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27/04/2020

Information for Healthcare Professionals and End users

RE: Adrenaline (Epinephrine) Injection 1:10,000 in a prefilled syringe; PL 12064/0006 – MAH letter on FMD/Serialisation information on the packs.

Dear Healthcare Professional and End user.

Summary:

The Marketing Authorisation Holder, in agreement with the MHRA, would like to inform you of the following:

- Due to increase demand of this critical care product during this COVID-19 crisis, we increased the production to meet the demand.
- In order to meet this increased demand we have manufactured a few batches without FMD/Serialisation features such as GTIN, unique identifier/serial number and 2D barcode.
- These FMD/Serialisation features will not appear on the packaging and hence will differ with the product that has already been released to market with FMD/Serialisation features.
- The way the product is intended to be used remain unchanged.
- There are no additional safety concerns due to this change.
- Both batches with or without FMD/Serialisation features will remain in use.

Adrenaline (Epinephrine) Injection 1 in 10,000 may be used in the

- Cardiopulmonary Resuscitation in adults and children over 5kg
- Acute anaphylaxis in adults¹

The Adrenaline 1 in 10,000 PFS SmPC/PIL can be accessed via the following links:

SmPC: <https://www.medicines.org.uk/emc/product/3448/smpc>

PIL: <https://www.medicines.org.uk/emc/product/3448/pil>

Call for reporting:

Report suspected adverse reactions to the MHRA via the Yellow Card Scheme. It is easiest and quickest to report online via the Yellow Cards website <https://yellowcard.mhra.gov.uk/> or search for MHRA Yellow Card in the Google Play or Apple App Store.

Pharmacovigilance department in Aurum Pharmaceuticals Ltd (an entity of Ethypharm):

Email: drugsafety.uk@ethypharm.com

Please contact Ethypharm Medical Information at medinfo@ethypharm.com should you require anything further.

Yours sincerely
ETHYPHARM UK LTD

References

1. Summary of Product Characteristics for Adrenaline 1 in 10,000 PFS at <https://www.medicines.org.uk/emc/product/3448/smpc>

Date of Preparation: April 2020