

Hospira™ Levetiracetam concentrate for IV infusion

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I being treated with Hospira Levetiracetam concentrate for IV infusion?

Hospira Levetiracetam concentrate for IV infusion contains the active ingredient levetiracetam. Hospira Levetiracetam concentrate for IV infusion is used to control epilepsy.

For more information, see Section [1. Why am I being treated with Hospira Levetiracetam concentrate for IV infusion?](#) in the full CMI.

2. What should I know before treatment with Hospira Levetiracetam concentrate for IV infusion?

Do not start treatment if you have ever had an allergic reaction to Hospira Levetiracetam concentrate for IV infusion or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before treatment with Hospira Levetiracetam concentrate for IV infusion?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Hospira Levetiracetam concentrate for IV infusion and affect how it works. A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How is Hospira Levetiracetam concentrate for IV infusion 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. More instructions can be found in Section [4. How is Hospira Levetiracetam concentrate for IV infusion given?](#) in the full CMI.

5. What should I know during treatment with Hospira Levetiracetam concentrate for IV infusion?

Things you should do	• Call your doctor straight away if you notice an increase in seizures; have symptoms of depression or thoughts of harming yourself; or if you become pregnant while being given this medicine. • Remind any doctor, nurse, dentist or pharmacist who is treating you that you are being given this medicine.
Things to be careful of	• 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.
Drinking alcohol	• 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 this medicine.

For more information, see Section [5. What should I know during treatment with Hospira Levetiracetam concentrate for IV infusion?](#) in the full CMI.

6. Are there any side effects?

Common side effects include dizziness, feeling weak, headache, common cold, stomach complaints, feeling tired, drowsy or sleepy, difficulty walking and trouble with balance. Serious side effects include changes in behaviour, thinking or mood (e.g. thoughts of harming yourself), upper respiratory tract infections, weight loss, muscle pain and dark red or brown urine or decreased urination, more frequent or more severe seizures, high fever, fast heartbeat and muscle stiffness, fainting and allergic type reactions. Do not be alarmed by this list. You may not experience any of them.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Hospira™ Levetiracetam concentrate for IV infusion

Active ingredient(s): *Levetiracetam* (LEE ve tye RA se tam)

Consumer Medicine Information (CMI)

This leaflet provides important information about using Hospira Levetiracetam concentrate for IV infusion. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Hospira Levetiracetam concentrate for IV infusion.**

Where to find information in this leaflet:

1. [Why am I being treated with Hospira Levetiracetam concentrate for IV infusion?](#)
2. [What should I know before treatment with Hospira Levetiracetam concentrate for IV infusion?](#)
3. [What if I am taking other medicines?](#)
4. [How is Hospira Levetiracetam concentrate for IV infusion given?](#)
5. [What should I know during treatment with Hospira Levetiracetam concentrate for IV infusion?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I being treated with Hospira Levetiracetam concentrate for IV infusion?

Hospira Levetiracetam concentrate for IV infusion contains the active ingredient levetiracetam.

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.

Hospira Levetiracetam concentrate for IV infusion 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.

2. What should I know before treatment with Hospira Levetiracetam concentrate for IV infusion?

Warnings

You must not be given Hospira Levetiracetam concentrate for IV infusion if:

- you are allergic to levetiracetam, or 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.

Always check the ingredients to make sure you can use this medicine.

- the expiry date (EXP) printed on the pack has passed.

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

- 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.

Check with your doctor if you:

- have any 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.
- have or have had any other medical conditions, especially the following:
 - kidney problems
 - liver problems
 - heart problems.
- take any medicines for any other condition.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with 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.

Talk to your doctor if you are breastfeeding or intend 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.

Use in Children

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

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements 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.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Hospira Levetiracetam concentrate for IV infusion.

4. How is Hospira Levetiracetam concentrate for IV infusion 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 are given too much Hospira Levetiracetam concentrate for IV infusion

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 Hospira Levetiracetam concentrate for IV infusion, or if you experience severe side effects tell your doctor immediately. You may need urgent medical attention.

Symptoms of an overdose may include feeling drowsy.

You should immediately:

- contact your doctor, or
- phone the Poisons Information Centre
(by calling 13 11 26), or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know during treatment with Hospira Levetiracetam concentrate for IV infusion?

Things you should do

Call your doctor straight away if you:

- notice an increase in seizures.
- have symptoms of depression or thoughts of harming yourself.
- feel Hospira Levetiracetam concentrate for IV infusion is not helping your condition.

Your doctor may need to change your medicine.

- become pregnant while being given this medicine.

Remind any doctor, nurse, dentist or pharmacist who is treating you that you are being given Hospira Levetiracetam concentrate for IV infusion. Tell them that you are being given Hospira Levetiracetam concentrate for IV infusion:

- before starting on any new medicine
- before any surgery and/or emergency treatment.

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 before you drive or use any machines or tools until you know how Hospira Levetiracetam concentrate

for IV infusion 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.

Drinking alcohol

Tell your doctor if you drink alcohol.

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.

6. Are there any side effects?

All medicines can have side effects. This medicine helps most people with epilepsy, but it may have unwanted side effects in a few people. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

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.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

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.

Side effects

Side effects	What to do
<u>Alertness related side effects:</u> - Dizziness - Feeling tired, drowsy or sleepy	Speak to your doctor if you have any of these side effects and they worry you. They are usually mild and short-lived.
<u>Pain related side effects:</u> Headache	
<u>Stomach complaints:</u> - Nausea - Vomiting - Upset stomach - Diarrhoea	
<u>Other side effects:</u> Feeling weak	

Side effects	What to do
- Common cold - Difficulty walking - Trouble with balance.	
<u>Changes in behaviour, thinking or mood:</u> - 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 - Thoughts of harming yourself	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects. You may need urgent medical attention or hospitalisation.
<u>Breathing and heart related side effects:</u> - Upper respiratory tract infections - Fast heartbeat	
<u>Gastro-related side effects:</u> - Weight loss - Dark red or brown urine or decreased urination	
<u>Other:</u> - Fainting - Muscle pain - More frequent or more severe seizures - High fever, - Muscle stiffness	
<u>Allergic type reactions:</u> - 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.	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur 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.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop treatment with any of your medicines.

7. Product details

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

What Hospira Levetiracetam concentrate for IV infusion contains

Active ingredient (main ingredient)	Levetiracetam
Other ingredients (inactive ingredients)	Glacial acetic acid Sodium acetate trihydrate Sodium chloride Water for injections

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

Do not use this medicine if you are allergic to any of these ingredients.

What Hospira Levetiracetam concentrate for IV infusion looks like

Hospira Levetiracetam concentrate for IV infusion is a clear, colourless solution (AUST R 211468).

How is Hospira Levetiracetam concentrate for IV infusion stored?

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.

Who distributes Hospira Levetiracetam concentrate for IV infusion

Pfizer Australia Pty Ltd
Sydney NSW
Toll Free number: 1800 675 229
www.pfizermedicalinformation.com.au

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