

Levetiracetam AN tablets

levetiracetam

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Levetiracetam AN.

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 Levetiracetam AN 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 Levetiracetam AN is used for

Levetiracetam AN is used to control epilepsy.

Epilepsy is a condition where you have repeated seizures. There are many different types of seizures, ranging from mild to severe.

Levetiracetam AN belong 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.

Levetiracetam AN may be used alone or in combination with other medicines, to treat your condition.

Your doctor may have prescribed Levetiracetam AN in addition to your current therapy.

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

There is no evidence that Levetiracetam AN is addictive. This medicine is available only with a doctor's prescription.

The safety and effectiveness of Levetiracetam AN has not been established in patients less than 4 years of age.

Before you take Levetiracetam AN

When you must not take it

Do not take Levetiracetam AN if you have an allergy to:

- 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 Levetiracetam AN after the expiry date (EXP) printed on the pack.

Do not take Levetiracetam AN if the packaging is torn or shows signs of tampering or if the tablets do not look quite right.

If Levetiracetam AN has expired or are damaged, return to your pharmacist for disposal.

If you are not sure whether you should start taking Levetiracetam AN, talk to your doctor or pharmacist.

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)
- any other substances, such as foods, preservatives or dyes

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

- kidney problems
- liver problems

Tell your doctor if you are pregnant or intend to become pregnant.

Levetiracetam AN 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 Levetiracetam AN during pregnancy to help decide whether or not you should take it.

Tell your doctor if you are breastfeeding or plan to breastfeed.

The active ingredient in Levetiracetam AN passes into breast milk and there is a possibility that your baby may be affected. Your doctor will discuss the risks and benefits of using Levetiracetam AN if you are breastfeeding.

If you have not told your doctor or pharmacist about any of the above, tell them before you start taking Levetiracetam AN.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicine, including any that you buy without a prescription from your pharmacy, supermarket or health food shop. Levetiracetam AN does not interact with the oral contraceptive pill.

However, you may be given Levetiracetam AN together with other antiepileptic medicines that do interact and may affect the effectiveness of your contraceptives.

Your doctor may advise you to use an additional method of contraception if you take Levetiracetam AN with other antiepileptic medicines.

How to take Levetiracetam AN

Follow all directions given to you by your doctor carefully.

They may differ from the information contained in this leaflet.

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

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 Levetiracetam AN first and slowly increase the amount of medicine until you are taking enough to control your epilepsy and you are not having seizures.

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

How to take it

Swallow the Levetiracetam AN whole with a glass of water.

When to take it

Take Levetiracetam AN twice a day, once in the morning and once at night. Take it at about the same time each day.

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

It does not matter if you take Levetiracetam AN before or after food.

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.

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 Levetiracetam AN for as long as your doctor tells you to.

Levetiracetam AN helps control your condition, but does not cure it. Therefore you must take your medicine every day, even if you feel well.

Do not stop taking Levetiracetam AN, or change the dosage, without checking with your doctor. Do not let yourself run out of medicine over the weekend or on holidays.

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

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (the telephone number in Australia is 13 11 26 and in New Zealand is 0800 POISON or 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 Levetiracetam AN. 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.

While you are using Levetiracetam AN

Things you must do

Tell your doctor immediately if you notice an increase in seizures.

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

Tell any other doctors, dentists, and pharmacists who are treating you that you are taking Levetiracetam AN.

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are taking Levetiracetam AN.

Before you have any surgery or emergency treatment, tell your doctor or dentist that you are taking Levetiracetam AN. Tell your doctor if you feel Levetiracetam AN is not helping your condition.

Your doctor may need to change your medicine.

Tell your doctor if, for any reason, you have not taken Levetiracetam AN exactly as prescribed.

Otherwise, your doctor may change your treatment unnecessarily.

If you become pregnant while taking Levetiracetam AN, tell your doctor.

Be sure to keep all of your doctor's appointments so that your progress can be checked.

Your doctor will check your progress and may want to take some tests from time to time. This helps to prevent unwanted side effects.

Things you must not do

Do not give Levetiracetam AN to anyone else, even if their symptoms seem similar to yours or they have the same condition as you.

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

Things to be careful of

Be careful driving or operating machinery until you know how Levetiracetam AN affects you.

Children should be careful doing things like riding bicycles or climbing trees.

As with other antiepileptic medicines, Levetiracetam AN 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 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.

Be careful when drinking alcohol while taking Levetiracetam AN.

Combining Levetiracetam AN and alcohol can make you more drowsy. Your doctor may suggest you avoid alcohol while you are being treated with Levetiracetam AN.

Side effects

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

Levetiracetam AN 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 treatment if you get some of the side effects.

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

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

If you get any side effects, do not stop taking Levetiracetam AN without first talking to your doctor or pharmacist.

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

- dizziness
- feeling weak
- headache

- common cold
- upset stomach
- diarrhoea
- feeling tired, drowsy or sleepy
- lethargy
- muscular weakness

The above list includes the more common side effects of Levetiracetam AN. 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, panic attack, 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 if you notice anything else that is making you feel unwell.

Other side effects not listed above may happen in some people.

After using Levetiracetam AN

Storage

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

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

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

Do not store Levetiracetam AN or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car on hot days.

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 Levetiracetam AN or expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

- Levetiracetam AN 250 mg tablets - White to off white, oval biconvex, film-coated tablets, debossed 'L 64' and breakline on one side and plain on the other side.

- Levetiracetam AN 500 mg - Yellow coloured, oval biconvex, film-coated tablets, debossed 'L 65' and breakline on one side and plain on the other side.
- Levetiracetam AN 1000 mg - White to off white, oval biconvex, film-coated tablets, debossed 'L 67' and breakline on one side and plain on the other side.

Levetiracetam AN 250/500/1000 is available in blister packs of 60 tablets.

Ingredients

Active ingredient(s):

- Levetiracetam AN 250 - contains 250 mg of Levetiracetam as the active ingredient.
- Levetiracetam AN 500 - contains 500 mg of Levetiracetam as the active ingredient.
- Levetiracetam AN 1000 - contains 1000 mg of Levetiracetam as the active ingredient.

Other ingredients:

- carmellose sodium,
- povidone,
- colloidal anhydrous silica and
- magnesium stearate.

Levetiracetam AN tablets are film-coated. The coating for each tablet strength contains polyvinyl alcohol, macrogol, talc and titanium dioxide.

The following strength also contains:

- 500 mg - iron oxide yellow (C177492).

Levetiracetam AN does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Name and Address of the Sponsor

Scentia Pharmaceuticals Pty Ltd.,

8 - 12 Ordish Road
Dandenong South,
VIC - 3175, Australia

Levetiracetam AN 250 mg: AUST R 189879
Levetiracetam AN 500 mg AUST R 189880
Levetiracetam AN 1000 mg: AUST R 189881

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