ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

OUTER CARTON

1. NAME OF THE MEDICINAL PRODUCT

Inovelon 100 mg film-coated tablets
Rufinamide

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each tablet contains 100 mg rufinamide

3. LIST OF EXCIPIENTS

Contains lactose. See leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

10
10 film-coated tablets
30
30 film-coated tablets
50
50 film-coated tablets
60
60 film-coated tablets
100
100 film-coated tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral Use
Read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE REACH AND SIGHT OF CHILDREN

Keep out of the reach and sight of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP (MM/YYYY)

9. SPECIAL STORAGE CONDITIONS

Do not store above 30°C

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Eisai Limited., 3 Shortlands, London W6 8EE, UK

12. MARKETING AUTHORISATION NUMBER(S)

EU/0/00/000/000

13. BATCH NUMBER

Lot: {number}

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Inovelon 100 mg tablets

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

1. NAME OF THE MEDICINAL PRODUCT

Inovelon 100 mg film-coated tablets
Rufinamide

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Eisai Limited.

3. EXPIRY DATE

EXP: {MM/YYYY}

4. BATCH NUMBER

Lot: {number}

5. OTHER

PACKAGE LEAFLET: INFORMATION FOR THE USER

Inovelon 100 mg film-coated tablets
Inovelon 200 mg film-coated tablets
Inovelon 400 mg film-coated tablets
Rufinamide

Read all of this leaflet carefully before you start taking this medicine.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. WHAT INOVELON IS AND WHAT IT IS USED FOR

Inovelon contains rufinamide, which is an antiepileptic medicine. It is used to treat seizures associated with Lennox-Gastaut syndrome.

2. BEFORE YOU TAKE INOVELON

Do not take Inovelon

- if you are allergic (hypersensitive) to rufinamide or any of the other ingredients of Inovelon and triazole derivatives.

Take special care with Inovelon

- if you suffer from liver problems, because there is limited information on the use of Inovelon in this group and the dose of your medicine may need to be increased more slowly.
- if you get a skin rash. See your doctor immediately as very occasionally this may become serious.
- if you suffer an increase in the number or severity or duration of your seizures, you should contact your doctor immediately.
- if you experience dizziness or sleepiness inform your doctor.

Please consult your doctor, even if these statements were applicable to you at any time in the past.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

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

Taking Inovelon with food and drink

Inovelon should preferably be taken with food. As a precaution, do not take Inovelon with alcohol.

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, tell your doctor. You must only take Inovelon during your pregnancy if your doctor tells you to.

You must not breast-feed while taking Inovelon.

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

Driving and using machines

Do not drive or operate machinery if you feel drowsy, dizzy or experience blurred vision whilst taking this medicine. Be particularly careful at the start of treatment or after your dose is increased.

Important information about some of the ingredients of Inovelon

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

3. HOW TO TAKE INOVELON?

Always take Inovelon exactly as your doctor has told you. You must check with your doctor or pharmacist if you are not sure.

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

The usual starting dose in children weighing less than 30 kg is 200 mg a day taken in two doses. The dose will be adjusted for you by your doctor and may be increased by 200 mg at intervals of two days, to a daily dose of no more than 1000 mg.

The usual starting dose in adults and children weighing 30 kg or over is 400 mg a day taken in two doses. The dose will be adjusted for you by your 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. The dose may be increased more slowly if you experience side effects.

Inovelon is meant to be taken as a long-term medicine. Do not reduce your dose or stop your medicine unless your doctor tells you to.

If you take more Inovelon than you should

If you may have taken more Inovelon than you should, tell a carer (relative or friend), your doctor or pharmacist immediately, or contact your nearest hospital casualty department, taking your medicine with you. You may become sleepy and could lose consciousness. Do not drive at this time.

If you forget to take Inovelon

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

If you stop taking Inovelon

If your doctor advises you to stop treatment, follow your doctor's 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 your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

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

Tell your doctor if you have any of the following and if they are too uncomfortable for you:

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

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

Less commonly reported (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.

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).

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE INOVELON

Keep Inovelon out of the reach and sight of children.

Do not use Inovelon after the expiry date which is stated on the blister and carton

Do not store above 30°C.

Do not use Inovelon if you notice a change in colour of the tablets.

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.

6. FURTHER INFORMATION

What Inovelon contains

- The active substance is rufinamide.
  Each Inovelon 100 mg flim-coated tablet contains 100 mg of rufinamide.
  Each Inovelon 200 mg film-coated tablet contains 200 mg of rufinamide.
  Each Inovelon 400 mg film-coated tablet contains 400 mg of rufinamide.

- The other ingredients are lactose monohydrate, microcrystalline cellulose, maize starch, croscarmellose sodium, hypromellose, magnesium stearate, sodium laurilsulfate and colloidal anhydrous silica. The film-coating consists of Opadry 00F44042 [hypromellose, macrogols (8000), titanium dioxide (E171), talc and ferric oxide red (E172)].

What Inovelon looks like and contents of the pack

- Inovelon 100 mg tablets are pink, oval, slightly convex film-coated tablets, scored on both sides, embossed '€261' on one side and blank on the other side.
  They are available as packs of 10, 30, 50, 60 and 100 film-coated tablets.

- Inovelon 200 mg tablets are pink, oval, slightly convex film-coated tablets, scored on both sides, embossed '€262' on one side and blank on the other side.
  They are available as packs of 10, 30, 50, 60 and 100 film-coated tablets.

- Inovelon 400 mg tablets are pink, oval, slightly convex film-coated tablets, scored on both sides, embossed '€263' on one side and blank on the other side.

  They are available as packs of 10, 30, 50, 60,100 and 200 film-coated tablets.

Marketing Authorisation Holder and Manufacturer

Eisai Limited, 3 Shortlands, London W6 8EE, UK.

For any information about this medicinal product, please contact the local representative of the Marketing Authorisation Holder:

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This leaflet was last approved in {MM/YYYY}.

Detailed information on this product is available on the European Medicines Agency (EMEA) website http://www.emea.europa.eu