

INOVELON[®] Film-Coated Tablets

Rufinamide (200mg)

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What INOVELON[®] 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 over 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.

How INOVELON[®] works

INOVELON[®] acts on the sodium channels, prolonging their inactive state.

Before you use INOVELON[®]

- When you must not use it

Do not take INOVELON[®]:

- if you are allergic to rufinamide or triazole derivatives or any of the other ingredients of INOVELON[®].

Pregnancy and breast-feeding

If you are a woman of childbearing age, you must use contraceptive measures while taking INOVELON[®].

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.

Ask the doctor or pharmacist for advice before taking any medicine.

Children

INOVELON[®] should not be given to children younger than 4 years of age since there is not enough information on its use in this age group.

INOVELON[®] contains lactose

If you have been told by the doctor that you have an intolerance to some sugars, contact the doctor before taking this medicinal product.

- Before you start use it

Before you take INOVELON[®], tell your healthcare providers if you:

- have heart problems
- have liver problems
- have any other medical problems
- have or have had suicidal thoughts or actions, depression or mood problems
- are pregnant or plan to become pregnant. It is not known if INOVELON[®] can harm your unborn baby. Tell your healthcare provider right away if you become pregnant while taking INOVELON[®]. You and your healthcare provider will decide if you should take INOVELON[®] while you are pregnant.
- INOVELON[®] may make certain types of birth control less effective. Talk to your healthcare provider about the best birth control methods for you while you take INOVELON[®].
- If you become pregnant while taking INOVELON[®], talk to your healthcare provider.
- are breastfeeding or plan to breastfeed. INOVELON[®] may pass into your breast milk. You and your healthcare provider should decide if you will take INOVELON[®] or breastfeed. You should not do both.

- Taking other medicines

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 other medicines removed from the body by the CYP3A4 enzyme system 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.

Tell the doctor if you are taking hormonal/oral contraceptives. INOVELON[®] may make hormonal/oral contraceptives such as the contraceptive pill less effective. Therefore, it is recommended that you use an additional safe and effective contraceptive method 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.

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.

How to use INOVELON[®]

- How much to use

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

Children four years of age or older weighing less than 30 kg (not taking valproate)

The recommended starting dose is 200 mg a day taken in two doses. The dose will be adjusted for you by the doctor and may be increased by 200 mg at intervals of two days, to a daily dose of no more than 1000 mg.

Children four years of age or older weighing less than 30 kg (taking valproate)

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Rufinamide (200mg)

For children less than 30 kg who are taking valproate (a treatment for epilepsy) the maximum recommended daily dose of INOVELON[®] is 600 mg a day.

The recommended starting dose is 200 mg a day taken in two doses. The dose will be adjusted for you by the doctor and may be increased by 200 mg at intervals of two days, to the maximum recommended dose of 600 mg a day.

Adults and children weighing 30 kg or over

The usual starting dose is 400 mg a day taken in two doses. The dose will be adjusted for you by the doctor and may be increased by 400 mg at intervals of two days, to a daily dose of no more than 3200 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.

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

- When to use it

INOVELON[®] tablets must be taken twice daily with water, in the morning and in the evening.

INOVELON[®] should be taken with food. If you have difficulty swallowing, you can crush the tablet, then mix the powder in about half a glass (100 ml) of water and drink immediately.

- How long to use it

Do not stop taking INOVELON[®] without first talking to your healthcare provider.

Stopping INOVELON[®] suddenly can cause serious problems.

Stopping a seizure medicine suddenly in a patient who has epilepsy can cause seizures that will not stop (status epilepticus).

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 forget to use it

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 use too much (overdose)

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.

While you are using it

- Things you must do

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

- Things you must not do

Do not drink alcohol or take other medicines that make you sleepy or dizzy while taking INOVELON[®] until you talk to your healthcare provider. INOVELON[®] taken with alcohol or medicines that cause sleepiness or dizziness may make your sleepiness or dizziness worse.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use INOVELON[®] for a condition for which it was not prescribed. Do not give INOVELON[®] to other people, even if they have the same symptoms that you have. It may harm them.

- Things to be careful of

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.

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 status epilepticus (seizures which last a long time, repeated seizures). 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.

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).

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website

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npra.moh.gov.my

(Public→Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)).

Product Registration Holder

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No. 5, Jalan SS21/39, Damansara
Uptown, 47400 Petaling Jaya,
Selangor, Malaysia

Storage and Disposal of INOVELON[®]

- Storage

Keep INOVELON[®] and all medicines out of the reach of children.

Do not store above 30°C.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Date of revision

25 July 2019

Serial Number

BPFK (R1) 18/010

Product Description

- What it looks like

INOVELON[®] 200 mg tablets are pink, oval, slightly convex film-coated tablets, scored on both sides, embossed 'E262' on one side and blank on the other side.

- Ingredients

- Active ingredient
Rufinamide

- Inactive ingredients
lactose monohydrate,
microcrystalline cellulose,
maize starch,
croscarmellose sodium,
hypromellose,
magnesium stearate,
sodium laurilsulfate
colloidal anhydrous silica.

The film-coating consists
hypromellose, macrogols (8000),
titanium dioxide (E171),
talc
ferric oxide red (E172).

- MAL number:

MAL18046016ACZ

Manufacturer

Bushu Pharmaceuticals Ltd.
Misato Factory
950, Hiroki, Ohaza, Misato-machi,
Kodama-gun, Saitama-ken, Japan