

## Direct Healthcare Professional Communication

1 July 2025

### **Products: the Aurum range of 10ml Pre-filled syringes**

Adrenaline (Epinephrine) Injection 1:10,000 glass prefilled syringe (PL 12064/0006)

Amiodarone 30mg/ml Solution for injection/infusion in pre-filled syringe (PL 12064/0047)

Calcium Chloride Intravenous Infusion, 10% w/v pre-filled syringe (PL 12064/0020)

### **Change of established syringe barrel to new 10ml *CONNECT* syringe barrel. New syringe barrel will have a wider internal channel and fixed Luer lock adapter.**

Dear Healthcare Professional,

Aurum Pharmaceuticals Limited (an Ethypharm Group company) in agreement with the MHRA would like to inform you of the following:

#### **Summary**

- A new **10 ml *CONNECT*** syringe glass barrel has been introduced to the Aurum Range of Prefilled Syringes.
- The new **10ml *CONNECT*** syringe barrel has a wider internal channel and fixed Luer lock adapter.
- This change is being made to increase the number of Needle Free Connectors (NFCs) that are compatible with the Aurum Range of 10ml Prefilled Syringes.
- Attaching an incompatible NFC to an Aurum pre-filled syringe may block the syringe and potentially delay the delivery of a lifesaving medicine.
- The Aurum **CONNECT** 10ml syringes will be launched from July 2025. Adrenaline 1 in 10,000 will launch first, with amiodarone and calcium chloride to follow before the end of September 2025.
- Both barrel types will be on the market for an extended period due to the long shelf life of the pre-filled syringe.
- To differentiate between both barrels, clear visual differences in the packaging will be implemented:
  - Text: Updated layout with the word "**CONNECT**."
  - Icon: "Twist to open" icon on **CONNECT** packaging.
  - Colour: Green with white stripes box closure label on **CONNECT** packaging (previously plain white or labelled 'tamper').

#### Current Packaging



#### New CONNECT Packaging



- In addition, the new **CONNECT** barrel products will have new product codes.
- Only compatible NFCs should be used with the Aurum range of pre-filled syringes.

### Background on the safety concern

The Aurum range of pre-filled syringes are critical care products used in life threatening situations. Use of incompatible NFCs with an Aurum pre-filled syringe may block the syringe, potentially delaying the delivery of an emergency medicine.

This DHPC is being disseminated to communicate that a new **10ml** **CONNECT** syringe glass barrel has been introduced with a wider internal channel and a fixed Luer lock adapter. This change in barrel will increase the number of NFCs that are compatible with **10ml** **CONNECT** pre-filled syringes in the Aurum Range, minimising the current safety concern of delay in administering emergency medication when an incompatible needle-free connector is used.

**10ml** **CONNECT** pre-filled syringes will be available from July 2025. Adrenaline 1 in 10,000 will be the first product available at launch, while amiodarone and calcium chloride will follow, with both scheduled for release by the end of September 2025.

Due to the current shelf life of the pre-filled syringes (18 – 36mths) there will be an extended period when both the established barrels and the **CONNECT** barrels will be available. It is important that stakeholders can identify which barrels they have in stock, and which needle-free connectors they should use.

**The appropriate sections of the Summary of Product Characteristics (section 4.4) and Patient information leaflet (section 2) for the **10ml** **CONNECT** pre-filled syringes have been updated to mention precaution of use in case of use of incompatible NFC and to ensure compatible NFCs are procured in advance and stored together with the Aurum range of pre-filled syringes.**

### Advice for Healthcare Professionals

Knowing that the Aurum range with the established syringe barrel is still available until March 2028, healthcare professionals are requested to:

- ensure that only compatible NFCs are used with pre-filled syringes in the Aurum Range.
  - There are now 2 lists of compatible NFCs
    - The list of NFCs compatible with the established barrel
    - The list of NFCs compatible with the **CONNECT** barrel.
  - Please note: all NFCs that are compatible with the established barrel will continue to be compatible with the **CONNECT** barrel. However, the reverse is not applicable.

- ensure compatible NFCs are procured in advance and stored together with appropriate Aurum pre-filled syringes in stock.

Please note that both lists of compatible NFCs can be viewed by scanning or clicking the below QR code.



In addition, the lists are also accessible from the listing for each pre-filled syringe on the eMC website

- [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](#)

### Call for reporting

Please continue to report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card scheme.

Please report:

- all suspected ADRs that are serious or result in harm. Serious reactions are those that are fatal, life-threatening, disabling or incapacitating, those that cause a congenital abnormality or result in hospitalisation, and those that are considered medically significant for any other reason
- all suspected ADRs associated with new drugs and vaccines identified by the black triangle ▼

You can report via:

- the [Yellow Card website](#)
- the free Yellow Card app available from the Apple App Store or Google Play Store
- some clinical IT systems (EMIS/SystmOne/Vision/MiDatabank) for healthcare professionals

Alternatively, you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm.

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, timing onset, treatment dates, and product brand name.

**Company contact point**

For medical information enquiries please contact [medinfo@ethypharm.com](mailto:medinfo@ethypharm.com) or call 01277 266 600 (select option 2).

Yours sincerely,

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Aurum Pharmaceuticals Limited (an Ethypharm Group Company)