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 • bleeding oesophageal varices
Dosage	**Hepatorenal syndrome (HRS) type 1** The recommended starting dose is 0.85mg terlipressin 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 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 transplant 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. **Bleeding Oesophageal Varices** Adults: Initially an IV injection of 1.7 mg terlipressin is given every 4 hours. When the bleeding is under control the dose can be adjusted to 0.85 mg terlipressin IV every 4 hours. After the initial dose, the dose can also be adjusted to 0.85 mg terlipressin IV every 4 hours in patients with body weight < 50 kg or if adverse effects occur. The treatment should not continue for more than 48 hours in total. Children and Elderly: No data are available regarding dosage recommendations in these patient populations.
How to prescribe	LUCASSIN 0.85 mg IV every 6 hours (HRS-1) or every 4 hours (BOV)
Preparation	Reconstitute each LUCASSIN vial with 5 mL of sterile 0.9% sodium chloride injection to prepare a 0.85 mg/5mL terlipressin solution. 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 occurred 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, pallor, hypertension, peripheral vasoconstriction/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 contact: • Australia Customer Care 1300 198 565 or email CritCare-Australia_CCcontacts@mallinckrodt.com • Global Pharmacovigilance globalpv@mallinckrodt.com • TGA at http://www.tga.gov.au/reporting-problems
Key studies	**Hepatorenal syndrome (HRS) type 1** 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 **Bleeding Oesophageal Varices** 1. Walker S, Kreichgauer, HP, Bode JC. Terlipressin (Glypressin) Versus Somatostatin in the Treatment of Bleeding Esophageal Varices--Final Report of a Placebo-Controlled, Double-Blind Study. Z. *Gastroenterol*. 1996; 34(10): 692-698 2. Söderlund, C, Magnusson I, Tomgren S, Lundell L. Terlipressin (Triglycyl-Lysine Vasopressin) Controls Acute Bleeding Oesophageal Varices. A Double-Blind, Randomized, Placebo-Controlled Trial. *Scand. J. Gastroenterol*. 1990; 25(6): 622-630 3. Freeman JG, Cobden I, Record CO. Placebo-Controlled Trial of Terlipressin (Glypressin) in the Management of Acute Variceal Bleeding. *J. Clin. Gastroenterol*. 1989; 11(1): 58-60 4. Levacher S, Letoumelin P, Pateron D, Blaise M, Lapandry C, Pourriat JL. Early Administration of Terlipressin Plus Glyceryl Trinitrate to Control Active Upper Gastrointestinal Bleeding in Cirrhotic Patients. *Lancet*. 1995; 346(8979): 865-868

Please review Full Product Information before prescribing.
Product Information is available from Ikaria Australia at the following link:
https://mallinckrodt.com.au/sites/default/files/Lucassin-PI-2018-06.pdf

Minimum Product Information

Lucassin® (Terlipressin 0.85 mg powder for injection).

Indication: Treatment of patients with (1) hepatorenal syndrome (HRS) type 1 who are actively being considered for a liver transplant or (2) bleeding oesophageal varices. **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, pallor, hypertension, peripheral vasoconstriction / ischaemia. **Post marketing experience** (see full PI). **Dosage and Administration: HRS-1** The recommended starting dose is 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 1.7 mg terlipressin every 6 hours. **BOV:** Initially 1.7 mg terlipressin IV every 4 hours adjusted to 0.85 mg terlipressin IV every 4 hours when bleeding is controlled. The treatment should not continue for more than 48 hours in total. Refer to full PI for complete dosing instructions.

PBS Information: This product is not listed on the PBS

Date of first inclusion in ARTG: 9 January 2012. Date of most recent amendment: 07 June 2018.
Lucassin® is a registered trademark of Mallinckrodt Pharmaceuticals. Etal 7703MAL. Date of Preparation: June 2018
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ACN 134 086 089. PRC INTL/Luca/0618/0001 6/18.

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