

Hospira™ Levetiracetam concentrate for IV infusion

Levetiracetam (LEE ve tye RA se tam)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Hospira Levetiracetam concentrate for IV infusion.

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 Hospira Levetiracetam concentrate for IV infusion 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 in a safe place. You may need to read it again.

What Hospira Levetiracetam concentrate for IV infusion is used for

Hospira Levetiracetam concentrate for IV infusion 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.

This medicine 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.

Hospira Levetiracetam concentrate for IV infusion 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.

There is no evidence that this medicine is addictive.

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

The safety and effectiveness of Hospira Levetiracetam concentrate for IV infusion has not been established in patients less than 4 years of age.

Before you are given Hospira Levetiracetam concentrate for IV infusion

When you must not be given it

You must not be given Hospira Levetiracetam concentrate for IV infusion 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.

This medicine should not be given to you after the expiry date (EXP) printed on the pack.

If you are given this medicine after the expiry date has passed, it may not work as well.

It should not be given to you if the packaging is torn or shows signs of tampering.

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
- heart problems.

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

Hospira Levetiracetam concentrate for IV infusion 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. Your doctor will outline and weigh up all the risks and benefits, and help you to decide whether or not you should be given it during pregnancy.

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

The active ingredient in Hospira Levetiracetam concentrate for IV infusion passes into breast milk and there is a possibility that your baby may be affected. It is not recommended for use while breastfeeding.

Your doctor will discuss the risks and benefits of the treatment and the importance of breastfeeding.

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

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.

Your doctor and pharmacist may have more information on medicines to be careful with or avoid while you are being given the levetiracetam injection.

Hospira Levetiracetam concentrate for IV infusion does not interact with the oral contraceptive pill.

However, you may be given Hospira Levetiracetam concentrate for IV infusion 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 are given Hospira Levetiracetam concentrate for IV infusion with other antiepileptic medicines

How Hospira Levetiracetam concentrate for IV infusion is given

How much is given

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

How it is given

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

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

If you take too much (overdose)

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

However, if you think you have been given too much levetiracetam injection, or if you experience severe side effects tell your doctor immediately.

Symptoms of an overdose may include feeling drowsy.

Immediately telephone your doctor or the Poisons Information Centre on 13 11 26 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 Hospira Levetiracetam concentrate for IV infusion. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are using Hospira Levetiracetam concentrate for IV infusion

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 Hospira Levetiracetam concentrate for IV infusion.

Tell your doctor if you feel Hospira Levetiracetam concentrate for IV infusion 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 Hospira Levetiracetam concentrate for IV infusion 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, Hospira Levetiracetam concentrate for IV infusion 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 being given this medicine.

Combining Hospira Levetiracetam concentrate for IV infusion and alcohol can make you more drowsy. Your doctor may suggest you avoid alcohol while you are being treated with Hospira Levetiracetam concentrate for IV infusion.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are treated with Hospira Levetiracetam concentrate for IV infusion.

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 the treatment with Hospira Levetiracetam concentrate for IV infusion 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
- nausea
- vomiting
- upset stomach
- diarrhoea
- feeling tired, drowsy or sleepy
- difficulty walking
- trouble with balance.

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
- abnormal thoughts, feeling irritable or reacting more aggressively than usual
- upper respiratory tract infections
- weight loss
- muscle pain
- dark red or brown urine or decreased urination.

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
- fainting
- 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.

Sometimes you may have side effects without experiencing any symptoms. It is important to keep your routine doctor's appointments so that your condition can be checked.

After you have been given Hospira Levetiracetam concentrate for IV infusion

Storage

Hospira Levetiracetam concentrate for IV infusion 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

Hospira Levetiracetam concentrate for IV infusion is a clear, colourless solution.

Ingredients

Each vial of Hospira Levetiracetam concentrate for IV infusion contains 500 mg/5 mL levetiracetam.

It also contains:

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

Sponsor

Pfizer Australia Pty Ltd
Sydney NSW
Toll Free number:

1800 675 229

www.pfizer.com.au.

Australian registration number

Hospira Levetiracetam concentrate for IV infusion:

AUST R 211468

Date of Preparation

February 2021

™ Trademark

© Pfizer Australia Pty Ltd 2021