



MEDICINES NOTIFICATION

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use
Distribute to Pharmacy / Wholesaler Level

Date: 17 March 2022

EL (22)A/15

Our Ref: MDR 033-03/22

Dear Healthcare Professional,

Brancaster Pharma Limited

Benzylpenicillin benzathine 1.2 Million I.U. powder and solvent for suspension for injection

PL 41542/0006

Batch Number	Expiry Date	Pack Size	First Distributed
72C00215	April 2021	1	February 2020
72C00116	August 2022	1	December 2020

The batch below has been packed and is awaiting distribution:

Batch Number	Expiry Date	Pack Size	First Distributed
72N00206	May 2024	1	-

Benzylpenicillin benzathine 2.4 Million I.U. powder and solvent for suspension for injection

PL 41542/0007

Batch Number	Expiry Date	Pack Size	First Distributed
72C00216	April 2021	1	February 2020
72C00220	August 2022	1	August 2020
72C00223	February 2023	1	September 2021

The batch below has been packed and is awaiting distribution:

Batch Number	Expiry Date	Pack Size	First Distributed
72N00207	May 2024	1	-

Active Pharmaceutical Ingredients: Benzylpenicillin benzathine; Water for Injections

Brief description of the problem

Brancaster Pharma Limited have notified us of an issue relating to the label affixed to the 5mL ampoule of Water for Injections (solvent) that is packaged in each finished product pack.

This label is not in accordance with the approved marketing authorisation: it is written in French language rather than English, and relates to the approved French benzathine benzylpenicillin combination product ("Extencilline").



The Water for Injections for the French product is identical to the approved UK product, except for the labelling on the ampoule. The label affixed to the vials of benzylpenicillin benzathine powder, outer carton of the finished product packs and patient information leaflets for the above batches are in accordance with the marketing authorisations.

Advice for healthcare professionals

Healthcare professionals are advised to note this issue. The Water for Injections ampoule contains 5mL water for injections; there is no risk to the quality of the reconstituted injection as a result of this issue, therefore the affected batches are not being recalled.

Further Information

For medical information and stock control queries please contact: safety@brancasterpharma.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

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