



ProPharmaceuticalsGroup

Pro Pharmaceuticals Group Pty LTD

ABN: 20 605 457 430

www.propg.com.au

Dear Healthcare Professional,

Shortage of GLUCAGEN HYPOKIT glucagon (rys) 1mg (1IU) powder for injection vial with diluent syringe (AUST R: 47105)

Pro Pharmaceuticals Group recognises the importance of supplying essential medicines in Australia and would like to advise you the change in supply status of GLUCAGEN HYPOKIT glucagon (rys) 1mg (1IU) powder for injection vial with diluent syringe (AUST R: 47105) in Australia.

The Australian registered medicine, GLUCAGEN HYPOKIT glucagon (rys) 1mg (1IU) powder for injection vial with diluent syringe (AUST R: 47105) is currently in shortage due to manufacturing issues.

Pro Pharmaceuticals Group has arranged for the supply of an alternative product, **Glucagon Emergency Kit for Low Blood Sugar glucagon for injection 1mg per vial (Amphastar Pharmaceuticals, USA)**. This product is NOT registered in Australia and supply is authorised under an exemption granted by the Therapeutic Goods Administration (TGA) under section 19A of the *Therapeutic Goods Act 1989* until **31st October 2023** for the following indication(s):

Therapeutic • *Treatment of severe hypoglycaemic reactions which may occur in the management of diabetic patients receiving insulin or oral hypoglycaemic agents. To prevent the occurrence of secondary hypoglycaemia, oral carbohydrate should be given to restore the hepatic glycogen when the patient has responded to the treatment. The mechanism and hence treatment of sulfonylurea-induced hypoglycaemia differs from that of severe insulin-induced hypoglycaemia in some important ways. Consciousness should preferably be restored by the administration of intravenous glucose. If glucagon is used due to the unavailability of intravenous glucose (e.g. before reaching a hospital) care should be taken to protect against secondary hypoglycaemia with constant monitoring of the patient's blood sugar level by medical personnel. Subsequent administration of intravenous glucose may be required.*

Diagnostic • *Motility inhibitor in examinations of the gastrointestinal tract in adults, e.g. double contrast radiography and endoscopy.*

Glucagon Emergency Kit for Low Blood Sugar glucagon for injection 1mg per vial (Amphastar Pharmaceuticals, USA) is identical in active ingredient and strength to the Australian registered product. It is registered and marketed in USA by Amphastar Pharmaceuticals, therefore all labelling is in English.

Pro Pharmaceuticals Group recommends that healthcare professionals refer to the Australian Product Information for GLUCAGEN HYPOKIT glucagon (rys) 1mg (1IU) powder for injection vial with diluent syringe, AUST R: 47105 for recommended dosing for the above indications. This is available at <https://www.ebs.tga.gov.au>.

There are minor differences in the preparation and dosage instructions of the Australian and the USA product.

Please ensure the patient and their carer are aware of the prescribed dose.

Refer the patient and their carer to the provided USA INFORMATION FOR THE USER leaflet so that they are familiar with the preparation instructions.

The Australian and USA products differ in their excipient ingredients as shown in the table below:

	ARTG product GLUCAGEN HYPOKIT glucagon (rys) 1mg (1IU) powder for injection vial with diluent syringe, AUST R: 47105	S19A Product Glucagon Emergency Kit for Low Blood Sugar glucagon for injection 1mg per vial (Amphastar Pharmaceuticals, USA)
Excipients	lactose monohydrate hydrochloric acid (for pH adjustment) sodium hydroxide (for pH adjustment) water for injections	lactose hydrochloric acid water glycerin

Reporting suspected adverse events is important for the continued monitoring of the safety of all medicines. Any adverse events which are experienced with Glucagon Emergency Kit for Low Blood Sugar glucagon for injection 1mg per vial (Amphastar Pharmaceuticals, USA) must be reported by healthcare professionals, pharmacists, and patients to the TGA at <https://www.tga.gov.au/reporting-problems> or to Pro Pharmaceuticals Group on 1300077674 or email regulatory@propg.com.au

Any product complaints with Glucagon Emergency Kit for Low Blood Sugar glucagon for injection 1mg per vial (Amphastar Pharmaceuticals, USA) should be reported to Pro Pharmaceuticals Group on 1300 077674 or email regulatory@propg.com.au

For any orders please contact Pro Pharmaceuticals Group on 1300077674 or email orders@propg.com.au

Please forward this information to relevant staff members in your organisation.

For further information, please contact Pro Pharmaceuticals Group on 1300077674 or email info@propg.com.au

Sincerely,
Sandip Manku – Director Pro Pharmaceuticals Group