

Levetiracetam APOTEX Solution for Infusion

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 solution for infusion. 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 Levetiracetam APOTEX Solution for Infusion. It contains the active ingredient levetiracetam.

It 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 solution for infusion may be used alone, or in combination with other medicines, to treat your condition.

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

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

There is no evidence that this medicine is addictive.

Use in children

This medicine should not be used in children. The safety and effectiveness of this medicine has not been established in patients less than 4 years of age.

Before you are given this medicine

When you must not be given it

You must not be given this medicine if:

- 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: cough, 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 hay fever-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.

- 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.

Before you are given it

Before you are given this medicine, tell your doctor if:

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

This medicine may affect your developing baby if you take it during pregnancy. However, it is very important to control your seizures while you are pregnant.

Do not take this medicine whilst pregnant until you and your doctor have discussed the risks and benefits involved.

4. You are currently breastfeeding or you plan to breastfeed.

Do not take this medicine whilst breastfeeding until you and your doctor have discussed the risks and benefits involved.

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

5. You are planning to have surgery or an anaesthetic.
6. 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 may also interact with this medicine.

How this medicine is given

How much is given

Your doctor will decide how much of this medicine you will receive. This will depend on your age, your condition and whether you are taking any other medicines.

How it is given

Levetiracetam solution for infusion is diluted and given as an infusion (intravenous drip) into a vein.

Levetiracetam solution for infusion must only be given by a doctor, nurse or other trained person.

If you take too much (overdose)

As levetiracetam solution for infusion is given to you under the supervision of your doctor, it is very unlikely that you will receive too much.

However, if you experience severe side effects tell your doctor immediately.

Symptoms of an overdose may include feeling drowsy, agitation, aggression or coma.

If you think that you or anyone else may have been given 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.

While you are being given this medicine

Things you must do

Tell your doctor immediately that you are taking this medicine if:

- you are about to be started on any new medicine
- you are pregnant or are planning to become pregnant
- you are breastfeeding or are planning to breastfeed
- 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 you feel levetiracetam solution for infusion is not helping your condition.

Your doctor may need to change your medicine.

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. Stopping levetiracetam solution for infusion suddenly may cause unwanted side effects or make your condition worse.

Things to be careful of

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

As with other antiepileptic medicines, 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 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.

Possible side effects

Tell your doctor as soon as possible if you do not feel well while you are taking this medicine 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 if you notice any of the following:

- dizziness
- feeling weak
- headache
- common cold
- upset stomach
- diarrhoea
- 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 and you may need medical attention:

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

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 and you may need urgent medical attention or hospitalisation:

- thoughts of harming yourself
- more frequent or more severe seizures

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

Allergic reactions

If you think you are having an allergic reaction to levetiracetam solution for infusion, 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:

- cough, 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
- hay fever-like symptoms.

Storage and disposal

Storage

Levetiracetam solution for infusion will be stored in the pharmacy or kept at the hospital. The vials should be kept in a cool dry place where the temperature stays below 25°C.

Product description

What Levetiracetam APOTEX Solution for Infusion looks like

Levetiracetam concentrate solution is intended for IV infusion after dilution. It is a clear, colourless, sterile solution.

The primary container is a glass vial closed with a grey rubber stopper and sealed with an aluminium/polypropylene flip off cap.

Available in a carton containing 10 vials.

Ingredients

One vial of levetiracetam solution for infusion contains 500 mg of levetiracetam (500 mg/5 mL) as the active ingredient.

It also contains the following inactive ingredients:

- sodium acetate trihydrate
- sodium chloride
- glacial acetic acid
- water for injections

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

Latex free.

Australian Registration Numbers

Levetiracetam APOTEX Solution for Injection
500 mg/5 mL.AUST R 222092

Sponsor

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This leaflet was last updated in March 2015.