HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Safety Notice

Medical Devices

Autopen Classic
Autopen 24
Densupen
Autopen 3ml for Teriparatide

Priority 2 – Warning

HPRA Safety Notice: SN2014(47) **Issue Date: 19 December 2014**

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
Owen Mumford Ltd	V22838

ISSUE

The Health Products Regulatory Authority (HPRA) has been advised of the recall of certain lots of a range of injection pens due to a potential mechanical fault.

The manufacturer has advised that the fault presents itself in the following ways:-

A) A dose may be dialled-up but the dose selector will not hold that dose and instead will spin straight back to zero
B) The dose may be dialled-up and the dose selector will hold the dose momentarily, but will then spin straight back to zero

As a result of the fault, the following scenarios may arise:-

A) The patient will not be able to use the pen, no dose can be delivered
B) The patient may only receive a partial dose and will not know how much has been delivered

There is a risk of no dose or under-dose of Insulin or Teriparatide

- An under-dose of Insulin may lead to hyperglycaemia
- There is no possibility of over-dose

ACTION OR RECOMMENDATIONS

The HPRA advises users to:

1. Refer to the attached Field Safety Notice (FSN) for details of the affected devices
2. Determine if your device is affected by this issue
3. Stop using the affected devices
4. Consult your healthcare professional to arrange for a suitable alternative device to continue your treatment
5. Report any concerns regarding these devices to the manufacturer and to the HPRA

The HPRA advises Healthcare professionals looking after people who use these devices to:

1. Refer to the attached FSN for details of the affected devices
2. Ensure that all patients are informed of this issue and are advised to stop using these devices
3. Ensure that patients are provided with a suitable alternative device to continue treatment
4. Ensure relevant personnel receive a copy of this Safety Notice and the FSN
5. Forward the FSN and Safety Notice to any other persons/organisations where these devices have been transferred
6. Report any concerns regarding these devices to the manufacturer and the HPRA

TARGET GROUPS

All Hospital staff	Healthcare professionals managing patients who use these devices
All Nursing Home staff	Nursing Managers
Carers	Purchasing / Procurement / Material Managers
Diabetic Clinics / outpatients	Risk Managers
Diabetic nurse specialists	General Practitioners
Diabetic departments	Community Pharmacists
Endocrinology units	General public
Endocrinology Consultants	
Hospital Pharmacists	

BACKGROUND

The manufacturer has issued a FSN advising of the issue – see attached. The FSN provided is focused on the UK market, however the HPRA has learned that these devices may also have been supplied to the Irish market. The FSN provides details of the lots that are potentially affected. Please note that not all lots of these devices are affected.

MANUFACTURER / DISTRIBUTOR CONTACT INFORMATION

Enquiries to the **manufacturer** should be addressed to:

Owen Mumford Ltd
Brook Hill
Woodstock
Oxon
OX20 1TU

Telephone: +44 1993 812021
Fax: +44 1993 813466
Email: Technical.Support@owenmumford.co.uk

HPRA CONTACT INFORMATION

All **adverse incidents** relating to a medical device should be reported to:

Health Products Regulatory Authority
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2

Telephone: +353-1-6764971
Fax: +353-1-6344033
E-mail: devicesafety@hpra.ie
Website: www.hpra.ie