January 31, 2024

Direct Healthcare Professional Communication

Plasma-Lyte 148 and Glucose 5% w/v Discolouration

FA Number: FA-2024-006

Dear Healthcare professional,

In agreement with the Medicines and Healthcare products Regulatory Agency (MHRA), Baxter Healthcare would like to inform you of the following:

Actions to be taken by the user:

- Continue to use the product in accordance with the Summary of Product Characteristics (SmPC). The solution should be inspected visually prior to administration whenever solution and container permit and also after adding substance or medication. Please refer to:
    - product "a" shown in Ref1 below for the expected solution colour of product manufactured at Baxter Sabinanigo, Spain (product code FE2584).
    - product "b" shown in Ref1 below for the expected solution colour of product manufactured at Baxter Thetford, UK (product code FKE2584).

Actions to be taken by customer/distributor:

- If you distribute this product to other facilities or departments within your institution, please forward a copy of this communication to them.

Background on the concern:

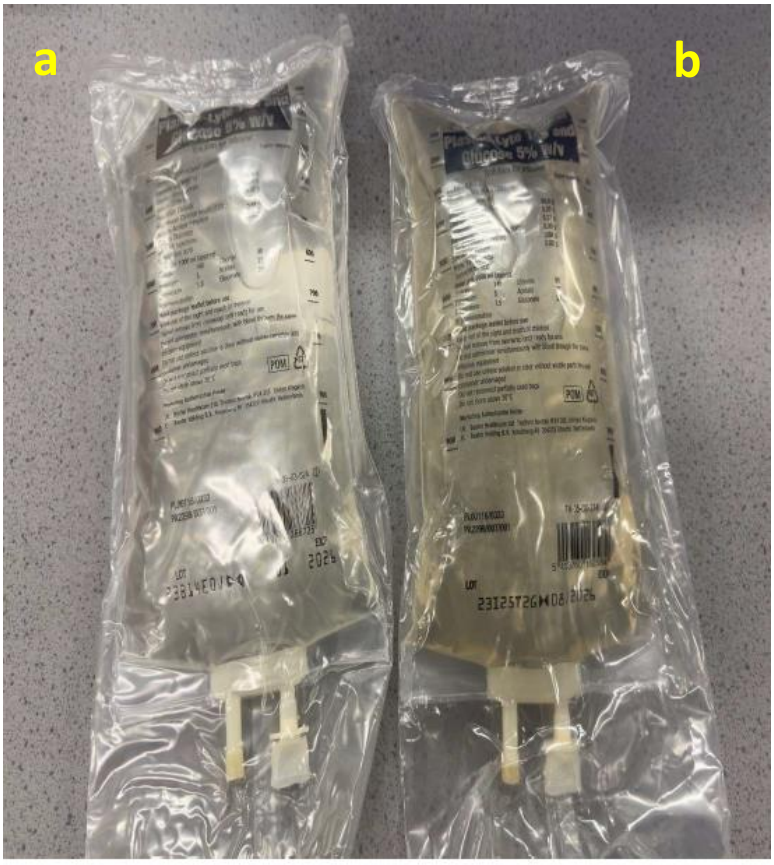
Plasma-Lyte 148 and Glucose 5% w/v Lot 23I25T2G and subsequent Lots are now manufactured by Baxter Healthcare at Thetford, UK (product code FKE2584), previously the product was manufactured in Sabinanigo, Spain (product code FE2584). This has resulted in a change in the physical appearance of the final product, where the product manufactured now in Thetford,UK exhibits darker straw-like yellow solution appearance.

It is worth noting that Plasma-Lyte 148 and Glucose 5% w/v has been manufactured at Thetford and distributed on the EU market since 2012 and the product has always exhibited this straw-like yellow solution colour.

Solution color is typically associated with Maillard (caramelisation) reaction which is expected to be observed following exposure of Glucose containing solutions to high temperature. Intensity and extent of the reaction is driven by temperature, heat quantity, sterilisation time and product pH used at sterilisation of the product.

Baxter's investigation has concluded that the root cause was related to different terminal sterilisation techniques utilised at Sabinanigo and Thetford sites and that there is no safety/quality risk associated with the use of Thetford Plasma-Lyte 148 and Glucose 5% w/v products exhibiting straw-like yellow solution appearance (see Ref1 below).

Ref1. Sabinanigo and Thetford final product colour comparison



a) Sabinanigo (Spain), product code FE2584

b) Thetford (UK), product code FKE2584

Call for reporting:

Reporting suspected adverse reactions is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

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 ▼

It is easiest and quickest to report ADRs online 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

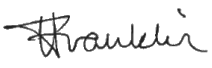
Alternatively, you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm.

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:

Baxter Medical Information
Email: medinfo_uki@baxter.com
Tel. no. +44 (0)1635 206345

Sincerely,



Electronically signed by:
Victoria Franklin
Reason: I have reviewed this document
Date: Jan 31, 2024 13:45 GMT

Victoria Franklin
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Baxter Healthcare Ltd