

Direct Healthcare Professional Communication Version 1.0

15 April 2026

Dear Healthcare Professional,

By the present letter, Aurum Pharmaceuticals Limited (an Ethypharm Group company) would like to provide instructions to ensure labels at either end of the box are intact prior to use. A new label design has been included to support identification of broken labels.

Products under consideration: The Aurum range

- Adrenaline (Epinephrine) Injection 1:10,000 glass prefilled syringe (PL 12064/0006)
- Adrenaline (Epinephrine) Injection 1:1000 prefilled syringe for Anaphylaxis (PL 12064/0058)
- 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)
- Naloxone Hydrochloride 1mg/ml Solution for Injection in a pre-filled syringe (PL 12064/0060)

Background on the safety concern

As the labels on the twist box at times appear to realign upon closure, this may result in twist boxes with empty syringes being placed back on the crash trolley instead of being discarded per local procedures.

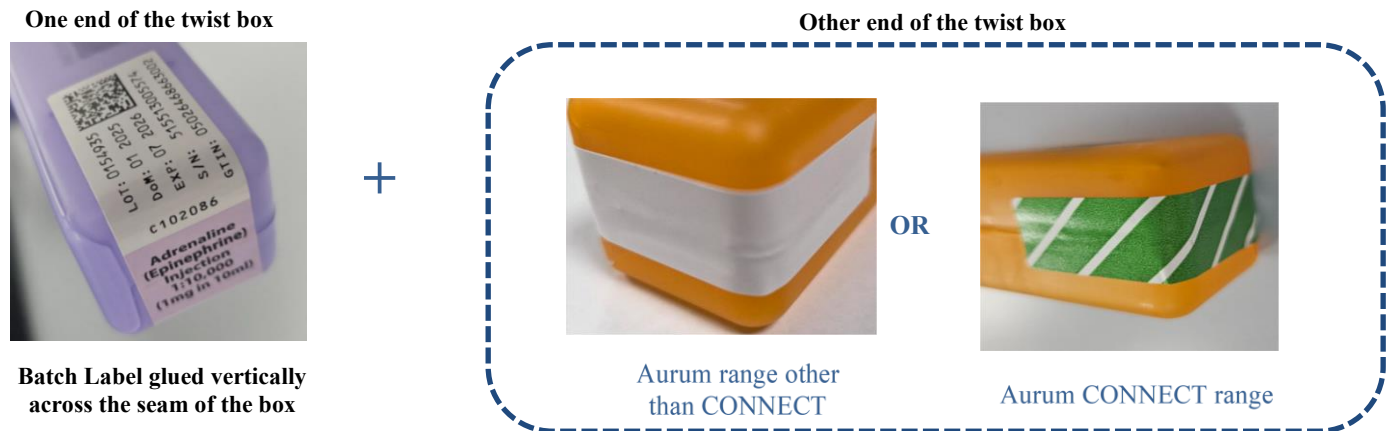
This DHPC letter provides information to mitigate the risk of empty syringes being placed back into circulation and potentially delaying the delivery of an emergency medicine.

Explanation of caution

As shown in the illustrations below, the closure of the boxes is achieved using two different labels placed at each end of the Twist box. All boxes display the Batch Variable Data label at one end of the box whereas, at the other end of the box, the Aurum Legacy barrels have a plain white label and the CONNECT barrels have a label with green with white stripes.

Both extremities of the box should be checked for the integrity of the labels.

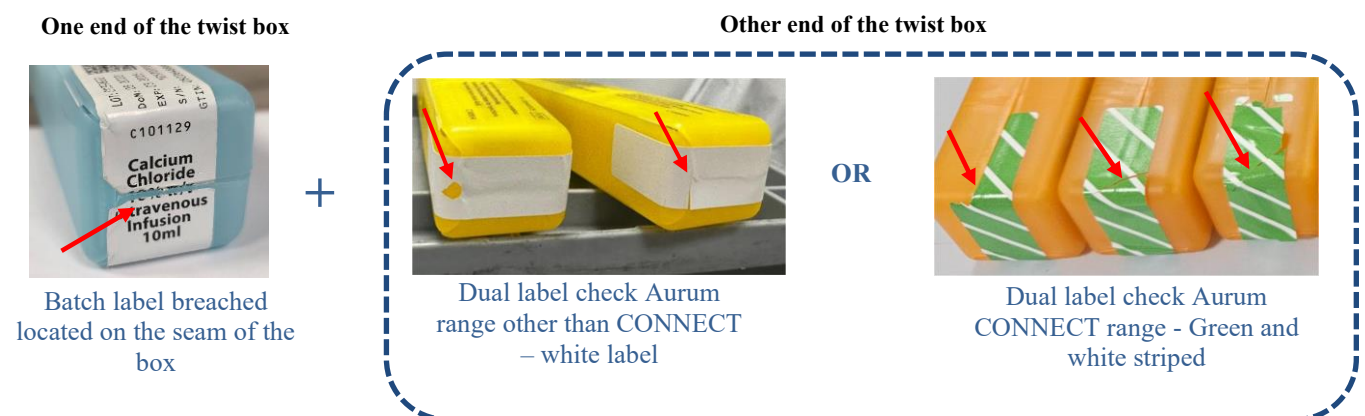
Examples of labels at each end of the box:



Advice for Healthcare Professionals

- As the labels on the twist box at times may appear to realign upon closure, visual checks of **labels at either end of the box** should be performed to identify whether the twist box was previously used. This is to mitigate the risk of empty syringes being placed back into circulation and delaying the delivery of an emergency medicine.

Examples of label breaches at each end of the box:



- To aid with the identification of the opening of the boxes, the labels design has been improved. **The colour scheme and dimensions remain identical** across the products range, i.e. white label for the initial Aurum range and the green striped label for the new CONNECT barrel. The main distinguishing feature, only visible following the box opening is a jagged asymmetrical cut that will improve the detection of use of the product.

CONNECT range:



Integral new closure label with improved cut pattern

Following opening →



Broken new closure label along new cut pattern

Other Aurum syringes:



Integral new closure label with improved cut pattern

Following opening →



Broken new closure label along new cut pattern

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

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/SystemOne/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 or call 01277 266 600 (select option 2).

Yours sincerely,

Signé par :

Helene Raynal



Nom du signataire : Helene Raynal

Motif de la signature : J'approuve ce document

Heure de signature : 02-avr.-2026 | 11:22 BST

DA01C2B31DF34DF5AF42687878C90AEE

Helene Raynal

UK-QPPV

Signed by:

Genevieve Brass



Signer Name: Genevieve Brass

Signing Reason: I approve this document

Signing Time: 02-Apr-2026 | 11:33 BST

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Genevieve Braas

Quality Director

Aurum Pharmaceuticals Limited (an Ethypharm Group Company)