

Caution-In-Use Notification

Incompatibility of Various Glass Pre-filled Syringe Products with Certain Needle-free Connection Systems

Product Name	MAH	Authorisation No.*
Adrenaline (Epinephrine) Injection 1:10,000	Aurum Pharmaceuticals	PL12064/0006 (UK)
Adrenaline (Epinephrine) Injection 1:1,000	Aurum Pharmaceuticals	PL12064/0058 (UK)
Atropine Sulphate Injection 600mcg/ml	Aurum Pharmaceuticals	PL12064/0040 (UK)
Amiodarone Injection 30mg/ml	Aurum Pharmaceuticals	PL12064/0047 (UK)
Calcium Chloride Intravenous Infusion 10% w/v	Aurum Pharmaceuticals	PL12064/0020 (UK)
Other Glass Pre-filled Syringes are potentially implicated – please check with your supplier(s) for compatibility with needle-free connection systems used in your hospital.		

* The above listed products are supplied to the Irish market as Exempt Medicinal Products

Dear Healthcare Professional,

Please read carefully the below information, relating to medicinal products contained in glass pre-filled syringes and the requirement to use syringe adapters with certain needle-free connection systems.

Background / Problem Statement

Usage of glass pre-filled syringes with certain needle-free systems, without a syringe adapter can cause blockage of the fluid path.

In 2007, the presentation of the Aurum Pharmaceuticals emergency products listed above, changed to a glass pre-filled syringe (Hypak), manufactured by BD. Since this change, a number of reports has been received from Irish hospitals of blocked syringe bores, identified during administration of those products through a needle-free intravenous injection system. Blockage of the syringe makes administration of these (potentially life-saving) products impossible and can have life-threatening consequences for the patient.

In each case of blockage investigated by the manufacturer of the above products, Martindale Pharma, it was confirmed that the blockage consisted of extraneous material and that, when it was analysed, the material closely matched that of which the needle-free system is composed, in composition and dimensions.

Syringes manufactured from glass are required to have a thick tip and a narrow bore, which does not allow the internal cannula of certain needle-free systems to pass through the bore and allow flow of liquid. To use such systems, a **syringe adapter** is required. The cause of the blockages is thus attributed to attachment of the syringe **without prior attachment of an adapter**.

Impacted Medicinal Products

Medicinal Products contained in the BD Hypak Pre-filled Syringes include, but may not be limited to, the above-listed Aurum Pharmaceuticals products. **Although the HPRA is not aware of reports implicating products other than those listed above, BD Hypak and other glass pre-filled syringes may also be included in other unauthorised and authorised medicinal products.**

Compatibility of these products with needle-free systems in use in your hospital should be checked with the MAH and/or supplier.

The above Aurum Pharmaceuticals products are manufactured by Martindale for the UK market and have been distributed in Ireland as Exempt (unlicensed) Medicinal Products, since approximately 2007.

Needle-free Systems Requiring an Adapter during use with above-referenced products

Needle-free Connection Systems which are incompatible with the above-referenced products and therefore require the use of a syringe adapter include the following:

- **Clave** and **MicroClave** systems from ICU Medical, supplied by Fannin Healthcare
- **Bionector** from Vygon, supplied by Vygon
- **Neutraclear – Cair LLG** from BD, supplied by Aquilant Medical

These needle-free systems all contain a cannula at the connection point, which may block the syringe fluid path. Please note that there are more needle-free connection systems on the market, some of which may also be incompatible with the BD Hypak syringe.

Please check with your supplier as to whether or not the needle-free systems in use in your hospital are compatible.

Available Adapters

Adapters, which can be used with the above needle-free connection systems, are available, as follows:

- **ICU Medical CS-25 Adapter**, available free of charge from Fannin Healthcare, the main supplier of the Aurum products in Ireland and also supplied with the Aurum range of pre-filled syringes, above. Note: If you receive Aurum or other incompatible pre-filled syringes from a supplier other than Fannin, you may not automatically receive adapters from that supplier, so please contact your supplier or Fannin to arrange supply.
- **Vygon 853.02 Anti-Syphon Adapter**, available free of charge from Vygon.
- **Back Check Valve Adapter**, available free of charge from Aquilant Medical

Please ensure that the adapter(s) in use in your hospital are compatible with the relevant needle-free system. Availability of adapters and awareness of emergency staff at the point of administration are critical for ensuring they are used where necessary. Good practice methods of ensuring correct use of an adapter with the syringe include the following:

- Availability of the adapters in the pharmacy to dispense one with each single PFS along with Pharmacy Alert stickers if available.
- Storage of adapters in crash kits, next to the pre-filled syringes
- Attachment of adapter to pre-filled syringe container (plastic box or carton)
- Location of training posters (see 'Communication and Training Materials' below) with the pre-filled syringes

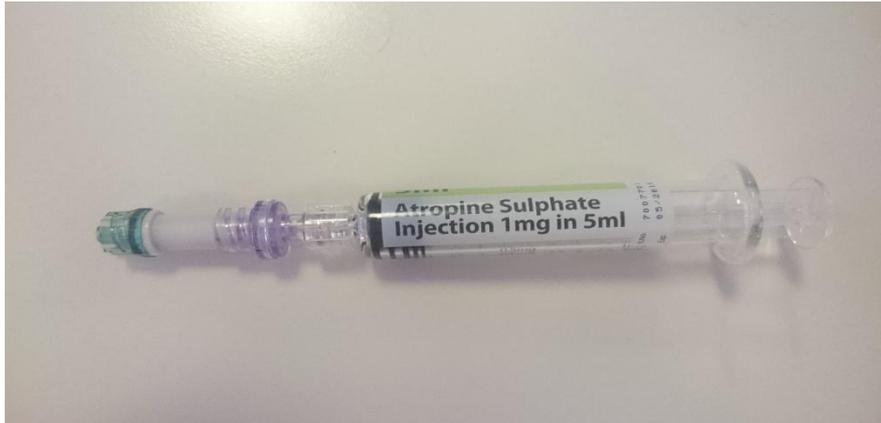


Figure Showing Pre-filled Syringe, with adapter (Vygon 853.02 Anti-syphon) and attached to Needle-free connection tip

Communication and Training Materials

Training materials on how to use the Aurum pre-filled syringes along with needle-free systems are available from Fannin Limited. Once the training materials have been obtained, it is imperative that the following steps are taken, to ensure their incorporation to the relevant areas of your hospital:

1. All relevant staff should be familiarised with the products, incompatible needle-free systems and the use, where necessary, of syringe adapters. Particularly important areas include resuscitation, emergency departments, ICU, CCU, pharmacy dispensing.
2. Training materials should be displayed in prominent areas in your hospital, to promote use of syringe adapters where necessary.
3. Periodic training, as well as training of new staff, should be carried out, to ensure effective implementation of the materials provided and appropriate use of the pre-filled syringe products.
4. Adapters should be provided with every single pre-filled syringe dispensed and included with the pre-filled syringes in emergency storage.

Staff are encouraged to contact supplier(s) of the needle-free connection systems, to ascertain compatibility with glass pre-filled syringes and arrange provision of adapters and training materials, as necessary.

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Please ensure that the information contained within this notification is brought to the attention of relevant healthcare professionals within your hospital / facility.

If you have any queries on the use of the above-referenced products or systems in your hospital or healthcare facility, please do not hesitate to contact qualitydefects@hpra.ie or the company / companies listed above, for further information.

Yours sincerely,

Rob Smyth

Market Compliance Scientific Officer