

MHRA Device Safety Information

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Ethypharm Aurum pre-filled syringes are incompatible with some manufactured needle-free connectors: risk of delay in administering potentially lifesaving medication

This is a copy of web content published by the Medicines & Healthcare products Regulatory Agency on 22 August 2023. The original webpage can be accessed [here](#).

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.

Action

Actions for healthcare providers

1. 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:
 - a. [Adrenaline \(Epinephrine\) Injection 1:10,000 \(glass prefilled syringe\)](#)
 - b. [Amiodarone 30mg/ml Solution for injection/infusion in pre-filled syringe](#)
 - c. [Calcium Chloride Intravenous Infusion, 10% w/v pre-filled syringe](#)
 - d. [Naloxone Hydrochloride 1mg/ml Solution for Injection in a pre-filled syringe](#)
2. Procure compatible NFCs for use with the Aurum pre-filled syringes
3. 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
4. Refer to the compatibility warnings and Luer size limits in the instructions for use of the NFC
5. 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
6. Ensure sufficient supply of product in emergency drug boxes and on emergency trolleys to maintain care provision in case of maladministration
7. Co-locate compatible NFCs with the Aurum pre-filled syringes where it is stored for use (for example, emergency trolleys or kits)
8. Where possible, dispense compatible NFCs with the Aurum pre-filled syringes
9. Consider displaying the [Aurum connector compatibility chart](#) which shows 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
10. If compatible NFCs cannot be procured, it is recommended to complete a risk assessment as per local clinical protocol, and refer to the links on the [eMC website](#) to procure specified adaptors for use with the Aurum pre-filled syringes

11. 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

1. Ensure compatible needle free connectors (NFCs) are used with the Ethypharm Aurum pre-filled syringes
2. 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 via the links below:
 - a. [Adrenaline \(Epinephrine\) Injection 1:10,000 \(glass prefilled syringe\)](#)
 - b. [Amiodarone 30mg/ml Solution for injection/infusion in pre-filled syringe](#)
 - c. [Calcium Chloride Intravenous Infusion, 10% w/v pre-filled syringe](#)
 - d. [Naloxone Hydrochloride 1mg/ml Solution for Injection in a pre-filled syringe](#)
3. Refer to the compatibility warnings and Luer size limits in the instructions for use of the NFC
4. Refer to [Aurum connector compatibility chart](#) 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
5. If the NFC is not compatible with the Aurum pre-filled syringe:
 - a. seek an alternative compatible NFC
 - b. 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.
 - c. **Remove adaptors immediately after the Aurum pre-filled syringe has been used to reduce the risk of infection and/or air embolus**

Equipment details

Device Name:	Needle free connectors (NFCs)
Manufactured by:	Various manufacturers
Devices Name:	Aurum pre-filled syringes
Manufactured by:	Macarthys Laboratories (Trading as Martindale Pharma, an Ethypharm Group Company, Marketing authorisation holder: Aurum Pharmaceuticals Ltd)

Background

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](#) 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.

Additional information

[Aurum connector compatibility chart](#)

Suggested onward distribution

Anaesthetics	Intensive Therapy Units	Resuscitation Teams
Coronary Care Units	Maternity	Special Care Baby Units
Emergency Department	Medical Admissions	Wards
General Dental Practitioners	Nursing	Ambulance Services
General Medical Practitioners	Operating Departments	Health & Safety
Health Centres	Practice Nurses	Risk Management

Enquiries

Enquiries and adverse incident reports should be addressed to:

Incident Reporting & Investigation Centre (IRIC)

NHS National Services Scotland

Tel: 0131 275 7575 Email: nss.irc@nhs.scot

Accessibility: Please contact us using the above details if you are blind or have a sight impairment and would like to request this alert in a more suitable format.

IRIC remit: general information about adverse incidents, safety alerts and IRIC's role can be found in [CEL 43 \(2009\)](#), *Safety of Health, Social Care, Estates and Facilities Equipment: NHS Board and Local Authority Responsibilities*, issued 30 October 2009.

Report an incident: Information on [how to report an adverse incident](#)

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