30.10.2014

TRIOMEL – Medication errors: reminder of the importance of correct preparation and administration

Dear Healthcare Professional,

In order to prevent medication errors in the preparing and administration of TRIOMEL, and potential harm to patients, Baxter Healthcare, in agreement with the Medicines Authority, would like to inform you of the following:

Summary

- Errors have been reported during TRIOMEL use with respect to either incomplete or failed “activation” (mixing) of the chambers of the bag, or other types of medication errors, such as excessive infusion rate or incorrect route of administration.
- The instructions for preparation and administration as described in the product information **MUST** be followed carefully to prevent incomplete activation of the bag before administration or other medication errors from occurring.
- All TRIOMEL formulations can be administered via the central intravenous route. Only TRIOMEL Peripheral 4 g/l nitrogen 700 kcal/l with electrolytes can also be administered via the peripheral intravenous route due to its osmolarity (760 mosm/l).
- The attached poster is a user guide to remind healthcare professionals and illustrate the correct way to use TRIOMEL, in order to avoid such medication errors (**Attachment 1**).

Further information

Triomel is a range of products indicated for parenteral nutrition (PN) for adults and children greater than 2 years of age when oral or enteral nutrition is impossible, insufficient or contraindicated.

These products provide a 3-in-1 parenteral nutrition emulsion that contains macronutrients (lipids, amino acids and glucose); certain TRIOMEL formulations also include electrolytes.

These products are presented as a 3-chamber bag which must be “activated” in order to mix the contents of the chambers before administration to the patient.

The product information for TRIOMEL currently contains detailed information regarding preparation, handling, posology and method/route of administration, as well as special warnings and precautions for use.

Baxter Healthcare Ltd
Caxton Way / Thetford / Norfolk / IP24 3SE / Great Britain
T 01842 767000 **F** 01842 767099
Registered Office: Caxton Way / Thetford / Norfolk / IP24 3SE Registered in England No. 461365

The reports of medication errors received by Baxter occurred at different steps before and during TRIOMEL administration. Such medication errors may lead to serious adverse reaction, such as hyperglycaemia, manifestations of overdose, or injection site reactions related to extravasation.

Call for reporting

Please continue to report suspected adverse drug reactions (ADRs) to the Medicines Authority.

ADR Reporting
The Medicines Authority
Post-Licensing Directorate
203 Level 3, Rue D'Argens
GŻR-1368 Gżira

Website: www.medicinesauthority.gov.mt
e-mail: postlicensing.medicinesauthority@gov.mt

Any suspected adverse reactions observed during use of TRIOMEL may also be reported to Baxter Healthcare Pharmacovigilance on telephone number +44 1635 206360, by fax to +44 1635 206281 or by email to vigilanceuk@baxter.com.

Should you have any questions or require additional information on the use of TRIOMEL, please contact Drugsales Ltd at +356 21 419 070/1/2 or by email at safety@drugsalesltd.com.

Yours faithfully,

Dr Iain McNeil
Medical Director
Baxter Healthcare Ltd, UK