11/07/2025

eREC-6
eNC/D-389

Direct Healthcare Professional Communication (DHPC)

Vitamin B and C Intravenous High Potency, Concentrate for Solution for Infusion 5mL x 6 ampoule pairs (PL 35533/0195): Potential ampoule damages in unopened cartons.

Dear Healthcare Professional,

Aspire Pharma Limited (APL), in agreement with the Medicines and Healthcare Products Regulatory Agency (MHRA), National Health Service (NHS) England and Health and Social Care Northern Ireland (HSCNI) would like to inform you of the following:

Summary:

- Damages to some ampoules of the aforementioned product have been identified during sampling of stock for batches 30733 and 30972. Predominantly the damage is identified where the neck of the ampoule has snapped;
- Damages were identified in cartons with no external damages to the carton packs or shippers;
- Batches 30733, 30972, 30973, 30974 and 30975 will be distributed to the UK market in agreement with the MHRA, NHS England and HSCNI;
- 100% inspection will be performed on all 5 batches being distributed to the UK market;
- A portion of units have been identified with the ampoule tray foil not being fully adhered to the ampoule tray. There is no product quality impact with a lack of adherence of this foil and these packs can be used;
- **Healthcare Professionals should not use any packs identified to have damaged ampoules, regardless of the number of ampoules damaged;**
- **Any damages identified are to be reported to the supplying wholesalers or APL directly;**
- Full, undamaged packs can be used and pose no risk to patients.

Background:

Upon receipt of stock for batch 30733 to the UK, APL identified damages to some ampoules. After additional sampling was performed it was estimated that potentially 15% of the batch could be affected. APL imported a second batch, 30972, with additional transport mitigations in place and performed a larger AQL upon receipt into the UK. APL identified 2.4% damaged ampoules in the samples reviewed.

Due to the shortage of the product in the UK market, with agreement from the MHRA, NHS England and HSCNI, the affected batches will be 100% inspected prior to distribution to the UK market. The package design includes a paper foil covering the ampoule tray. During APL's sampling of the affected batches, it was identified that damages could be confirmed without requiring the paper foil to be opened. Some units have been identified with the ampoule tray foil not being fully adhered to the ampoule tray. These affected units have been reviewed for ampoule damages (Figure 1). The ampoule tray foil is not required for the product stability and there is no impact on the product quality. APL will perform 100% inspection of the ampoule trays for all 5 batches, discarding any damages. The remaining undamaged packs will be distributed to the UK market with agreement from the MHRA, NHS England and HSCNI.

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Figure 1. Example of ampoule tray with paper foil not fully adhered to the ampoule tray:

Figure 2. Example of undamaged ampoules within an ampoule tray without paper foil:

Figure 3. Example of ampoule damages:

Call for reporting:
Please continue to report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card scheme.

Please report:

- all suspected ADRs that are serious or result in harm. Serious reactions are those that are fatal, life-threatening, disabling or incapacitating, those that cause a congenital abnormality or result in hospitalisation, and those that are considered medically significant for any other reason
- all suspected ADRs associated with new drugs and vaccines identified by the black triangle ▼

You can report via:

- the Yellow Card website
- the free Yellow Card app available from the Apple App Store or Google Play Store
- some clinical IT systems (EMIS/SystmOne/Vision/MiDatabank) for healthcare professionals

Alternatively, you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm.
When reporting please provide as much information as possible, including information about medical history, any concomitant medication, timing onset, treatment dates, and product brand name.

Please also report any adverse events by email or phone to APL's Medical Information Team at medinfo@aspirepharma.co.uk or 01730 231148.

In agreement with the MHRA, NHS England and HSCNI, reports of damages will be reconciled by APL on a monthly basis as part of any claims or returns made to wholesalers by Healthcare Professionals and be shared with the MHRA, NHS England and HSCNI. Any claims or replacements should be made via the wholesale supply chain (e.g. for NHS England this is Mawdsleys Hospital and for HSCNI this is AAH).

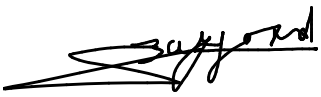
Company contact point:
If you have any questions about this letter, stock availability or reports of damages this can be made by Healthcare Professionals directly to APL's Customer Service Team. Reports of adverse events or complaints, or any other medical enquiry, please contact APL's Medical Information Team:

Medical Information
Tel: 01730 231148
Email: medinfo@aspirepharma.co.uk

Customer Services
Tel: 01730 231148
Email: customerservices@aspirepharma.com

Address:
4 Rotherbrook Court, Bedford Road, Petersfield, Hampshire, GU32 3QG, United Kingdom

Sincerely,



Electronically signed by: Felicity Bayford
Reason: Approver
Date: Jul 7, 2025 12:20 GMT+1

Felicity Bayford
Quality Director