

MEDICINES NOTIFICATION

CLASS 4 MEDICINES DEFECT INFORMATION, EL(26)A/30

Caution In Use

Issued 29 June 2026

Distribute to Pharmacy/Wholesaler Level

MARKETING AUTHORISATION HOLDER (MAH)

Brancaster Pharma Limited

MEDICINE DETAILS

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

PL: 41542/0006

Active Ingredient: benzylpenicillin benzathine

SNOMED code: 42677711000001104

GTIN: 05060432470258

MANUFACTURED BY

Haupt Pharma Latina, Italy

AFFECTED LOT BATCH NUMBERS

Batch No.	Expiry Date	Pack Size	First Distributed
72500107	31/10/2029	1	26/06/2026

MEDICINE DETAILS

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

PL: 41542/0007

Active Ingredient: benzylpenicillin benzathine

SNOMED code: 44166911000001101

GTIN: 05060432470265

AFFECTED LOT BATCH NUMBERS

Batch No.	Expiry Date	Pack Size	First Distributed
72500105	31/10/2029	1	26/06/2026

Background

Brancaster Pharma Limited has informed the MHRA that the Patient Information Leaflet (PIL) in the cartons for the batches listed in this notification were released with an outdated PIL. These packs contain the previous PIL that was revised in April 2023. The latest approved PIL is dated November 2025.

The update was limited to the information intended for healthcare professionals only section, subsection “Special precautions for disposal and other handling”, and reflects an update to section 6.6 of the Summary of Product Characteristics (SPC). Additional information was added regarding (1) the potential for benzylpenicillin benzathine formulations to block in the needle if intramuscular injection of the reconstituted product to the patient is not made at a slow, steady rate, and (2) introducing practical guidance to healthcare professionals regarding how to mitigate this issue.

The notification relates only to the listed batches, all future batches will have the correct PIL included.

The updated subsection “Special precautions for disposal and other handling” in the information for healthcare professionals only section is presented below for information:

Special precautions for disposal and other handling

The suspension must be prepared aseptically.

Studies on numerous formulations of benzylpenicillin benzathine have identified an issue that aggregation of particles in the reconstituted suspension occurs in a small proportion of samples tested.

Difficulty with reconstitution has been reported with Benzylpenicillin benzathine 2.4 Million I.U. powder for suspension for injection. The following instructions concerning reconstitution should be followed to minimise reconstitution issues:

- introduce the diluent into the vial of powder using a needle suitable for reconstitution (such as a blunt filter needle (18G));
- agitate this suspension carefully for at least 40 seconds until a homogeneous suspension is obtained.

The product should be used immediately after reconstituting the suspension. If there is any delay in using the suspension the suspension should be gently agitated again prior to drawing up the suspension into the syringe.

Please note that should a blockage occur during withdrawal of reconstituted product from the vial, the vial concerned should be discarded and a new vial used to administer the prescribed dose to the patient.

The suspension for injection is intended for single use only.

After drawing the suspension into the syringe for administration using the needle suitable for reconstitution, change this needle for a new needle suitable for intramuscular administration: a needle of a diameter of at least 700µm (needle gauge: 22G, 21G or 20G) for intramuscular injection is preferred.

Because of the high concentration of suspended material, the needle may become blocked if intramuscular injection of the reconstituted product to the patient is not made at a slow, steady rate.

If a blockage is observed during intramuscular administration, the blocked needle should be replaced with a new needle of the same diameter and administration of the remaining dose may then continue.

Prior to injection, intravascular administration should be excluded by aspiration. The injection site should be changed with repeated injections.

Advice for Healthcare Professionals:

Healthcare professionals should read the details in this notification and take this into account when reconstituting and administering these products.

Upon request, Brancaster Pharma Limited will provide hard copies of the updated PIL to wholesalers and pharmacies so that any packs can be supplemented with the correct PIL information.

To request hard copies of the PIL, please contact enquiries@brancasterpharma.com with your details, i.e. address, product with batch details, required number of leaflets.

The correct PIL is available:

[Click here](#)

The information in the updated PIL reflects the current section 6.6 of the SmPC:

[Click here](#)

Advice for Healthcare Professionals to Provide to Patients:

The quality of the powder for suspension for injection is not affected by this issue.

The information missing from the Patient Information Leaflet (PIL) relates only to updated instructions for healthcare professionals on the preparation and administration of the injection.

These products are prepared and administered by healthcare professionals and the missing information has been provided to them when preparing the medication. No further action is required for the patient.

Patients who experience adverse reactions or have any questions about their medication should seek medical attention. Any suspected adverse reactions should also be reported via the [MHRA Yellow Card scheme](#).

Additional information:

For all medical information enquiries and information on this product, please email safety@brancasterpharma.com, or telephone +44 (0) 1737 243 407.

For stock control enquiries please email enquiries@brancasterpharma.com, or telephone +44 (0) 1737 243 407.

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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