

Public Health Link

From the Chief Medical Officer for Wales

Distribution:	As Appendix 1
From:	Andrew Evans, Directorate of Health Policy
Date:	10 July 2018
Reference:	CEM/CPhA/2018/12
Category:	Class 2: Action within 48 hours
Title:	Drug Alert Class 2, Action Within 48 Hours, Novo Nordisk, Fiasp Flextouch 100 Units/MI Solution For Injection Pre-Filled Pen
What is this about:	<p>Full details are set out below.</p>
Why has it been sent:	For your information and to pass on to Colleagues

Issue:

One batch of the above product is being recalled as a precautionary measure due to the presence of particles in a small number of samples.

Full details of the drug alert are included in the attached PDF file. Please forward to listed recipients. This information is also published on the MHRA website <https://www.gov.uk/drug-device-alerts>

To: NHS Wales Shared Services Partnership to forward to:

All General practitioners - please ensure this message is seen by all practice nurses and non-principals working in your practice and retain a copy in your 'locum information pack'.

All Community Pharmacists

Deputising services

HB Chief Pharmacists

HB Prescribing Advisers

Independent/Private clinics and Hospitals and Hospices throughout Wales

To: Chief Executives of Health Boards

To: Medical Directors of Health Boards

To: Nurse Directors Health Boards

To: Directors of Public Health

To: Hospital Principals and Chief Pharmacists to action as per alert

cc: Public Health Wales

Consultants in Pharmaceutical Public Health

Chief Executives, NHS Trusts

Principal Pharmacist Welsh Quality Control

Principal Pharmacist Continuing Care Services

Principal Pharmacist Welsh Medicines Information Centre

CSSIW

NHS Direct



DRUG ALERT

CLASS 2 MEDICINES RECALL

Action Within 48 Hours
Pharmacy Level Recall

Date: 9 July 2018

EL (18) A/12

Our Ref: MDR 065-06/18

Dear Healthcare Professional,

Novo Nordisk

Fiasp FlexTouch 100 units/mL solution for injection pre-filled pen EU/ 1/16/1160/00

(Insulin Aspart)

Batch Number	Expiry Date	Pack Size	First Distributed
HP50949	30 November 2019	5	22 March 2018

Brief description of the problem

Novo Nordisk is recalling one batch as a precautionary measure due to the presence of particles in a small number of samples.

Advice for healthcare professionals

Stop dispensing the batch listed above. Return all remaining stock of this batch to your supplier using the supplier's approved process. Novo Nordisk will also be circulating the letter attached to pharmacies.

This is a pharmacy level recall so there is no requirement to contact patients. If you receive queries about this issue from patients, however, please advise them to follow the advice given in the patient information leaflet regarding checking their insulin before use:

'Check that the insulin in your pen is clear and colourless. Look through the insulin window. If the insulin looks cloudy, do not use the pen.'

Wholesalers

Quarantine any remaining stock of this batch and return to the original supplier for credit.

Company contact information

Medical enquiries

Novo Nordisk Customer Care +44 (0) 845 600 5055

Email: customercare@novonordisk.com



**Medicines & Healthcare products
Regulatory Agency**



Stock enquiries

Novo Nordisk Customer Care +44 (0) 845 600 5055

Email: customercare@novonordisk.com

Recipients of this Drug Alert should bring it to the attention of relevant contacts by copy of this letter. NHS regional teams are asked to forward this to relevant clinics, general practitioners, hospitals and community pharmacists.

Yours faithfully

**Defective Medicines Report Centre
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