



MEDICINES NOTIFICATION

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use Distribute to Pharmacy / Wholesaler Level

Date: 16 June 2022

EL (22)A/29

Our Ref: MDR 198-05/22

Dear Healthcare Professional,

Altan Pharma Limited

Phenylephrine 0.08 mg/ml - solution for injection/infusion PL 46788/0024

Batch No	Expiry Date	Pack Size	First Distributed
FE221001	05/2024	10 bags of 100ml	April 2022

Active Pharmaceutical Ingredient: Phenylephrine hydrochloride

Brief description of the problem

Altan Pharma Limited have identified an error relating to the product packaging. The incorrect concentration of phenylephrine base is provided on the overwrapping bag label.

- The label states that: 1 ml contains 0.08 mg of phenylephrine base. Each bag of 100 ml contains **10** mg of phenylephrine base that corresponds to 10 mg of phenylephrine hydrochloride.
- However, the correct label should state: 1 ml contains 0.08 mg of phenylephrine base. Each bag of 100 ml contains **8** mg of phenylephrine base that corresponds to 10 mg of phenylephrine hydrochloride.

Information on the product carton, bag label and SmPC remain correct, and this product is not being recalled.

Advice for healthcare professionals

Healthcare professionals are advised to exercise caution when using the product and in relation to the impacted batch and should refer to the label dose on the actual bag which remains correct.

As stated above, **each bag of 100 ml contains 8 mg of phenylephrine base that corresponds to 10 mg of phenylephrine hydrochloride** and this information should be used when using this product during dispensing and administering (i.e., for dose adjustments). Healthcare professionals may wish to retain a copy of this notification, and Altan Pharma Limited have confirmed that they will be supplying this notification with each pack.



Advice for patients

Patients are not required to take any action at this time. This product is administered by healthcare professionals directly and the medicine itself is not affected. If you have concerns about a medicine you may be using, please contact your healthcare professional.

Further Information

For medical information please contact: info@altanpharma.com

For stock control queries please contact: info@altanpharma.com

Recipients of this Medicines Notification should bring it to the attention of relevant contacts by copy of this notice. NHS regional teams are asked to forward this to community pharmacists and dispensing general practitioners for information.

Yours faithfully,

Defective Medicines Report Centre
10 South Colonnade
Canary Wharf
London
E14 4PU
Telephone +44 (0)20 3080 6574
DMRC@mhra.gov.uk