Safety Notice 020/23

Issue date
10 August 2023

Distributed to:
Chief Executives
Directors of Clinical Governance
Director, Regulation and Compliance Unit

Action required by:
Chief Executives
Directors of Clinical Governance

We recommend you also inform:
Directors, Managers and Staff of:

- Emergency Departments
- Intensive Care Units
- Endocrinology
- Diabetes Clinics
- Medical Imaging
- Medical Services
- Nursing/Midwifery Services
- Pharmacy Services

Drug & Therapeutics Committees
All other relevant clinicians and clinical departments where this product is prescribed, stored, and administered.

Expert Reference Group
Content reviewed by:
Medicine Shortage Assessment and Management Team
Medication Safety Expert Advisory Committee
ACI Diabetes and Endocrine Network

Clinical Excellence Commission
Tel: 02 9269 5500
Email
Internet
Intranet

Review date
November 2023

Disruption to supply – Glucagon 1 mg (GlucaGen® Hypokit®)

Situation

There is a current disruption to the supply of the Australian registered medicine glucagon 1 mg (GlucaGen Hypokit) powder for injection vial with diluent syringe (AUST R: 47105) due to manufacturing issues. This disruption is expected to continue until 30 September 2023. Alternative products have been approved under Section 19A (S19A) of the Therapeutic Goods Act. The lead time of the S19A alternatives is approximately 2 weeks.

Background

GlucaGen Hypokit is a medical device containing a pre-filled syringe with 1 mL water for injection and a vial with 1 mg lyophilised glucagon, a polypeptide hormone that raises blood glucose levels. Glucagon is indicated in the treatment of severe hypoglycaemia in patients with diabetes receiving insulin or particular oral hypoglycaemic agents. It is also indicated for use in diagnostics as a motility inhibitor for examinations of the gastrointestinal tract in adults.

The Therapeutic Goods Administration (TGA) have released a web statement regarding the shortage and are continuing to assess further S19A alternatives. For updates on the S19A alternatives, refer to the TGA Section 19A approvals database.

Assessment

The S19A alternatives currently available are identical in active ingredient, and strength to the Australian registered product. Some of the products feature labelling in foreign languages – **Swiss** (Reach alternative) and **German** (Medsurge alternative). See Table 1 (over page) for a comparison between the Australian registered product and the S19A alternatives.

Other alternatives

Intravenous glucose in the management of hypoglycaemia

Intravenous glucose infusions (e.g., using 10% or 20%) may be used for the treatment of severe hypoglycaemia and should be administered through a securely positioned cannula into an antecubital vein, as injections into veins in the hand may cause superficial thrombophlebitis. Concentrations and infusion rates differ between adult and paediatric populations; refer to the Australian Therapeutic Guidelines for further information.

50% glucose as a slow IV injection may be considered for the management of adult patients experiencing hypoglycaemia but must be used with extreme caution given its vesicant properties and the potential for extravasation. 50% Glucose **must not** be used for children or adolescents as it may cause hyperosmolarity and subsequent death.

Recommendations

To effectively manage the disruption to the supply of GlucaGen Hypokit stock, it is recommended that:

- Remaining stock of GlucaGen Hypokit is reserved for the treatment of severe hypoglycaemia (as a lifesaving drug), and alternative agents are used for diagnostic indications. Priority access should be given to:
  - patients who have just started treatment for type 1 diabetes and do not have a GlucaGen Hypokit
  - patients at particular risk of hypoglycaemia such as those with concomitant adrenal insufficiency, hypopituitarism or growth hormone deficiency
  - children
  - people living or travelling in remote areas.

Recommendations cont.

- A facility-wide review of stock holding, including inpatient and outpatient areas, should be undertaken and excess stock recalled from wards and clinics. Clinical requirements must be carefully assessed to ensure adequate stock remains in clinical areas for the treatment of life-threatening hypoglycaemia
- Kits nearing expiry should not be discarded. Only discard kits where the expiry date has passed.
- Facilities should ensure that patients being discharged who require GlucaGen Hypokit have access to stock that is in date. Facilities may be required to supply GlucaGen Hypokit upon discharge from hospital if deemed necessary.
- If storing the German or Swiss S19A products (available from Reach and Medsurge respectively) outside of the refrigerator, a label should be applied to the product with an appropriate expiry date following the manufacturers' storage guidelines (see Table 1 below) – either an expiry date of 18 months from removal from refrigeration or the product's original expiry date (whichever is shorter).
- Ensure glucose infusions (e.g., 10% or 20%) and 50% glucose vials are readily available in case of complete disruption to supply.

Table 1. Comparison between Australian registered and S19A alternative for glucagon (see **Appendix** for images).

Product	*ARTG listed product*	*S19A alternative – Reach*	*19A alternative – Medsurge*	*S19A alternative – ProPharmaceuticals*
	Glucagon (GlucaGen Hypokit)	**Glucagon (GlucaGen Hypokit)**	**Glucagon (GlucaGen Hypokit)**	**Glucagon (Glucagon Emergency Kit)**
Active ingredient	Glucagon hydrochloride			
Labelled strength	1 mg/mL			
Excipients	Lactose monohydrate, hydrochloric acid, sodium hydroxide and water for injection.			Lactose, hydrochloric acid, water for injection and glycerin.
Storage	Store below 25°C. Keep in original packaging and protect from light.	Refrigerate 2°C – 8°C **OR** Store below 25°C for up to 18 months but no longer than the stated expiry. Keep in original packaging and protect from light.		Store between 20 -25 °C. Keep in original packaging and protect from light.
Labelling language	English	Swiss	German	English

Required actions for the Local Health Districts/Networks

1. Distribute this Safety Notice to all relevant clinicians, clinical departments where GlucaGen Hypokit is stocked, prescribed, and administered, and include this Safety Notice in relevant handovers and safety huddles.
2. Undertake a local risk assessment and incorporate the above recommendations to manage the disruption to supply.
3. Ensure a system is in place to document actions taken in response to this Safety Notice.
4. Report any incidents associated with this disruption to supply into the local incident management system e.g., ims+.
5. Confirm receipt and distribution of this Safety Notice **within 72 hours** to CEC-MedicationSafety@health.nsw.gov.au

Appendix

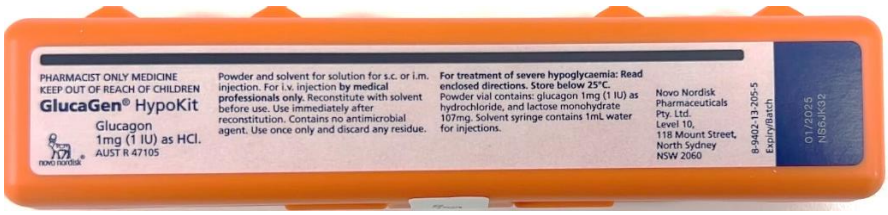

Figure 1: Australian registered GlucaGen Hypokit.

Figure 2. Reach S19A alternative from Switzerland with labelling in Swiss.

Figure 3. Medsurge S19A alternative from Germany with labelling in German.

Figure 4. ProPharmaceuticals S19A alternative from USA with labelling in English.