

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

This leaflet answers some common questions about this medicine. 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 being given this medicine against the benefits they expect it will have for you.

If you have any concerns about being given this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need 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 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.

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.

There is no evidence that this medicine is addictive.

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 should not be given this medicine 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

You should not be given 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 be given this medicine, talk to your doctor.

Before you are given it

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
- depression.

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

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

You should not be given this medicine whilst pregnant until you

and your doctor have discussed the risks and benefits involved.

Do not stop levetiracetam solution for infusion until you have discussed it with your doctor. If you stop this medication suddenly, it may cause unwanted side effects or make your condition worse. Your doctor will slowly reduce your dose before you can stop taking it completely.

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

You should not be given this medicine whilst breastfeeding until you and your doctor have discussed the risks and benefits involved.

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

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.

Some medicines may interact with levetiracetam. These include other antiepileptic drugs.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while you are being given this medicine.

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 are given 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

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are being given this medicine.

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

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

It may affect other medicines used during surgery.

If you become pregnant or start to breastfeed while being given this medicine, tell your doctor immediately.

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

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

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 your doctor if you feel levetiracetam solution for infusion is not helping your condition.

Your doctor may need to change your 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.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel

well while you are being given this medicine.

All medicines can have side effects. Sometimes they are serious but most of the time they are not.

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

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.

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.

These may be serious side effects and you may need 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
- symptoms of an allergic reaction including 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

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

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

Some of these side effects, such as changes to your blood cell count, can only be found when your doctor does tests from time to time to check your progress.

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. AUST R 222092.

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.

Sponsor

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