Medical Device Alert

Ref: MDA/2013/071 Issued: 05 September 2013 at 14:00

Device

Growth hormone pens.

NordiPen® used with 5mg and 10mg Norditropin® SimpleXx® ('somatropin') and NordiPenMate®.

Manufactured by Novo Nordisk.

Problem

There is a risk of under-dosing as the device may not fully screw together.

A change to the metal screw threads of the mechanical section may cause the user to experience increased resistance during assembly. Patients may assume the pen is correctly assembled when it is not, and therefore not receive the correct dose.

The manufacturer issued Field Safety Notices (FSNs) in July and September 2013 advising users of the problem and how to assemble the devices; however, they have received insufficient reconciliation data.

Action

Ensure that all staff who are responsible for managing patients with these devices are aware of the assembly instructions in the FSNs.

Identify all patients who use these devices and ensure that they receive the patient letter attached to either FSN explaining how to assemble the devices.

Return the confirmation of receipt form in the FSNs to the manufacturer.

Action by

All medical and nursing staff who use and supply these devices.

CAS deadlines

Action underway: 19 September 2013

Action complete: 03 October 2013

Note: These deadlines are for systems to be in place to distribute the information to patients.

Contact

Manufacturer
Customer Service
Novo Nordisk Limited

Tel: 0845 600 5055

Email: NNGB-Safety@novonordisk.com

Device

NordiPen®

NordiPenMate®

All devices with a lot number beginning with A or B.

Lot numbers beginning with a 'C' are referred to in the July 2013 FSN but they were never distributed by the manufacturer.

How to find the lot number

The lot number is located on the mechanical section below the push button and can be exposed by turning the dose selector clockwise.

The lot number in the example image begins with 'B'.

Distribution

This MDA has been sent to:

- Care Quality Commission (CQC) (headquarters) for information
- Clinical commissioning groups (CCGs)
- HSC trusts in Northern Ireland (chief executives)
- Local authorities in Scotland (equipment co-ordinators)
- NHS boards and trusts in Wales (chief executives)
- NHS boards in Scotland (equipment co-ordinators)
- NHS England area teams
- NHS trusts in England (chief executives)

Onward distribution

Please bring this notice to the attention of relevant employees in your establishment.
Below is a suggested list of recipients.

Trusts

CAS and SABS (NI) liaison officers for onward distribution to all relevant staff including:

- Chief pharmacists
- Clinical governance leads
- Community children's nurses
- Community hospitals
- Community nurses
- District nurses
- Endocrinology units
- Endocrinology, directors of
- Health and safety managers
- Health visitors

- Hospital at home units
- Hospital pharmacies
- Hospital pharmacists
- Medical directors
- Nursing executive directors
- Paediatric medicine, directors of
- Paediatric nurse specialists
- Pharmacists
- Risk managers

NHS England area teams

CAS liaison officers for onward distribution to all relevant staff including:

- Community pharmacists
- General practitioners
- Practice managers
- Practice nurses

Independent distribution

Establishments registered with the Care Quality Commission (CQC) (England only)

This alert should be read by:

- Clinics
- Hospitals in the independent sector
- Independent treatment centres
- Private medical practitioners

Please note: CQC and OFSTED do not distribute these alerts. Independent healthcare providers and social care providers can sign up to receive MDAs directly from the Department of Health's Central Alerting System (CAS) by sending an email to: safetyalerts@dh.gsi.gov.uk and requesting this facility.

Contacts

Manufacturer
Novo Nordisk Limited
Broadfield Park
Brighton Road, Crawley
West Sussex RH11 9RT

Tel: 0845 600 5055
Fax: 01293 611 819

Email: NNGB-Safety@novonordisk.com

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2013/071** or **2013/006/025/081/021**

Technical aspects
Claire Dunne and Ainsley Wickens
Medicines & Healthcare Products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ

Tel: 020 3080 7162 / 7273
Fax: 020 8754 3965

Email: claire.dunne@mhra.gsi.gov.uk
ainsley.wickens@mhra.gsi.gov.uk

Clinical aspects
Mark Grumbridge
Medicines & Healthcare Products Regulatory Agency
Floor 4, 151 Buckingham Palace Road, London SW1W 9SZ

Tel: 020 3080 7128
Fax: 020 8754 3965

Email: mark.grumbridge@mhra.gsi.gov.uk

How to report adverse incidents

Please report via our website http://www.mhra.gov.uk

Further information about **CAS** can be found at https://www.cas.dh.gov.uk/Home.aspx

Northern Ireland

Alerts in Northern Ireland will continue to be distributed via the NI SABS system.

Enquiries and adverse incident reports in Northern Ireland should be addressed to:

Northern Ireland Adverse Incident Centre
Health Estates Investment Group, Room 17, Annex 6, Castle Buildings, Stormont Estate, Dundonald BT4 3SQ

Tel: 02890 523 704 Fax: 02890 523 900 Email: NIAIC@dhsspsni.gov.uk

http://www.dhsspsni.gov.uk/index/hea/niaic.htm

How to report adverse incidents in Northern Ireland

Please report directly to NIAIC, further information can be found on our website http://www.dhsspsni.gov.uk/niaic

Further information about **SABS** can be found at http://sabs.dhsspsni.gov.uk/

Scotland

All requests regarding return, replacement or modification of the devices mentioned in this alert should be directed to the relevant supplier or manufacturer.

Other enquiries and adverse incident reports in Scotland should be addressed to:

Incident Reporting and Investigation Centre
NHS National Services Scotland, Gyle Square, 1 South Gyle Crescent, Edinburgh EH12 9EB

Tel: 0131 275 7575 Fax: 0131 314 0722 Email: nss.iric@nhs.net

http://www.hfs.scot.nhs.uk/online-services/incident-reporting-and-investigation-centre-iric/

Wales

Enquiries in Wales should be addressed to:

Improving Patient Safety Team
Medical Directorate, Welsh Government, Cathays Park, Cardiff CF10 3NQ

Tel: 029 2082 3922 Email: Haz-Aic@wales.gsi.gov.uk

MHRA is an executive agency of the Department of Health
© Crown Copyright 2013
Addressees may take copies for distribution within their own organisations