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Use of Luer adaptors with Needle-Free Connection Systems and prefilled Syringes

IMB Safety Notice: SN2013(01)

Circulation Date: 5th March 2013

MANUFACTURER/SUPPLIER

Exempt Medicinal Products (current supply): Manufactured by Aurum Pharmaceuticals Ltd, UK and Supplied by Fannin Limited, Dublin

Authorised Medicinal Products (future supply): Manufactured by International Medication Systems and supplied by UCB Pharma

TARGET GROUPS

Hospital Managers / CEOs
Risk Managers
Clinical Directors
Purchasing Managers
Supplies Managers
Nursing Managers
Hospital personnel
Private Medical Practitioners
Hospital Pharmacists
Resuscitation Officers
Ambulance Services

Please bring this safety notice to the attention of all who need to be aware of it.

ISSUE

Emergency Medicinal Products supplied in BD Hypak Pre-Filled Syringes are not compatible with certain needle-free connection systems, without the use of an adaptor.

BACKGROUND

Since November 2012, emergency medications such as adrenaline, atropine and amiodarone have been supplied to Irish hospitals in a new pre-filled syringe, which has replaced the Minijet presentation. Healthcare professionals have experienced some difficulty in preparing / administering these products to patients through certain needle-free connection systems. Reports have been received by the Irish Medicines Board (IMB) of blocked syringe bores, which made it impossible to administer a dose of potentially life-saving medication.

S A F E T Y NOTICE

The design of this new BD Hypak PRTC syringe renders it incompatible with some needle-free connection systems.

The IMB is issuing this Safety Notice to ensure all users are aware of the issue.

ACTION OR RECOMMENDATIONS

1. MicroCLAVE Connection Systems

When using BD Hypak PRTC Syringes with MicroCLAVE Connection Systems, **011 CS-25 Adaptors**, manufactured by ICU Medical, should be used. Failure to use an adaptor can cause the connector tip to break and lodge in the syringe tip.

Every delivery by Fannin of these pre-filled syringes is accompanied by the required number of **011 CS-25 Adaptors**. These adaptors are CE marked medical devices.

Extra adaptors are available from Fannin at the contact details below, as are instruction posters for distribution within your hospital. Please find a copy of the instructions poster attached.

2. Vygon Bionector 2 Connection System

When using BD Hypak PRTC Syringes with the Vygon Bionector 2 Connection System, **Vygon ATP431 Adaptors** should be used. Vygon supplies these adaptors on request. These adaptors are CE marked medical devices.

3. Other Connection Systems

There may also be other brands or products on the market which come in the Hypak PRTC syringe. Whichever needle-free system is being used, it is of critical importance to ensure that the necessary measures are in place, to allow safe and quick administration of these important medications. Information is available on the Martindale website, which confirms compatibility of the Hypak PRTC Prefilled Syringe with needle-free connection systems. Please find a copy of the Martindale Compatibility Statement attached.

ENQUIRIES

Enquiries should be addressed to:

Fannin Limited
Marie Walsh
Senior Regulatory Officer, Fannin Limited
Telephone: 01-2907183
E-mail: medinfo@fannin.eu

UCB Pharma Ltd.
208 Bath Road
Slough
Berkshire SL1 3WEC
Telephone: Med Info 0044-1753-534655
Adverse Events 0044-1753-447690

E-mail: medicalinformationuk@ucb.com

S A F E T Y

NOTICE

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

Irish Medicines Board
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2

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