

LEVETIRACETAM JUNO

Levetiracetam (pronounced "LEE vet ye RA se tam") solution for IV infusion

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Levetiracetam Juno solution 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 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 in a safe place.

You may need to read it again.

WHAT LEVETIRACETAM JUNO SOLUTION FOR IV INFUSION IS USED FOR

This medicine 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.

Levetiracetam Juno solution 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.

BEFORE YOU ARE GIVEN LEVETIRACETAM JUNO SOLUTION FOR IV INFUSION

When you must not be given it

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

- Levetiracetam, the active ingredient(s), or to any of the other ingredient(s) listed at the end of this leaflet under Product Description.

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.

Safety and effectiveness in children younger than 4 years of age has not been established.

Do not take 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 start taking this medicine, talk to your doctor.

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 of the following medical conditions:

- kidney problems;
- liver problems.

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

Levetiracetam Juno solution for IV infusion 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 Juno solution for IV infusion 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 Juno solution for IV infusion passes into breast milk and there is the possibility that your baby may be affected. Your doctor will discuss the risks and benefits of using Levetiracetam Juno solution for IV infusion if you are breastfeeding.

If you have not told your doctor about any of the above, tell him/her before you start taking Levetiracetam Juno solution for IV infusion.

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.

Levetiracetam Juno solution for IV infusion does not interact with the oral contraceptive pill.

However, you may be given Levetiracetam Juno solution 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 take Levetiracetam Juno solution for IV infusion with other antiepileptic medicines.

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

HOW LEVETIRACETAM JUNO SOLUTION FOR IV INFUSION IS GIVEN

How much is given

Your doctor will decide how much Levetiracetam Juno solution 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

Levetiracetam Juno solution for IV infusion is given as an infusion (intravenous drip) into your vein.

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

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone Australia 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 taken too much Levetiracetam Juno solution 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 LEVETIRACETAM JUNO SOLUTION 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.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Levetiracetam Juno solution for IV infusion.

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

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

It may affect other medicines used during surgery.

If you become pregnant while taking this medicine, tell your doctor immediately.

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

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Stopping Levetiracetam Juno solution 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 Levetiracetam Juno solution for IV infusion affects you.

As with other antiepileptic medicines, Levetiracetam Juno solution 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 be careful when riding bicycles or climbing trees or doing anything else that could be dangerous if they are feeling dizzy or drowsy.

Be careful when drinking alcohol while you are taking this medicine.

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

SIDE EFFECTS

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

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 lists 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 Juno solution 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;
- upset stomach;
- diarrhoea;
- feeling tired, drowsy or sleepy.

The above list includes the more common side effects of your medicine. These are mild side effects of the medicine and are 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;
- 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 or pharmacist if you notice anything else that is making you feel unwell.

Other side effects not listed above may also occur in some people.

AFTER YOU HAVE BEEN GIVEN LEVETIRACETAM JUNO SOLUTION FOR IV INFUSION

Storage

Levetiracetam Juno solution for IV infusion will be stored in the pharmacy or on the ward. The bags are kept in a cool dry place where the temperature stays below 25°C.

PRODUCT DESCRIPTION

What it looks like

Levetiracetam Juno solution for IV infusion is a clear, colourless solution.

Ingredients

Levetiracetam Juno solution for IV infusion is available in three strengths. Each bag contains 500 mg/100 mL, 1000 mg/100 mL or 1500 mg/100 mL of levetiracetam.

Inactive Ingredients

It also contains:

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

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

Sponsor

Horizon Hospital Healthcare
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Carnegie, VIC 3163

Distributor

Juno Pharmaceuticals Pty Ltd
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Australia

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500 mg/100 mL: AUST R 224492

1000 mg/100 mL: AUST R 224489

1500 mg/100 mL: AUST R 224490