

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using INOVELON?

INOVELON contains the active ingredient rufinamide. INOVELON is used to treat seizures associated with Lennox-Gastaut syndrome in adults, adolescents and children from 4 years of age.

For more information, see Section [1. Why am I using INOVELON?](#) in the full CMI.

2. What should I know before I use INOVELON?

Do not use if you have ever had an allergic reaction to INOVELON or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use INOVELON?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with INOVELON and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use INOVELON?

- The recommended dose of INOVELON varies depending on which age/weight group INOVELON is being used to treat. Your doctor will tell you the correct dose.

More instructions can be found in Section [4. How do I use INOVELON?](#) in the full CMI.

5. What should I know while using INOVELON?

Things you should do	<ul style="list-style-type: none">Remind any doctor, dentist or pharmacist you visit that you are using INOVELON.
Things you should not do	<ul style="list-style-type: none">Do not stop taking INOVELON or lower the dosage without checking with your doctor.Do not take INOVELON to treat any other complaints unless your doctor tells you to.Do not give INOVELON to anyone else, even if they have the same condition as you.
Driving or using machines	<ul style="list-style-type: none">Do not drive or operating machinery until you know how INOVELON affects you.
Drinking alcohol	<ul style="list-style-type: none">Avoid alcohol while taking INOVELON.
Looking after your medicine	<ul style="list-style-type: none">Keep INOVELON in the original container.Keep INOVELON in a cool dry place where the temperature stays below 30°C.Keep INOVELON out of reach of children.

For more information, see Section [5. What should I know while using INOVELON?](#) in the full CMI.

6. Are there any side effects?

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

- Dizziness, headache, nausea, vomiting, sleepiness and fatigue

Common side effects (may affect up to 1 user in 10) 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 including ear infection, flu, nasal congestion, chest infection.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

INOVELON *

(in-nov-a-lon)

Active ingredient(s): *rufinamide* (*ru-fin-a-mide*)

Consumer Medicine Information (CMI)

This leaflet provides important information about using INOVELON. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using INOVELON.**

Where to find information in this leaflet:

1. [Why am I using INOVELON?](#)
2. [What should I know before I use INOVELON?](#)
3. [What if I am taking other medicines?](#)
4. [How do I use INOVELON?](#)
5. [What should I know while using INOVELON?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I using INOVELON?

INOVELON contains the active ingredient rufinamide.

Rufinamide belongs to a group of medicines called anti epileptics.

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 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.

2. What should I know before I use INOVELON?

Warnings

Do not use INOVELON if:

- You have an allergy to Rufinamide, the active ingredient, or to any other ingredients listed in Section 7 of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- INOVELON contains 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

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

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Take INOVELON during your pregnancy only if your 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.

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

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

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or

supplements that you buy 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 in adults and children.

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.

- Tell the doctor if you are taking the blood thinner – warfarin. The doctor may need to adjust the dose of warfarin.
- Tell the doctor if you are taking digoxin (a medicine used to treat heart conditions). The doctor may need to adjust the dose of digoxin.

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

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 INOVELON works. You may need different amounts of your medicines, or you may need to take different medicines.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect INOVELON.

4. How do I use 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 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.

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

How much to take/use

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.

When to take / use 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/use 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 use INOVELON

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 use too much INOVELON

If you think that you have used too much INOVELON, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre **(by calling 13 11 26)**, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using INOVELON?

Things you should do

Call your doctor straight away if:

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

Remind any doctor, dentist or pharmacist you visit that you are using INOVELON.

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

Things you should not do

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

Driving or using machines

Do not drive or operate 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.

Drinking alcohol

Avoid alcohol while taking INOVELON as it may make these effects (dizziness, drowsiness and vision impairment) worse.

Looking after your medicine

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 young children cannot reach it. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

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.

Serious side effects

Serious side effects	What to do
Allergic reaction related:	Call your doctor straight away, or go straight

<ul style="list-style-type: none"> rash and/or fever. These could be signs of an allergic reaction. <p>Nervous system related:</p> <ul style="list-style-type: none"> change in the types of seizures you experience or if you experience more frequent seizures which last a long time (called status epilepticus). 	<p>to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>
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Less serious side effects

Less serious side effects	What to do
<p>Skin related:</p> <ul style="list-style-type: none"> rash bruising acne <p>Gastrointestinal related:</p> <ul style="list-style-type: none"> nausea vomiting <p>General disorders:</p> <ul style="list-style-type: none"> fatigue <p>Nervous system related:</p> <ul style="list-style-type: none"> dizziness headache problems associated with nerves including difficulty walking, abnormal movement, convulsions/seizures, unusual eye movements, blurred vision, trembling. <p>Gastrointestinal related:</p> <ul style="list-style-type: none"> problems associated with the stomach including stomach pain, constipation, indigestion, loose stools (diarrhoea), loss or change in appetite, weight loss. <p>Infection related:</p> <ul style="list-style-type: none"> infections: ear infection, flu, nasal congestion, chest infection. <p>Liver related:</p> <ul style="list-style-type: none"> increase in markers of liver function (hepatic enzyme increase) <p>Psychiatric related:</p> <ul style="list-style-type: none"> anxiety insomnia sleepiness <p>Bleeding related:</p> <ul style="list-style-type: none"> nose bleeds <p>Muscle or bone related:</p> <ul style="list-style-type: none"> back pain 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

<ul style="list-style-type: none"> head injury (as a result of accidental injury during a seizure). <p>Hormone related:</p> <ul style="list-style-type: none"> infrequent periods 	
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Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What INOVELON contains

Active ingredient (main ingredient)	rufinamide
Other ingredients (inactive ingredients)	sodium lauryl sulfate maize starch hypromellose lactose monohydrate microcrystalline cellulose croscarmellose sodium colloidal anhydrous silica magnesium stearate macrogol 8000 titanium dioxide purified talc iron oxide red
Potential allergens	Contains sugars (as lactose)

Do not take this medicine if you are allergic to any of these ingredients.

What INOVELON looks like

INOVELON 100 mg (Aust R 287523), 200 mg (Aust R 287524), and 400 mg (Aust R 287537), film coated tablets are pink, oval, slightly convex film-coated tablets, scored on both sides, embossed 'E261', 'E262' or 'E263' on one side and blank on the other side for the 100 mg, 200 mg

and 400 mg respectively. They are available as blister packs of 10, 30, 50, 60 and 100 film-coated tablets.

Who distributes INOVELON

Eisai Australia Pty Ltd

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Melbourne, VIC, 3004

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