

## DRUG ALERT

### CLASS 4 MEDICINES DEFECT INFORMATION

#### Caution in Use

#### Distribute to Pharmacy / Wholesaler Level

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](mailto:info@altanpharma.com)

For stock control queries please contact: [info@altanpharma.com](mailto:info@altanpharma.com)

Recipients of this Medicines Notification should bring it to the attention of relevant contacts by copy of this notice

RQIA should bring this information to the attention of private hospitals/clinics registered with them and any other relevant care facilities

The Business Services Organisation is asked to bring this information to the attention of Community Pharmacists and General Medical Practitioners directly.

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### **TO ALL CHEMISTS, DOCTORS ON THE LISTS**

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**16<sup>th</sup> June 2022**

Pharmaceutical website: <http://www.hscbusiness.hscni.net>