

Date:

DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION

GlucaGen® HypoKit (Human Glucagon) 1mg/ml: supply shortage in the UK

Dear Healthcare Professional,

Novo Nordisk UK in agreement with the Medicines and Healthcare products Regulatory Agency (MHRA) and the Department of Health and Social Care (DHSC) would like to inform you of the following:

Novo Nordisk is experiencing an intermittent supply shortage for GlucaGen® HypoKit 1mg/ml in the UK.

Summary:

- GlucaGen HypoKit 1mg/ml is indicated for treatment of severe hypoglycaemic reactions and for diagnostic purposes of the gastrointestinal tract.
- Novo Nordisk is experiencing an intermittent supply shortage of GlucaGen HypoKit 1mg/ml in the UK. Supply issues are expected to commence end Jun 2023 with resupply expected around mid-July 2023 (~4 weeks). The supply situation will be closely monitored.
- Use Glucagon for injection from other Marketing Authorization Holders (MAHs) for treating severe hypoglycaemia – please refer to the advice provided in the Medicines Shortage Notification (MSN/2023/051) issued by the DHSC.
- You are recommended to use GlucaGen HypoKit 1mg/ml, only for treating severe hypoglycaemia (as a life-saving drug) and not for diagnostic purposes.

Background on the safety concern:

GlucaGen HypoKit 1mg/ml is indicated for treatment of severe hypoglycaemic reactions, which may occur in the management of insulin treated children and adults with diabetes mellitus. It is also indicated for diagnostic purposes for motility inhibition in examinations of the gastrointestinal tract in adults. Please refer to the [Summary of Product Characteristics \(SmPC\)](#) for the detailed therapeutic indication (<https://www.medicines.org.uk/emc/product/1289>).

Supply issues are expected to commence end Jun 2023 with resupply expected around mid-July 2023 (~4 weeks). The supply situation will be closely monitored. The cause of the intermittent supply shortage is a shortfall in the release and supply of pre-filled syringes from an external vendor which has resulted in limited supply of GlucaGen® HypoKit 1mg/ml to the UK. The shortage is not a consequence of any safety or quality related concern with Glucagen HypoKit 1mg/ml.

A Medicines Shortage Notification (MSN/2023/051) has been issued by the Department of Health and Social Care (DHSC) for GlucaGen HypoKit 18th May 2023. Further guidance is available via the MSN. This is available on the Medicines Supply Tool within the Specialist Pharmacy Service website.

Advice for healthcare professionals:

- Delayed awareness of the out-of-stock situation may result in a clinical consequence for patients.

- You are recommended to use GlucaGen HypoKit 1mg/ml, only for treating severe hypoglycaemia (as a life-saving drug) and not for diagnostic purposes.
- Use of the alternative product available is at your discretion and based on local clinical practices, along with the requirements in the prescribing information.
- There is an alternative: Glucagon for injection from another Marketing Authorization Holder for treating severe hypoglycaemia – please refer to the advice provided in the MSN
- Ensure that patients using GlucaGen HypoKit 1mg/ml are made aware of this issue and that patients at risk are safely switched to a suitable alternative based on your clinical judgment.
- Remind your colleagues of these actions, particularly if they are known to use/prescribe GlucaGen HypoKit 1mg/ml.

Please ensure all relevant staff are made aware of the content of this letter and that the information is communicated to the patients.

Call for reporting:

Healthcare professionals are asked to report any suspected adverse reactions to the Yellow Card Scheme

You can report via:

- The Yellow Card website - <https://yellowcard.mhra.gov.uk/>,
- The free Yellow Card app available from the [Apple App Store](#) or [Google Play Store](#)
- Some clinical IT systems (EMIS, SystmOne, Vision, MiDatabank) for healthcare professionals.

Alternatively, you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm.

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, onset timing, treatment dates, and product brand name.

Company contact point:

If you have any questions about this letter or require more information about GlucaGen HypoKit 1mg/ml, please contact Novo Nordisk customer care centre on 0800 023 2573.

I understand the uncertainty and concern this shortage may cause people living with diabetes. This is not something we are taking lightly, and we are working hard to solve these challenges.

Yours sincerely,

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Novo Nordisk