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10th Aug 2023

Dear Healthcare Professional

Shortage of GlucaGen Hypokit Aust R 47105 and alternative supply arrangement under section 19A of the *Therapeutic Goods Act 1989*

The Australian registered medicine, **GlucaGen Hypokit (glucagon (rys) 1mg (1IU) powder for injection vial with diluent syringe) Aust R 47105** sponsored by Novo Nordisk Pharmaceuticals is currently unavailable due to manufacturing issues. It is in the interest of public health to continue supply of an overseas substitute product.

LINK has been able to arrange supply of an alternative product **GlucaGen Hypokit glucagon 1 mg powder and solvent for solution for injection (Germany)** on a temporary basis. This product is NOT registered in Australia and supply is authorised under an approval 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 inhibition in examinations of the gastrointestinal tract in adults, e.g. double contrast radiography and endoscopy.*

GlucaGen HypoKit glucagon 1 mg powder and solvent for solution for injection (Germany) is identical in active ingredient and strength to the Australian registered product. It is registered and marketed in Germany & therefore the labelling is in German. A translated package leaflet has been provided with this 19A approved product. Please direct the patient or their carer to this leaflet for administration and storage instructions.

Please note the following information regarding differences between the German and the Australian registered medicine.

	Australian Product GlucaGen Hypokit ARTG 47105	S19A Product GlucaGen Hypokit glucagon 1 mg powder and solvent for solution for injection (Germany)
Storage	Store below 25°C	Store at 2-8°C. The user can store GlucaGen HypoKit at a temperature not exceeding 25ºC for 18 months provided that the expiry date is not exceeded.

Australian Product Information for GLUCAGEN HYPOKIT glucagon (rys) 1mg (1IU) powder for injection vial with diluent syringe, AUST R: 47105 is available at: www.ebs.tga.gov.au

Adverse Event Reporting
Reporting any suspected adverse event is important for the continued monitoring of the safety of all medicines. Any adverse events which are experienced with **GlucaGen Hypokit glucagon 1 mg powder and solvent for solution for injection (Germany)** should be reported by healthcare professionals and patients to the LINK healthcare Pharmacovigilance at pv@linkhealthcare.co or 1800 181 060. Alternatively, this information can be reported to the TGA at https://www.tga.gov.au/reporting-problems

Any product complaints regarding **GlucaGen Hypokit glucagon 1 mg powder and solvent for solution for injection (Germany)** should be reported to LINK on 1800 161 181.

Please forward this information to relevant staff members in your organisation.
For further information, please contact LINK on 1800 161 060 or email customerservice@linkhealthcare.com.au.

Yours faithfully

Ameena Rabe

Ameena Rabe
Head of Unlicensed Medicines and Access Services
Link Healthcare