

Direct Healthcare Professional Communication

- Adrenaline (Epinephrine) Injection 1:10,000 glass prefilled syringe (MA number: 2-5077-19 (Initial); 2707257860 (Renewal))**
- Calcium Chloride Intravenous Infusion, 10% w/v pre-filled syringe (MA number: 3-5077-20)**

Notification on change of syringe barrel for Aurum range of 10ml pre-filled syringes (Adrenaline Injection 1:10,000 glass and Calcium Chloride Intravenous Infusion 10% w/v) in Saudi Arabia – change of current syringe barrel to new 10ml CONNECT syringe barrel with a wider internal channel and fixed Luer lock adapter.

Dear Healthcare Professional,

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

Summary

- The use of incompatible needle-free connectors (NFCs) with Aurum pre-filled syringes has led to adverse incidents in emergency situations.
- Attaching an incompatible NFC can block the syringe and prevent delivery of emergency medicine.
- A new 10ml barrel design for the Aurum pre-filled syringes, CONNECT, is compatible with a wider range of NFCs to minimise the occurrence of these adverse incidents. For the transition period, both the new syringe and the current syringe are available for affected products.

- The 10ml CONNECT barrel for the Calcium Chloride Intravenous Infusion 10% pre-filled syringe is introduced on the market in 02 August 2026. And For Adrenaline 1:10,000 pre-filled syringe, the new design will be available in 09 August 2026.
- All NFCs compatible with the current syringe design remain compatible with the CONNECT syringe design. However, the reverse is not applicable. Therefore, during the transition period of 2 years (approximately), there remains an increased risk of inadvertently using an incorrect NFC.
- Healthcare professionals should refer to the list of compatible NFCs available via the link below for use with both designs of the Aurum pre-filled syringes to eliminate the risk of NFC incompatibility during the transition period.
 - [Adrenaline \(Epinephrine\) Injection 1:10,000](#)
 - [Calcium Chloride](#)

This can be viewed by scanning or clicking the below QR code:



Further information on the safety concern and the recommendations

➤ Advice for healthcare providers:

- Refer to the list of compatible needle-free connectors (NFCs) for the Aurum pre-filled syringes above and procure compatible NFCs for use with the current and/or new CONNECT syringe barrel.

- Ensure that the specifications 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 and ensure procedures are in place to determine the compatibility of NFCs with the Aurum pre-filled syringes.
- Consider displaying a list of compatible NFCs for use with Aurum pre-filled syringes in clinical areas containing the emergency drug boxes and resuscitation training rooms -
- When appropriate adaptors and specified NFCs are procured for use with the **current syringe barrel**, 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).

➤ **Advice for healthcare professionals:**

- Use compatible needle free connectors (NFCs) with the current or new CONNECT syringe barrel for the Aurum pre-filled syringes, refer to the list of NFCs available (see summary section above).
- Remove adaptors immediately after use to reduce the risk of infection and air embolus.
- Ensure that the luer lock fitting attached to the line is the correct size and type for the NFC used.

Explanation of identified safety issue

Incompatibility between needle-free connectors (NFCs) and Luer tips of the Aurum Range pre-filled syringe barrel can lead to blockage and delayed delivery of medication.

Further information

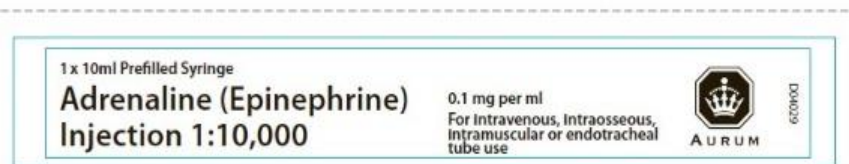
Refer to the reference images below for the Aurum Range of pre-filled syringes.



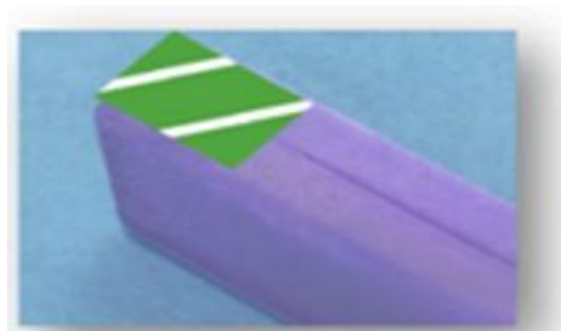
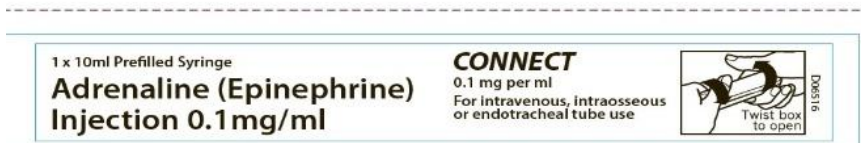
To aid in-product identification between both barrels, the new CONNECT barrel products have new internal product codes, and the following changes have been made to the packaging:

- Text: Updated layout with the word “CONNECT.”
- Icon: “Twist to open” icon on CONNECT packaging.
- Color: Green with white stripes box closure label on CONNECT packaging (previously white).

Current packaging



New CONNECT Packaging



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

Call for reporting

Adverse events should be reported to local authorities in accordance with the national spontaneous reporting system:

National Pharmacovigilance Center (NPC) - Saudi Food and Drug Authority (SFDA)	
SFDA call center: 19999	
E-mail: npc.drug@sfda.gov.sa	
Website: https://ade.sfda.gov.sa	

Company Contact point

Local qualified person for Pharmacovigilance	E-mail: ksa_pvoffice@ethypharm.com Copy: mpv@mesned.com Website: https://www.ethypharm.com/saudi-arabia/ Phone: +966 9200 19011
Medical information	For medical information enquiries please contact medinfo@ethypharm.com or call 00441277 266 600 (select option 2).

Yours sincerely,

Nihal Howsawi

Local qualified person for Pharmacovigilance