Wednesday 7th September 2016

URGENT MEDICINE RECALL

GlucaGen® HypoKit (glucagon (rys) as HCl 1 mg (1 IU) powder vial with 1 mL, pre-filled solvent syringe); AUST R 47105
Batch numbers: FS6X465, FS6X536, FS6X715 & FS6X891
Expiry dates: All of the above batches have a shelf life expiry of August 2017

Important safety information for pharmacies in possession of GlucaGen® HypoKit

Dear Pharmacist-in-Charge,

Novo Nordisk is recalling 4 batches of GlucaGen® HypoKit in Australia. GlucaGen® HypoKit is used for the 'Treatment of severe hypoglycaemic reactions which may occur in the management of diabetic patients receiving insulin or oral hypoglycaemic agents'. It is therefore important to have a functioning GlucaGen® HypoKit that can be used effectively.

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

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

Batch Number	Expiry date
FS6X465	31-Aug-2017
FS6X536	31-Aug-2017
FS6X715	31-Aug-2017
FS6X891	31-Aug-2017

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

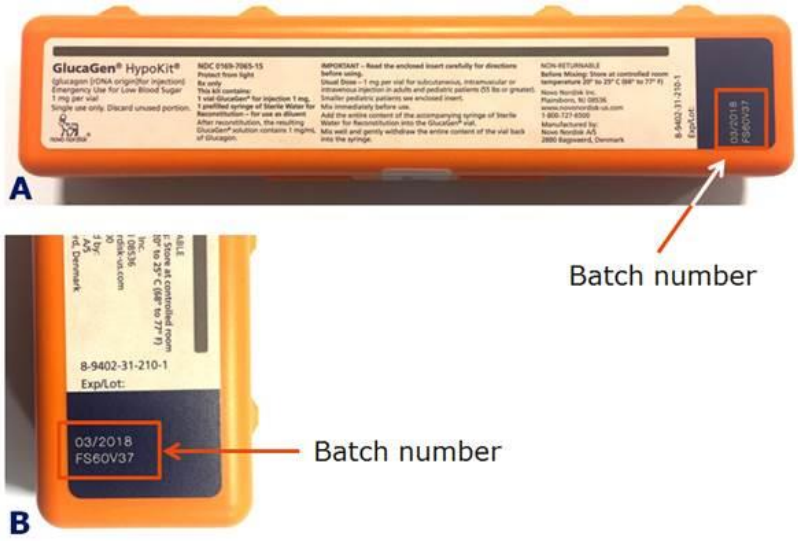

Figure 1. A) GlucaGen® HypoKit where the batch number is found in the red box, B) close up of the batch number

What to do if your pharmacy is in possession of a GlucaGen® HypoKit with one of the above-mentioned batch numbers

Please take the following action:

1. Please immediately quarantine all affected batches to prevent further distribution.
2. Please contact any patients you have supplied with a GlucaGen® HypoKit and ask them to check the batch numbers on any product in their possession. Ask them to return any affected batches to you as soon as possible for exchange. These batches of GlucaGen® HypoKit have been available to wholesalers since Feb 2016.

Replacement stock of an unaffected batch is available. We suggest you estimate your replacement needs and obtain this now from your usual supplier so that you can replace recalled stock as it is returned to you. However in the event that you do NOT have stock from unaffected batches when a patient presents, please direct the patient to retain their current GlucaGen® HypoKit from the affected batch until a replacement can be provided, as the likelihood of a detached needle is very low.

In order to conserve stock and reduce possible future shortage, please do not return or accept for replacement any other batches than those listed above. Any patient returning a kit from another batch can be reassured about the quality of their GlucaGen® HypoKit.

Note that medical practitioners will also be contacted and requested to follow up with patients they have supplied since February 2016 and will be asked to return any stock they hold from affected batches.

We have produced and enclosed a patient information leaflet you may find useful when explaining to patients the nature of the issue. You may wish to post this to customers you are unable to contact.

The recalled stock should be forwarded to the wholesaler from which the product was purchased. All returned stock will be credited on receipt by your wholesaler.

All recipients of this letter are requested to complete the accompanying Acknowledgement Form / Inventory of Returned Medicines **(including nil stock if applicable)** and return within 2 days of receipt by fax to (02) 8858 3697.

If you have any questions regarding this recall, please contact NovoCare® Customer Care Centre on 1800 668 626 for further information.

This action has been undertaken following consultation with the Therapeutic Goods Administration (TGA).

We sincerely regret the inconvenience caused by this action and assure you that Novo Nordisk takes this very seriously and has a rigorous quality assurance philosophy. Your support with this action is very much appreciated.

Yours sincerely,

Michala Fischer-Hansen
Managing Director
Novo Nordisk Australia & New Zealand
Further information:
NovoCare® Customer Care Centre
Phone: 1800 668 626
Email: aunrccc@novonordisk.com

ACKNOWLEDGEMENT FORM/
INVENTORY OF RETURNED MEDICINES

Please complete and fax this form to (02) 8858 3697 within 2 days of receipt.

Note: This form must be completed and returned even if no stock is held

Product	Batch No.	No. of packs
GlucaGen® HypoKit	**FS6X465**	
GlucaGen® HypoKit	**FS6X536**	
GlucaGen® HypoKit	**FS6X715**	
GlucaGen® HypoKit	**FS6X891**	

IF NO STOCK IS HELD, TICK THIS BOX ☐

Signature:

Name:

Position:

Pharmacy name and address:

Date:

PATIENT INFORMATION LETTER

Wednesday 7th September 2016

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

Novo Nordisk Pharmaceuticals Pty Ltd is recalling 4 batches of GlucaGen® HypoKit in Australia. The GlucaGen® HypoKit is indicated for the 'treatment of severe hypoglycaemic reactions which may occur in the management of diabetic patients receiving insulin or oral hypoglycaemic agents'.

Novo Nordisk conducted an investigation showing a small number of needles (0.006 %) were detached from the pre-filled syringe supplied 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 Australia.

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

Batch no.	Expiry date
FS6X465	31-Aug-2017
FS6X536	31-Aug-2017
FS6X715	31-Aug-2017
FS6X891	31-Aug-2017

The batch numbers are printed on the GlucaGen® HypoKit as indicated below in the red box

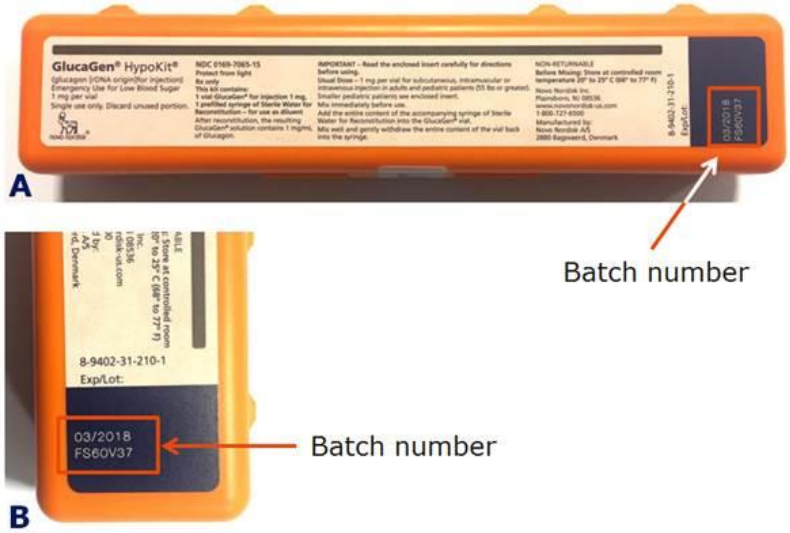

Figure 1. A) GlucaGen® HypoKit where the batch number is found in the red box, B) close-up of the batch number

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 either immediately (if pharmacy stock is present) or within a few days (if pharmacy

needs to await re-supply). If you do not receive a replacement immediately, retain your GlucaGen® HypoKit until the replacement can be provided, as the likelihood of a detached needle is very low.

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.

Importantly, 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.

If you have any questions regarding this recall, please contact NovoCare® Customer Care Centre on 1800 668 626 for further information.

This action has been undertaken following consultation with the Therapeutic Goods Administration (TGA).

We sincerely regret the inconvenience caused by this action and assure you that Novo Nordisk takes this very seriously and has a rigorous quality assurance philosophy.

Yours sincerely,

Michala Fischer-Hansen
Managing Director
Novo Nordisk Australia & New Zealand

Further information:
NovoCare® Customer Care Centre
Phone: 1800 668 626
Email: aunrccc@novonordisk.com
www.novonordisk.com.au