



Direct Healthcare Professional Communication

07 September 2023

Paracetamol 10mg/ml solution for infusion PL 46788/0008 - Blushing of PVC bags

Dear Healthcare Professional,

Altan (An Ethypharm Group company) in agreement with the MHRA would like to inform you of the following:

Summary

- We have received reports that when removing the medicinal product from the foil cover (overwrapping), the plastic infusion bags containing this solution may appear opalescent rather than transparent; a phenomenon known as blushing.
- Blushing of the plastic does not affect the quality, efficacy or safety of the contents.
- This effect is an aesthetic phenomenon, inherent to the nature of the PVC material. It does not result from the precipitation or adsorption of the product onto the container.
- The blushing effect will reduce over time after the bag is removed from the overwrapping.

Background on the safety concern

Blushing has been observed in filled PVC infusion bags stored in protective foil overwrapping. This is due to small amounts of moisture in the atmosphere between the plastic and the foil (depending on storage conditions). This is a temporary, aesthetic phenomenon and may vary depending on the storage conditions (even though the product is kept below 25°C). The blushing effect is not completely uniform and it reduces and eventually tends to disappear as the container remains out of the protective/barrier pouch.

Advice for Healthcare Professionals

If blushing of the plastic is extensive when the medication is removed from the overwrapping it may be more difficult to visually inspect the contents. Under these circumstances, it is recommended to perform the inspection against a white background.

Visual inspection of product before use should focus mainly on verifying the following:



- absence of leaks
- absence of visible particles (visible foreign matter or particles resulting from the aggregation/precipitation of product)
- absence of colour or, as the expiry date gets closer, presence of pale yellowish/brownish colour of the solution

If you have any doubts or concerns about using the product, please contact our medical information department at medinfo@ethypharm.com

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.

Company contact point

For medical information enquiries please contact medinfo@ethypharm.com or call 01277 266 600 (select option 2).

Yours sincerely,

DocuSigned by:
Lorena Hermosilla
Nombre del firmante: Lorena Hermosilla
Motivo de la firma: Apruebo este documento
Hora de firma: 07-sep.-2023 | 17:10 CEST
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Quality Manager / QP

Altan Pharmaceuticals, S.A. (an Ethypharm Group Company)