

# NOUMED LEVETIRACETAM

Levetiracetam tablets

## Consumer Medicine Information

### What is in this leaflet

This leaflet answers some common questions about NOUMED LEVETIRACETAM tablets. 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 NOUMED LEVETIRACETAM tablets 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 NOUMED LEVETIRACETAM TABLETS is used for

NOUMED LEVETIRACETAM tablets may be used alone, or in combination with other medicines, to treat your condition.

Your doctor may have prescribed this medicine in addition to your current therapy. NOUMED LEVETIRACETAM tablet is used to treat epilepsy. Epilepsy is a condition where you have repeated seizures. There are many different types of seizures, ranging from mild to severe.

This medicine belongs to a group of medicines called antiepileptics. These medicines are thought to work by controlling brain chemicals which send signals to nerves so that seizures do not happen.

**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.

There is no evidence that this medicine is addictive.

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

There is not enough information to recommend the use of this medicine for children under the age of 4 years.

### Before you take AMED LEVETIRACETAM TABLETS

#### *When you must not take it*

**Do not take NOUMED LEVETIRACETAM tablets if you have an allergy to:**

- any medicine containing levetiracetam
- any of the ingredients listed at the end of this leaflet.

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 if you are pregnant.**

It may affect your developing baby if you take it during pregnancy.

**Do not breast-feed if you are taking this medicine.**

The active ingredient in NOUMED LEVETIRACETAM tablets passes into breast milk and there is a possibility that your baby may be affected.

**Do not give this medicine to a child under the age of 4 years.**

Safety and effectiveness in children younger than 4 years have not been established.

**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 or pharmacist if you have allergies to:**

- any other medicines, especially barbiturates (such as phenobarbitone) or any other antiepileptic medicines (such as carbamazepine, lamotrigine or valproate)

**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:**

- kidney problems
- liver problems

**Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.**

Your doctor can discuss with you the risks and benefits involved.

NOUMED LEVETIRACETAM tablets may affect your developing baby if you take it during pregnancy. However, it is very important to control your seizures while you are pregnant. Your doctor will outline and weigh up all the risks and benefits of taking NOUMED LEVETIRACETAM tablets during pregnancy to help decide whether or not you should take it.

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

#### *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.**

NOUMED LEVETIRACETAM tablets does not interact with the oral contraceptive pill.

However, you may be given NOUMED LEVETIRACETAM tablets together with other antiepileptic medicines that do interact and may affect the effectiveness of your contraceptive.

Your doctor may advise you to use an additional method of contraception if you take NOUMED LEVETIRACETAM tablets with other antiepileptic medicines.

### How to take NOUMED LEVETIRACETAM TABLETS

**Follow all directions given to you by your doctor or pharmacist carefully.**

They may differ from the information contained in this leaflet.

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

#### *How much to take*

Your doctor will tell you how much NOUMED LEVETIRACETAM tablets you will need to take each day. This may depend on your age, your condition and whether or not you are taking any other medicines.

For patients 12 years of age and older, the dosage is generally between 1000 mg and 3000 mg each day, taken in two doses.

For children 4 to 11 years of age the doctor will calculate the dosage based on the child's weight and tell you how much to give. The medicine is to be given twice daily.

Your doctor may start you on a low dose of NOUMED LEVETIRACETAM tablets first.

Your doctor will slowly increase the amount of medicine until you are taking enough to control your epilepsy and you are not having seizures.

#### *How to take it*

**Swallow the tablets whole with a full glass of water. Do not halve the tablets.**

#### *When to take it*

Take NOUMED LEVETIRACETAM tablets twice a day, once in the morning and once at night.

**Take your medicine at about the same time each day.**

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

It does not matter if you take this medicine before or after food.

**Take your medicine on an empty stomach, for example, 1 hour before food or 2 hours after food.**

**If you need to take an antacid, take it at least 2 hours before or 2 hours after your dose of NOUMED LEVETIRACETAM tablets.**

#### *How long to take it*

Most antiepileptic medicines take time to work, so do not be discouraged if you do not feel better straight away.

**Continue taking your medicine for as long as your doctor tells you.**

This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

**Do not stop taking NOUMED LEVETIRACETAM tablets, or change the dose, without checking with your doctor.**

**Do not let yourself run out of medicine over the weekend or on holidays.**

Stopping NOUMED LEVETIRACETAM tablets suddenly may cause unwanted side effects or make your condition worse. Your doctor will slowly reduce your dose before you can stop taking it completely.

*If you forget to take it*

Contact your doctor if you have missed one or more doses.

**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 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 13 11 26) 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 NOUMED LEVETIRACETAM tablets. Do this even if there are no signs of discomfort or poisoning.**

You may need urgent medical attention.

Symptoms of an overdose may include feeling drowsy.

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## While you are using NOUMED LEVETIRACETAM TABLETS

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*Things you must do*

**Tell your doctor immediately if you notice any increase in seizures.**

**Tell your doctor immediately if you have symptoms of depression or thoughts of harming yourself.**

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

**Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.**

**If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.**

It may affect other medicines used during surgery.

**If you become pregnant while taking this medicine, tell your doctor immediately.**

**If you are about to have any blood tests, tell your doctor that you are taking this medicine.**

It may interfere with the results of some tests.

**Tell your doctor if, for any reason, you have not taken this medicine exactly as prescribed.**

Otherwise, your doctor may change your treatment unnecessarily.

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

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

*Things you must not do*

**Do not take NOUMED LEVETIRACETAM tablets 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.**

If you stop taking it suddenly, your condition may worsen or you may have unwanted side effects. If possible, your doctor will gradually reduce the amount you take each day before stopping the medicine completely.

*Things to be careful of*

**Be careful driving or operating machinery until you know how NOUMED LEVETIRACETAM tablets affects you.**

This medicine may cause dizziness or drowsiness in some people. This is more frequent at the beginning of treatment or after an increase in the dose. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous. Children should be careful when riding bicycles or climbing trees.

If you are feeling dizzy or drowsy do not drive, operate machinery, or do anything else that could be dangerous. Children should not ride a bike, climb trees or do anything else that could be dangerous if they are feeling dizzy or drowsy.

**If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.**

Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

**Be careful when drinking alcohol while you are taking this medicine.**

Combining NOUMED LEVETIRACETAM tablets and alcohol can make you more drowsy. Your doctor may suggest you avoid alcohol while you are being treated with NOUMED LEVETIRACETAM tablets.

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## Side effects

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**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking NOUMED LEVETIRACETAM tablets.**

This medicine helps most people with epilepsy, but it may have unwanted side effects in a few people. 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.**

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

**Tell your doctor or pharmacist if you notice any of the following and they worry you:**

- dizziness
- feeling weak
- headache
- common cold
- diarrhoea
- feeling tired, drowsy or sleepy

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

**Tell your doctor as soon as possible if you notice any of the following:**

- mood changes such as depression, nervousness, aggression, anger, anxiety, confusion, hallucination, irritability
- feelings of depression
- upper respiratory tract infections
- weight loss.

The above list includes serious side effects that may require medical attention.

**If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:**

- thoughts of harming yourself
- more frequent or more severe seizures
- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, mouth, throat or tongue or other parts of the body
- rash, itching or hives on the skin.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

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

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

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## After using NOUMED LEVETIRACETAM TABLETS

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*Storage*

**Keep your tablets in the pack until it is time to take them.**

If you take the tablets out of the pack, they may not keep well.

**Keep your tablets in a cool dry place where the temperature stays below 25°C.**

**Do not store NOUMED LEVETIRACETAM tablets 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.**

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## Product description

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*What it looks like*

**250 mg:**

Blue coloured, oval-shaped, film-coated tablets, embossed with "OL" bisect "250" on one side and plain on other side.

**500 mg:**

Yellow coloured, oval-shaped, film-coated tablets, embossed with "OL" bisect "500" on one side and plain on other side.

**1000 mg:**

White coloured, oval shaped, film-coated tablets, embossed with "OL" bisect "1000" on one side and plain on other side.

*Ingredients*

NOUMED LEVETIRACETAM tablets contain 250 mg, 500 mg or 1000 mg of levetiracetam as the active ingredient.

Other ingredients in NOUMED  
LEVETIRACETAM tablets include

- croscarmellose sodium
- pregelatinized maize starch
- copovidone
- magnesium stearate
- purified talc

NOUMED LEVETIRACETAM tablets are  
film-coated.

The coating for each tablet strength contains  
OPADRY II complete film coating system  
85F19250 Clear (PING# 11509).

The following strengths also contain:

250mg: OPADRY II complete film coating  
system 85F90814 Blue (PING# 114482)

500mg: OPADRY II complete film coating  
system 85F92153 Yellow (PING# 114483)

1000 mg: OPADRY II complete film coating  
system 85F18422 White (#PING 11376)

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

### *Sponsor*

AdiraMedica Pty Ltd.  
Level 1, 214 Bay Street  
Brighton VIC 3186  
Australia

### *Australian Register numbers*

NOUMED LEVETIRACETAM 250 mg  
tablets: AUST R 299310

NOUMED LEVETIRACETAM 500 mg  
tablets: AUST R 299312

NOUMED LEVETIRACETAM 1000 mg  
tablets: AUST R 299309

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