

DRUG ALERT

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use
Distribute to Hospital Pharmacy, Ward and Wholesale Level

Date: 05 December 2013

EL (13)A/27

Our Ref: MDR 61-11/13

Dear Healthcare Professional,

B. Braun Melsungen AG

8.4% w/v Sodium Bicarbonate

PL 03551/0069

Batch Number Range From and to inclusive	Expiry Date Range From and to inclusive	Pack Size	First Distributed
120428021 to 131558022	12/2013 to 03/2015	100ml & 250ml	03/2012

B. Braun Melsungen AG has informed us that during regular visual inspection of retained samples of Sodium Bicarbonate solutions with bromobutyl stoppers precipitation in solution was observed. The particles have been identified as aluminum salt precipitation. A fluctuation in the bromobutyl stopper quality, resulting in the leaching of aluminum compounds is believed to be the cause of the issue. The above batches have been released to market using bromobutyl stoppers.

No customer complaints or adverse drug reactions have been received in relation to these observations to date.

Due to concerns with continuity of supply these batches are not being recalled at this time. As a precaution we advise the following actions prior to administration:

- Visually inspect the product prior to use and only use if the product is clear and free from particles.
- Ensure that a standard fluid infusion set with integral filter (15 micron) is used for infusion.

Recipients of this Drug Alert should bring it to the attention of relevant contacts by copy of this letter. Local area teams are asked to forward this to relevant clinics, general practitioners and community pharmacists for information.

Yours faithfully

Adam Burgess

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