

LUCASSIN[®]

Terlipressin 0.85 mg powder for injection

Consumer Medicine Information

What is in this leaflet?

This leaflet answers some common questions about LUCASSIN. It does not contain all of the available information. It does not take the place of talking to your doctor, nurse or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the expected benefits of you having LUCASSIN against the risks this medicine could have for you.

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

Keep this leaflet. You may need to read it again.

What is LUCASSIN used for?

LUCASSIN contains terlipressin. This medicine is used to treat:

1) Hepatorenal syndrome, type 1 (HRS-1). LUCASSIN is given when a patient with HRS-1 is being considered for a liver transplant. HRS-1 is a condition in which the kidneys suddenly fail to work in a person with severe liver disease. HRS-1 is a life-threatening complication of severe liver disease. The cause of HRS-1 is not fully understood. It is thought to be due to the kidneys drastically reducing their own blood flow, in response to large changes in blood

flow in other parts of the body caused by severe liver disease. LUCASSIN works in HRS-1 by improving blood flow in the kidneys.

2) Bleeding Oesophageal Varices (BOV), which are bleeding veins in the lower end of the food-pipe in people with serious liver disease. When the liver is diseased, there is less blood flowing through it. This causes the blood to 'back up' in the veins in the lower end of the food pipe (and upper part of the stomach). The veins in the lining of the food pipe (and stomach) then become very large and stretched, much like varicose veins. Because the veins are also very fragile, they can rupture and then bleed severely into the stomach. LUCASSIN acts to stop the bleeding by lowering the blood pressure in the veins of the food-pipe.

Your doctor may have prescribed LUCASSIN for another reason. Ask your doctor if you have any questions about why LUCASSIN has been prescribed for you.

LUCASSIN is only available with a doctor's prescription.

LUCASSIN is not addictive.

Before you are treated with LUCASSIN

Things to be aware of before you are treated with LUCASSIN include:

LUCASSIN should not be used in patients who have had an allergic reaction to terlipressin or any of the ingredients listed toward the end of this leaflet. (See "Ingredients").

Symptoms of an allergic reaction to LUCASSIN 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.

Use in pregnancy

LUCASSIN is not recommended for use in women who are pregnant or intend to become pregnant. If there is a need to consider using LUCASSIN during your pregnancy, your doctor will discuss with you the benefits and risks of using it.

Use in lactation

Do not use LUCASSIN if you are breast-feeding or planning to breast-feed.

It is not known if it passes into breast milk or is safe for use in infants.

Use in children

The safety and effectiveness of LUCASSIN in children have not been established.

If you are not sure whether you should have LUCASSIN, talk to your doctor, nurse or pharmacist.

Tell your doctor if:

You must tell your doctor if:

- You are allergic to foods, dyes, preservatives or any other medicines.

Tell your doctor if you have or have had any medical conditions, especially the following:

- heart disease
- high blood pressure
- irregular heart beat
- circulation problems
- kidney problems
- asthma, chronic bronchitis, emphysema or a history of lung problems

Tell your doctor if you are breast-feeding or intending to breast-feed, or if you plan to have surgery.

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.

Some medicines and LUCASSIN may interfere with each other:

These include:

- Beta-blockers – used to treat high blood pressure and certain heart conditions
- Propofol – a short-acting anaesthetic

Taking LUCASSIN with these medicines may cause your heart to slow down or beat irregularly.

These medicines may be affected by LUCASSIN or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

Your doctor and pharmacist may have more information on

medicines to be careful with or avoid while you are receiving LUCASSIN.

How LUCASSIN is used

LUCASSIN is given as an injection, usually through an intravenous line, by a doctor or nurse.

Before LUCASSIN is used, it must be dissolved in sterile normal saline solution. LUCASSIN should not be mixed with dextrose solution for injection.

How much to use

Treatment with LUCASSIN is carried out in a hospital. You will not be taking the medicine by yourself. Instead, the medicine will be given to you as an injection by your doctor or nurse. The usual starting dose is 0.85 mg terlipressin injected into the vein every 6 hours for HRS-1) or 1.7 mg every 4 hours for BOV. Your doctor may adjust the dose depending on how you are responding to the treatment.

How long to use it for

LUCASSIN is generally used for up to two weeks or less in treating an occurrence of HRS-1 or for up to 48 hours in the treatment of BOV.

If you take too much (overdose)

As LUCASSIN will be given to you directly by your doctor or nurse in a hospital, it is unlikely that you will receive too much.

However, if you experience any side effects after you are discharged, immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26) or go to

Accident and Emergency at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you receive too much LUCASSIN, you may experience any of the following:

- headache
- pale skin
- blue lips and fingernails
- stomach pain or discomfort
- nausea
- diarrhoea.

While you are using LUCASSIN

Things you must do

Tell any other doctors, dentists, and pharmacists who are treating you that you are or have been treated with LUCASSIN.

Be sure to keep all your doctor's appointments.

Your doctor will want to do blood and other tests regularly to check on your progress and detect any unwanted side effects.

If you become pregnant while you are being given this medicine, tell your doctor, nurse or pharmacist immediately.

What are the side effects?

Tell your doctor or nurse as soon as possible if you experience any problems after having LUCASSIN, even if the

problems are not listed in this leaflet.

Like all medicines, LUCASSIN can cause side effects, although not everybody gets them. Sometimes the side effects can be serious, although most of the time they are not.

The hospital staff will be monitoring you for possible side effects. If you get some of the side effects, your doctor and/or nurse will help you manage them while you are in the hospital.

Ask your doctor, nurse or pharmacist to answer any questions you may have.

Don't be alarmed by the following list of side effects. You may not experience any of them. Tell your doctor or nurse AT ONCE if you experience any of the following while you are receiving LUCASSIN:

- Allergic reaction which can occur as skin rash; unusual wheezing or difficulty with breathing; swollen eyelids, lips or tongue; pain in muscles or joints; light-headedness or fainting.
- Chest pain or tightness.
- Any unusual feeling in your heart including irregular, fast or slow heart beat.
- Increased blood pressure.
- Stomach pain or discomfort.
- Passing out red or dark-coloured stool during bowel movement.
- Pain in your hands or feet.
- Skin, fingernails or lips turning blue or purple.
- Shortness of breath, wheezing or trouble with breathing.
- Feeling or being sick (nausea or vomiting).
- Diarrhoea.

- Swelling due to excess fluid in the body.
- Tingling or numbness of the hands or feet.
- Reddening and pain at the injection site.
- Headache
- Pale skin
- Hot flushes

This is not a complete list of all possible side effects. Others may occur in some people receiving LUCASSIN; and there may be some side effects not yet known.

Storing LUCASSIN

LUCASSIN is usually stored in the hospital pharmacy or in the hospital ward. It requires refrigeration between 2°C and 8°C.

After dissolving LUCASSIN in sterile normal saline, the solution may be refrigerated (2 - 8°C) for up to 24 hours before use.

Do not freeze. Prior to use, vials should be stored in original carton in order to protect from light.

Product description

What LUCASSIN looks like

LUCASSIN is a sterile white to off-white powder supplied in single use vials. Each vial contains 0.85 mg terlipressin.

LUCASSIN is supplied as single vials, and also in packs of 12 vials.

Ingredients

LUCASSIN contains the active ingredient, terlipressin, and an inactive ingredient, mannitol. It may also contain acetic acid and/or sodium hydroxide.

Sponsor

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Where to go for further information

Ikaria is not in a position to give people an individual diagnosis or medical advice. Your doctor, nurse or pharmacist is the best person to give you advice on the treatment of your condition. You may also be able to find general information about your condition and its treatment from patient support groups.

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