

6 September 2016

PATIENT INFORMATION LETTER

Important safety information for diabetes patients in possession of a GlucaGen® HypoKit

Novo Nordisk is recalling seven batches of GlucaGen® HypoKit in the United Kingdom. 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 of needles (0.006%) were detached from the syringe in certain batches of the GlucaGen® HypoKit. To protect patient safety, Novo Nordisk is recalling all products in the affected batches from wholesalers, pharmacies and patients in the United Kingdom.

The recalled GlucaGen® HypoKit batch numbers are:

Batch: FS6W939, Expiry: 05/2018

Batch: FS6X059, Expiry: 05/2018

Batch: FS6X196, Expiry: 09/2018

Batch: FS6X590, Expiry: 08/2018

Batch: FS6X717, Expiry: 08/2018

Batch: FS6X899, Expiry: 08/2018

Batch: FS6Y024, Expiry: 09/2018

The batch numbers are printed on the GlucaGen® HypoKit as indicated below in the red box (Figure 1).

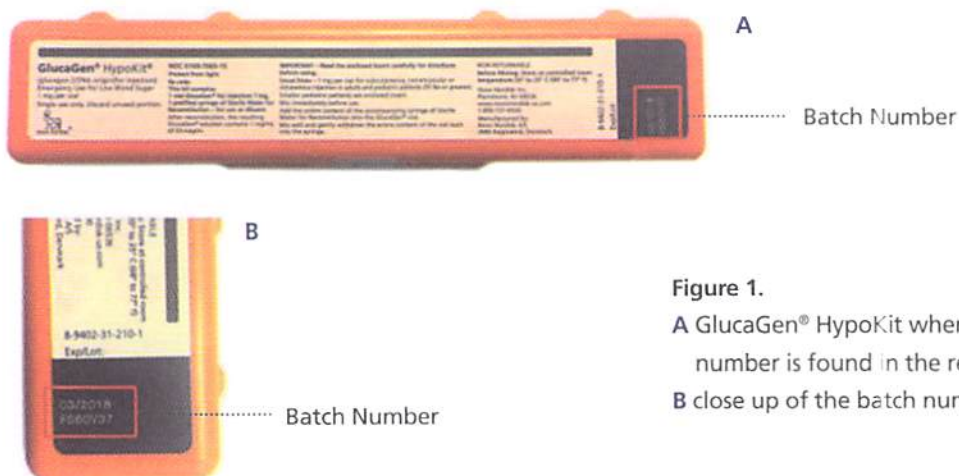


Figure 1.
A GlucaGen® HypoKit where the batch number is found in the red box,
B close up of the batch number.

What to do if you are in possession of a GlucaGen® HypoKit with one of the above-mentioned batch numbers:

Return your GlucaGen® HypoKit product with the above-mentioned batch numbers to your pharmacy. You will be given a free replacement GlucaGen® HypoKit when you return the product with one of the listed batch numbers.

GlucaGen® Hypokit is to be used for episodes of severe hypoglycaemia (low blood sugar) when you have become unconscious or are unable to ingest a source of sugar. It is therefore important that you have a functioning GlucaGen® HypoKit that can be used effectively. Please check the batch number on your GlucaGen® Hypokit and take action as recommended in this communication.

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

Yours sincerely,



Dr Rahul Kapur
Head of Medical Affairs
Novo Nordisk Ltd.

Further information

For further information on GlucaGen® HypoKit please contact Novo Nordisk's customer services on **0845 600 5055**, visit www.novonordisk.co.uk or write to Novo Nordisk at:

Novo Nordisk Ltd.
3 City Place
Beehive Ring Road
Gatwick
West Sussex
RH6 0PA

Please report any adverse drug events occurring during treatment with the GlucaGen® HypoKit to Novo Nordisk's customer services on 0845 600 5055.
Adverse events should also be reported via the Medicine and Healthcare products Regulatory Agency's (MHRA) Yellow Card Reporting Scheme: <http://yellowcard.mhra.gov.uk>