



MEDICINES RECALL

CLASS 2 MEDICINES RECALL

Action Within 48 Hours
Pharmacy/Wholesaler Level Recall

Date: 20 October 2022

EL (22)A/44

Our Ref: MDR 235-11/21

Dear Healthcare Professional,

hameln pharma ltd

Ephedrine Hydrochloride 30 mg/ml Solution for Injection

PL 01502/0103

Batch Number	Expiry Date	Pack Size	First Distributed
11081120C	11/ 2023	10 x 1 ml	14/06/2021
04600520C	05/ 2023	10 x 1 ml	30/09/2020

Active Pharmaceutical Ingredients: ephedrine hydrochloride

Brief description of the problem

hameln pharma ltd is initiating a recall of the affected batches of Ephedrine Hydrochloride 30 mg/ml Solution for Injection as a precautionary measure. This is due to out of specification results obtained during routine ongoing stability studies, for related substances. Due to the out of specification results observed at higher storage temperatures, ampoules from the affected batches may no longer be in line with the licensed product specification.

Advice for healthcare professionals

Please quarantine any remaining stock of this batch and contact hameln pharma ltd customer services on +44 (0)1452 621 661 or customer.services@hameln-pharma.co.uk to arrange credit for any unused ampoules from this batch.

Advice for patients

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

Further Information

For more information or supply queries, please contact or email hameln pharma ltd customer services on +44 (0)1452 621 661 or customer.services@hameln-pharma.co.uk

For medical information queries, please contact or email hameln pharma ltd Medicines Information on +44 (0)1452 621 661 or drug.safety@hameln-pharma.co.uk



Medicines & Healthcare products
Regulatory Agency

Recipients of this Medicines Recall 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

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