Lucassin®
terlipressin

Physicians guide to prescribing

Lucassin® (Terlipressin 0.85 mg powder for injection).

Indication	LUCASSIN is indicated for the treatment of patients with hepatorenal syndrome (HRS) type 1 who are actively being considered for a liver transplant
Dosage	The recommended starting dose is one vial of LUCASSIN (0.85mg terlipressin free base) every 6 hours by slow intravenous bolus injection. If serum creatinine (SCr) has not decreased by at least 30% from baseline after 3 days, the dose can be increased to 2 vials (1.7 mg terlipressin) every 6 hours. The dose should not be increased in patients with severe pre-existing cardiovascular disease or in the presence of an ongoing significant adverse event. Treatment with LUCASSIN should be continued until 2 days after the patient achieves HRS reversal (SCr ≤132.6 µmol/L). Treatment should be terminated if the patient undergoes dialysis or liver treatment or if serum creatinine remains at or above baseline after 7 days of treatment. The initial treatment course may be continued for up to two weeks.
How to prescribe	LUCASSIN 0.85 mg IV every 6 hours
Preparation	Reconstitute each LUCASSIN vial with 5 ml of sterile 0.9% sodium chloride injection. Inspect visually for particulate matter and discolouration prior to administration. **Do not use dextrose solutions to reconstitute the vial**
Administration	Administer LUCASSIN as a slow IV bolus. Flush the line with saline prior to and after the LUCASSIN bolus injection. If not administered immediately, the reconstituted solution should be refrigerated (2-8°C) up to 24 hours prior to use. Do not freeze.
Drug incompatibilities	LUCASSIN is incompatible with dextrose solutions
LUCASSIN should not be used in the following:	• Hypersensitivity to terlipressin or any of the excipients • Patients with unstable angina or recent acute myocardial infarction • Pregnancy (Category D)
Precautions	• Patients with coronary artery disease • Patients with severe asthma or COPD • Ischaemic events (cardiac, gastrointestinal, skin) have occured following administration of terlipressin and may require temporary interruption, dose decrease or discontinuation of LUCASSIN
Adverse effects	Vomiting, abdominal pain, diarrhoea, flatulence, bronchospasm, dyspnoea, pneumonia, pulmonary oedema, respiratory failure, epistaxis, sepsis, hypomagnesaemia, hepatic failure, headache, supraventricular tachycardia, bradycardia, pyrexia, multi-organ failure, anxiety, hypotension, pain in extremity, fluid overload, intestinal ischaemia.
Monitoring	• Serum creatinine daily, serum electrolytes periodically • ECG, blood pressure, fluid balance • Closely observe for signs and symptoms of skin and peripheral ischaemia
Reporting of suspected drug reactions	Ikaria Australia encourages the reporting of all suspected adverse reactions to its medicines. If there is a suspected adverse event call Ikaria Australia on 03 9851 9100 or contact us through www.IkariaAust.com
Key studies	1. OT-0401: Sanyal AJ, Boyer T, Garcia-Tsao G et al. A randomised, prospective, double-blind, placebo-controlled trial of terlipressin for type 1 hepatorenal syndrome. *Gastroenterology* 2008; 134:1360-1368 2. TAHRS: Martin-Llahi M, Pepin MN, Guevara M et al. Terlipressin and albumin vs albumin in patients with cirrhosis and hepatorenal syndrome: a randomised study. *Gastroenterology* 2008; 134:1352-1359

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Please review Full Product Information before prescribing.
Product Information is available from Ikaria Australia
at the following links:
https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2012-PI-02386-3
http://ikariaaust.com/sites/default/files/LUCASSIN-PI-2017-11.pdf

PBS Information: This product is not listed on the PBS

Minimum Product Information

Lucassin® (Terlipressin 0.85 mg powder for injection).

Indication: Treatment of patients with hepatorenal syndrome (HRS) type 1 who are actively being considered for a liver transplant. **Contraindications:** Hypersensitivity to terlipressin or any of the excipients. **Precautions:** Use with caution in patients with cononary artery disease, severe asthma or chronic obstructive pulmonary disease. Do not use in patients with unstable angina or recent myocardial infarction. Ischaemic events (cardiac, gastrointestinal, and skin) have occurred following administration of terlipressin. Serum creatinine should be monitored to assess response to therapy. **Interactions with other medicines (see full PI). Adverse effects:** Vomiting, abdominal pain, diarrhoea, flatulence, bronchospasm, dyspnoea, pneumonia, pulmonary oedema, respiratory failure, epistaxis, sepsis, hypomagnesaemia, hepatic failure, headache, supraventricular tachycardia, bradycardia, pyrexia, multi-organ failure, anxiety, hypotension, pain in extremity, fluid overload, intestinal ischaemia. **Post marketing experience (see full PI). Dosage and Administration:** The recommended starting dose is one vial of LUCASSIN (0.85 mg terlipressin) every 6 hours by slow intravenous bolus injection. If serum creatinine has not decreased by ≥30% from baseline value after 3 days the dose can be increased to 2 vials of LUCASSIN (1.7 mg terlipressin) every 6 hours. Date of first inclusion in ARTG: 9 January 2012. Date of most recent amendment: 1 December 2015.

Sponsor: Ikaria Australia Pty Ltd, part of Mallinckrodt Pharmaceuticals
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