



Medicines & Healthcare products Regulatory Agency

Ethypharm Aurum pre-filled syringes are incompatible with some manufactured needle-free connectors: risk of delay in administering potentially lifesaving medication (DSI/2023/008)

Product Details

Devices Name: Needle free connectors (NFCs)
Manufactured by: Various manufacturers

Devices Name: Aurum pre-filled syringes
Manufactured by:
Macarthy's Laboratories (Trading as Martindale Pharma, an Ethypharm Group Company,
Marketing authorisation holder: Aurum Pharmaceuticals Ltd)

Summary

Attaching an incompatible needle-free connector (NFC) to an Ethypharm Aurum pre-filled syringe can block the syringe and prevent delivery of potentially lifesaving medicine. Only compatible NFCs should be used with pre-filled syringes from the Aurum range.

Risk of Ethypharm Aurum syringe blockage during administration due to incompatible needle-free connectors (NFCs)

Incompatibility between some NFCs and Luer tips of the Aurum range pre-filled syringes can lead to delayed delivery of medication. The MHRA issued a Medical Device Alert ([MDA/2011/068](#)) in June 2011 to raise awareness of this safety issue.

The MHRA continues to receive reports of damage to the NFC and/or to the Aurum pre-filled syringe where incompatible devices were connected. In some cases, fragments from the NFC broke off and blocked the syringe outflow. Such damage has resulted in a delay in administering emergency medication.

Healthcare professionals are requested to ensure that only compatible NFCs are used with the Aurum pre-filled syringes.

Actions

Actions for healthcare providers

- refer to the list of compatible needle-free connectors (NFCs) for each pre-filled syringe in the Aurum range, which is available under the listing for each pre-filled syringe on the [electronic medicines compendium \(eMC\)](#) website. The lists of compatible NFCs are identical for all Ethypharm Aurum pre-filled syringes. See Product Information via the links below:
 - [Adrenaline \(Epinephrine\) Injection 1:10,000 \(glass prefilled syringe\)](#)
 - [Amiodarone 30mg/ml Solution for injection/infusion in pre-filled syringe](#)
 - [Calcium Chloride Intravenous Infusion, 10% w/v pre-filled syringe](#)
 - [Naloxone Hydrochloride 1mg/ml Solution for Injection in a pre-filled syringe](#)
- procure compatible NFCs for use with the Aurum pre-filled syringes
- ensure that the specification of NFCs which are integral to vascular access devices are checked for compatibility before procuring or putting into use in areas where Aurum pre-filled syringes may be used
- refer to the compatibility warnings and Luer size limits in the instructions for use of the NFC
- train administration and emergency teams to ensure procedures are in place to determine the compatibility of NFCs in use with the Aurum pre-filled syringes contained in emergency drug boxes and on emergency trolleys
- ensure sufficient supply of product in emergency drug boxes and on emergency trolleys to maintain care provision in case of maladministration
- co-locate compatible NFCs with the Aurum pre-filled syringes where it is stored for use (for example, emergency trolleys or kits).
- where possible, dispense compatible NFCs with the Aurum pre-filled syringes
- consider displaying [this poster](#) showing compatible NFCs for use with Aurum pre-filled syringes in clinical areas containing the emergency drug boxes and resuscitation training rooms. Hard copies can be obtained from the manufacturer - phone number: 01277 266 600 (select option 2), email: medinfo@ethypharm.com
- if trusts are unable to procure compatible NFCs, it is recommended that they complete a risk assessment as per local clinical protocol, and refer to the links on the eMC website above to procure specified adaptors for use with the Aurum pre-filled syringes
- when specified adaptors as outlined above are procured, ensure that they are stored with the Aurum pre-filled syringes in the location where they will be used (for example, emergency trolleys or kits)

Actions for healthcare professionals

- ensure compatible needle free connectors (NFCs) are used with the Ethypharm Aurum pre-filled syringes
- refer to the list of compatible NFCs for each pre-filled syringe in the Aurum range, which is available under the listing for each pre-filled syringe on the EMC website. The list of

compatible connectors is the same for all Aurum pre-filled syringes. See 'product information' on links below:

- [Adrenaline \(Epinephrine\) Injection 1:10,000 \(glass prefilled syringe\)](#)
- [Amiodarone 30mg/ml Solution for injection/infusion in pre-filled syringe](#)
- [Calcium Chloride Intravenous Infusion, 10% w/v pre-filled syringe](#)
- [Naloxone Hydrochloride 1mg/ml Solution for Injection in a pre-filled syringe](#)
- refer to the compatibility warnings and Luer size limits in the instructions for use of the NFC
- refer to [this poster](#) for compatible NFCs for use with Aurum pre-filled syringes. Hard copies can be obtained from the manufacturer - phone number: 01277 266 600 (select option 2), email: medinfo@ethypharm.com
- if the NFC is not compatible with the Aurum pre-filled syringe:
 - seek an alternative compatible NFC
 - if no compatible NFC is available, complete a risk assessment as per local clinical protocol and refer to the eMC website links above for specified adaptors. Remove adaptors immediately after the Aurum pre-filled syringe has been used to reduce the risk of infection and/or air embolus.

There are specific reporting arrangements for healthcare professionals to follow in each of the devolved administrations. Healthcare professionals should report incidents:

- in England and Wales to the [Yellow Card scheme](#) or via the Yellow Card app
- in Scotland to [Incident Reporting & Investigation Centre \(IRIC\)](#) and their local incident recording system
- in Northern Ireland to the [Northern Ireland Adverse Incident Centre](#) and their local incident recording system

Additional information

Manufacturer's connector compatibility chart:



Aurum connector
compatibility chart Au

Stakeholder engagement

National Infusion and Vascular Access Society (NIVAS)

NHS England National Patient Safety Team

NHS Wales

NHS National Services Scotland, Incident Reporting and Investigation Centre (IRIC)

Northern Ireland Adverse Incident Centre (NIAIC)

Health and Social Care, Northern Ireland

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