Fresenius Kabi Limited

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DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION

Parenteral nutrition: use of Inline filters during administration now required

Dear Sir/Madam

Fresenius Kabi in agreement with the Medicines and Healthcare products Regulatory Agency (MHRA) would like to inform you of the following:

Summary

Based upon information provided by Baxter and Torbay Pharmaceuticals (see background section) regarding a potential safety concern, Fresenius Kabi compounded PN products require the use of Inline filters during administration of Parenteral nutrition as below:

In case of Neonates and Paediatrics:

- For products manufactured in aqueous phases: a 0.22-micron filter
- For products manufactured in lipid phases: a 1.2-micron filter
- For products manufactured in all-in-one (AIO, 3-in1) systems, i.e. where lipids and aqueous phases are mixed: a 1.2-micron filter

In case of Adults and Pre-prepared bags:

- For products manufactured in non-lipid phases: a 1.2-micron filter
- For products manufactured in lipid phases: a 1.2-micron filter

We are in process of adding these instructions on the bag labels. Should you require any further information, please contact your local Account Manager.

Background on the safety concern

We have been notified by two of our suppliers of materials used in compounding of a possible particle contamination.

Baxter Healthcare has identified a Product Correction required for Exactamix and Exactamix Pro compounding machine inlets. They have discovered some numbers of complaints regarding particulate matter within the sterile fluid path tubing.

Torbay Pharmaceuticals has alerted us to a potential issue with Calcium Gluconate vials, where cellulose fibres may be present in their plastic bottles. Calcium Gluconate is being used as an ingredient in our compounding bags.

VAT No. GB 534 9347 26
Fresenius Kabi is a trading style of Fresenius Kabi Limited
Registered Office: Cestrian Court, Eastgate Way, Manor Park, Runcorn, Cheshire, WA7 1NT
Registered in England and Wales with company number: 02182135

Reporting of suspected adverse reactions

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

In case of any enquiries, please contact FK.complaints-uk@fresenius-kabi.com or telephone +44 (0) 1928 533758.

Yours faithfully

Chris Ashcroft
Director- Compounding operations
Fresenius Kabi- Runcorn