

Levetiracetam Sandoz®

Levetiracetam concentrate solution for IV infusion

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Levetiracetam Sandoz Concentrate for IV Infusion (Levetiracetam Sandoz IV).

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 this medicine 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.

You may need to read it again.

What Levetiracetam Sandoz IV is used for

Levetiracetam Sandoz IV 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.

It contains the active ingredient, levetiracetam which 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.

Levetiracetam Sandoz IV 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.

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.

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

Before you are given Levetiracetam Sandoz IV

When you must not be given it

You must not be given this medicine if you have an allergy to:

- levetiracetam, the active ingredient, or to any of the other ingredients listed at the end of this leaflet under Product Description
- any other similar medicines.

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.

If you are not sure whether you should be given this medicine, talk to your doctor, nurse or pharmacist.

Before you are given it

Tell your doctor 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
- blood disorders.

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

Levetiracetam Sandoz IV 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 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 Sandoz IV 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 Sandoz IV if you are breastfeeding.

If you have not told your doctor about any of the above, tell them before you are given Levetiracetam Sandoz IV.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Levetiracetam Sandoz IV does not interact with the oral contraceptive pill.

However, you may be given Levetiracetam Sandoz IV 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 Levetiracetam Sandoz IV with other antiepileptic medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How is Levetiracetam Sandoz IV given

How much is given

Your doctor will decide how much Levetiracetam Sandoz IV you will receive. This depends on your age, your condition and whether or not you are taking any other medicines.

How it is given

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

Levetiracetam Sandoz IV must only be given by a doctor, nurse or other trained person.

If you take too much (overdose)

As Levetiracetam Sandoz IV is given to you under the supervision of your doctor, it is very unlikely that you will receive too much.

Immediately telephone your doctor or the Poisons Information Centre (telephone Australia 13 11 26 or New Zealand 0800 POISON or 0800 764766) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have been given too much Levetiracetam Sandoz IV. Do this even if there are no signs of discomfort or poisoning.

You or they may need urgent medical attention.

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

Symptoms of an overdose may include feeling drowsy.

While you are using Levetiracetam Sandoz IV

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 being given this medicine.

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

Before you have any surgery or emergency treatment, tell your doctor or dentist that you are being given Levetiracetam Sandoz IV.

Tell your doctor if you feel Levetiracetam Sandoz IV is not helping your condition.

Your doctor may need to change your medicine.

If you become pregnant while taking this medicine, 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.

Stopping Levetiracetam Sandoz IV suddenly may cause unwanted side effects or make your condition worse.

Things to be careful of

Be careful driving or operating machinery until you know how this medicine affects you. Children should be careful doing things like riding bicycles or climbing trees.

As with other antiepileptic medicines, Levetiracetam Sandoz IV 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 this medicine.

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

Side effects

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

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 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 Sandoz IV 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.

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
- recurrent infections, fever
- 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 you have been given Levetiracetam Sandoz IV

Storage

Levetiracetam Sandoz IV will be stored in the pharmacy or on the ward. The vials are kept in a cool dry place where the temperature stays below 25°C.

Product description

What it looks like

Levetiracetam Sandoz IV 500 mg/5 ml - each colourless glass vial with rubber stopper and aluminium cap contains a clear, colourless solution.

Available in pack size of 1 and 10 vials.

Ingredients

Active ingredients:

Levetiracetam Sandoz IV 500 mg/5 ml - Each vial contains 500 mg/5 ml levetiracetam.

Inactive ingredients:

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

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

Supplier

Sandoz Pty Ltd
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