

APO-Levetiracetam

Contains the active ingredient, levetiracetam

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

Read this leaflet carefully before taking your medicine.

This leaflet answers some common questions about levetiracetam. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up to date leaflet from www.apotex.com.au.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine. You may want to read it again.

What this medicine is used for

The name of your medicine is APO-Levetiracetam. It contains the active ingredient Levetiracetam.

It is used to control epilepsy. Epilepsy is a condition where you have repeated seizures (fits). There are many different types of seizures, ranging from mild to severe.

Ask your doctor if you have any questions about why this medicine has been prescribed for you. Your doctor may have prescribed this medicine for another reason.

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

How it works

Levetiracetam 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.

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

Your doctor may prescribe levetiracetam in addition to your current therapy.

There is no evidence that this medicine is addictive.

Use in children

There is not enough information to recommend using this medicine in children less than 4 years of age.

Before you take this medicine

When you must not take it

Do not take this medicine if:

- The expiry date (EXP) printed on the pack has passed.
- The packaging is torn, shows signs of tampering or it does not look quite right.
- **You are hypersensitive to, or have had an allergic reaction to, levetiracetam or any of the ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body, rash, itching or hives on the skin; fainting or hayfever-like symptoms

If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.

Before you start to take it

Before you start taking this medicine, tell your doctor if:

1. You have allergies to:
 - any other medicines, especially barbiturates or any other anticonvulsant medicines

- any other substances, such as foods, preservatives or dyes.
2. You have or have had any medical conditions, especially the following:
 - kidney problems
 - liver problems
 - depression
 3. You are currently pregnant or you plan to become pregnant. Do not take this medicine whilst pregnant until you and your doctor have discussed the risks and benefits involved.
 4. You are currently breast-feeding or you plan to breast-feed. Do not take this medicine whilst breast-feeding until you and your doctor have discussed the risks and benefits involved.
 5. You have recently been vaccinated or plan to get a vaccination.
 6. You are planning to have surgery or an anaesthetic.
 7. You are currently receiving or are planning to receive dental treatment.
- 8 You are taking or are planning to take any other medicines. This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

Some medicines may interact with levetiracetam. These include:

- other antiepileptic drugs

Other medicines not listed above may also interact with levetiracetam.

How to take this medicine

Follow carefully all directions given to you by your doctor or pharmacist. Their instructions may be different to the information in this leaflet.

How much to take

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

For children 4 to 11 years of age the dose is 20 mg/kg to 60 mg/kg each day.

Your doctor or pharmacist will tell you how much of this medicine you should take. This will depend on your condition and whether you are taking any other medicines.

Do not stop taking your medicine or change your dosage without first checking with your doctor.

How to take it

Swallow the tablets whole with a glass of water.

When to take it

This medicine must be taken two times a day, once in the morning and once in the evening, at about the same time each day.

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

It does not matter if you take it before, with or after food.

How long to take it for

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

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

Make sure you have enough to last over weekends and holidays.

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 missed doses.

This may increase the chance of you experiencing side effects.

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 to help you remember.

If you take too much (overdose)

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively go to the Accident and Emergency Department at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

If you take too much levetiracetam, you may feel drowsy.

While you are taking this medicine

Things you must do

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine
- you plan to have any vaccinations or immunisations
- you are pregnant or are planning to become pregnant
- you are breast-feeding or are planning to breast-feed
- you are about to have any blood tests
- you are going to have surgery or an anaesthetic or are going into hospital.

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

Tell your doctor if you feel this medicine is not helping your condition. Your doctor may occasionally do tests to make sure the

medicine is working and to prevent side effects. Go to your doctor regularly for a check-up.

Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.

Things you must not do

Do not:

- Give this medicine to anyone else, even if their symptoms seem similar to yours
- Take your medicine to treat any other condition unless your doctor or pharmacist tells you to
- Stop taking your medicine, or change the dosage, without first checking with your doctor.

Things to be careful of

Be careful when driving or operating machinery until you know how this medicine affects you.

As with other anticonvulsant medicines, levetiracetam may cause drowsiness or affect alertness in some people. This is more frequent at the beginning of treatment or at dosage increase.

Make sure you know how you react to this medicine before you drive a car, operate machinery, or do anything else that could be dangerous if you are drowsy.

Possible side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking levetiracetam or if you have any questions or concerns.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

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
- hair loss
- feeling tired, drowsy or sleepy.

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

These may be serious side effects. You may need medical attention.

- mood changes such as depression, nervousness, aggression, anger, anxiety, confusion, hallucination and irritability
- upper respiratory tract infections
- weight loss
- strange involuntary movements.

If you experience any of the following, stop taking your medicine and contact your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

These are very serious side effects. You may need urgent medical attention or hospitalisation.

- thoughts of harming yourself
- more frequent or more severe seizures
- a fever or flu-like symptoms followed by a widespread skin rash.

Other side effects not listed above may occur in some patients.

Allergic reactions

If you think you are having an allergic reaction to levetiracetam, do not take any more of this medicine and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

Symptoms of an allergic reaction may include some or all of the following:

- 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
- fainting
- hayfever-like symptoms

Storage and disposal

Storage

Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging it may not keep well.

Keep your medicine in a cool dry place where the temperature will stay below 25°C.

Do not store your medicine, 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 this medicine 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 or pharmacist tells you to stop taking this medicine or it has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.

Product description

What APO-Levetiracetam looks like

APO-Levetiracetam 250 mg tablets: White, oval, biconvex, film-coated

tablets, engraved "LEV" score "250" on one side, "APO" on the other side.

Blister packs of 60 tablets.

Bottles of 60, 100 and 500 tablets.

APO-Levetiracetam 500 mg tablets: Yellow, oval, biconvex, film-coated tablets, engraved "LEV" score "500" on one side, "APO" on the other side.

Blister packs of 60 tablets.

Bottles of 60, 100 and 500 tablets.

APO-Levetiracetam 750 mg tablets: Orange, oval, biconvex, film-coated tablets, engraved "LEV" score "750" on one side, "APO" on the other side.

Blister packs of 60 tablets.

Bottles of 60, 100 and 500 tablets.

APO-Levetiracetam 1000 mg tablets: White, oval, biconvex, film-coated tablets, engraved "LEV" score "1000" on one side, "APO" on the other side.

Blister packs of 60 tablets.

Bottles of 60, 100 and 400 tablets.

* Not all strengths, pack types and/or pack sizes may be available.

Ingredients

Each tablet contains 250 mg, 500 mg, 750 mg or 1000 mg levetiracetam, as the active ingredient.

It also contains the following inactive ingredients:

- copovidone
- colloidal anhydrous silica
- hypromellose
- hydroxypropylcellulose
- macrogol 8000
- titanium dioxide
- anhydrous citric acid
- iron oxide yellow
(500 mg & 750 mg tablet only)
- iron oxide red
(750 mg tablet only).

This medicine is gluten-free, lactose-free, sucrose-free, tartrazine-free and other azo dyes-free.

Australian Registration Numbers

APO-Levetiracetam 250 mg tablets (blister pack): AUST R 156311.

APO-Levetiracetam 250 mg tablets (bottle): AUST R 156322.

APO-Levetiracetam 500 mg tablets (blister pack): AUST R 156313.

APO-Levetiracetam 500 mg tablets (bottle): AUST R 156321.

APO-Levetiracetam 750 mg tablets (blister pack): AUST R 156325.

APO-Levetiracetam 750 mg tablets (bottle): AUST R 156317.

APO-Levetiracetam 1000 mg tablets (blister pack): AUST R 156328.

APO-Levetiracetam 1000 mg tablets (bottle): AUST R 156320.

Sponsor

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