica
- magnesium stearate

- macrogol 8000,
- titanium dioxide,
- purified talc and
- iron oxide red.

This medicine does not contain gluten, tartrazine or any other azo dyes.

SPONSOR

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