

## Drug Alert

### CLASS 1 MEDICINES RECALL

#### Action Within 24 Hours

Date: 7<sup>th</sup> September 2016

Our Ref: MDR 01-09/16

## Novo Nordisk A/S is recalling 2 batches of GlucaGen® HypoKit in Malta

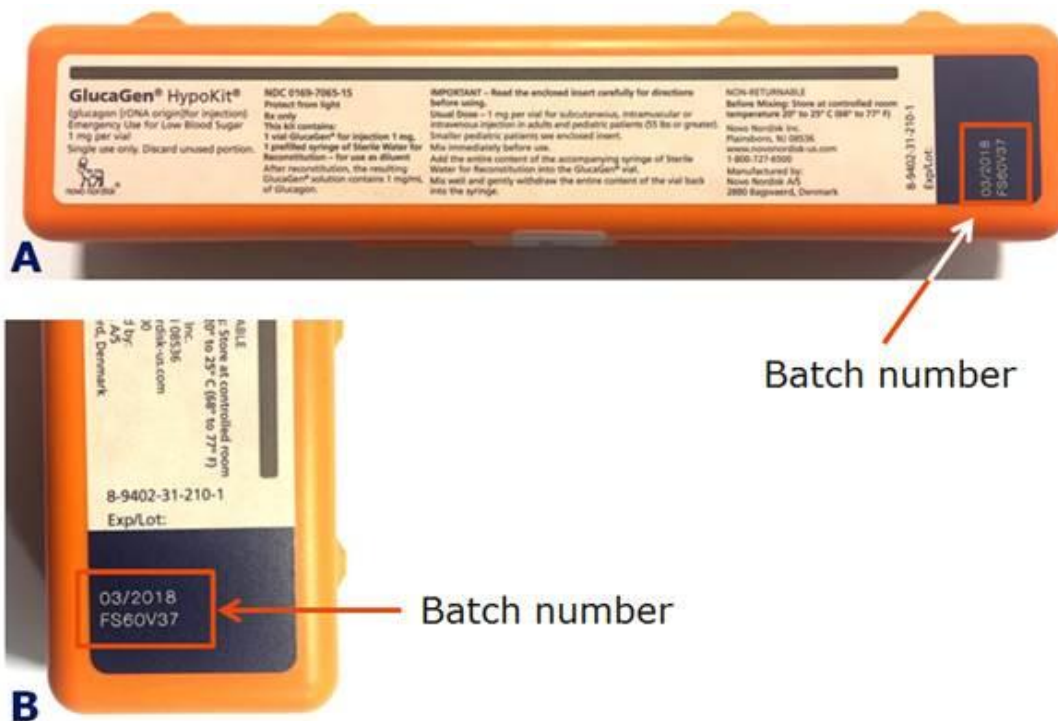
**Malta, 6<sup>th</sup> September 2016** – Novo Nordisk A/S is recalling 2 batches of GlucaGen® HypoKit in Malta at wholesaler, pharmacy and patient level (Class 1 recall). The GlucaGen® HypoKit is indicated for the treatment of severe hypoglycaemia (low blood sugar) in insulin treated diabetes patients.

Novo Nordisk conducted an investigation showing a small number (0.006%) of needles were detached from the syringe in certain batches of GlucaGen® HypoKit. To protect patient safety Novo Nordisk is recalling affected batches from wholesalers, pharmacies and patients in Malta.

The recalled GlucaGen® HypoKit batch numbers and expiry date are:

Batch no.	Expiry date
FS6X249	31/05/2018
FS6X592	31/08/2018

Patients or carers may themselves check the batch number to see if their GlucaGen® HypoKit is affected. The batch number is printed on the GlucaGen® HypoKit as indicated below in the red box (Figure 1).



**Figure 1.** A) GlucaGen® HypoKit where the batch number is found in the red box  
B) close up of the batch number.

**Advise to patients in possession of a GlucaGen® HypoKit with one of the above-mentioned batch numbers:**

- Return your GlucaGen® HypoKit with the above mentioned batch numbers to your pharmacy or hospital pharmacy.
- You will be given a free replacement GlucaGen® HypoKit when you return the product with one of the listed batch numbers.
- Report any adverse drug reactions to Novo Nordisk's customer service, which can be reached via email at [ITASafety@mail@novonordisk.com](mailto:ITASafety@mail@novonordisk.com) or to ADR Reporting Website: [www.medicinesauthority.gov.mt/adrportal](http://www.medicinesauthority.gov.mt/adrportal).

If you are in possession of a GlucaGen® HypoKit with a batch number **NOT** mentioned above there is no concern and you can be confident that the product will work as prescribed.

### About GlucaGen® HypoKit

GlucaGen® Hypokit is to be used for episodes of severe hypoglycaemia (low blood sugar) in diabetic patients when the patient has become unconscious or are unable to ingest a source of sugar. It is therefore important that to have a functioning GlucaGen® HypoKit that can be used effectively.

### Further information

[www.novonordisk.com](http://www.novonordisk.com)

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Yours faithfully

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Medicines Inspector

Medicines Authority Distribution (if applicable): None