

DRUG ALERT

CLASS 2 MEDICINES RECALL

Action Within 48 Hours
Pharmacy, Clinic and Wholesaler Level Recall

Date: 27 June 2013

EL (13)A/18

Our Ref: MDR 22-06/13

Dear Healthcare Professional,

B Braun Melsungen AG

Hydroxyethyl Starch (HES) products

Tetraspan 10% solution for infusion (500ml)	PL 03551/0107
Tetraspan 6% solution for infusion (500ml)	PL 03551/0106
Venofundin 60mg/ml solution for infusion (500ml)	PL 03551/0097

Fresenius Kabi Limited

Hydroxyethyl Starch (HES) products

Voluven 10% solution for infusion (500ml)	PL 08828/0207
Voluven 6% solution for infusion (500ml)	PL 08828/0145
Volulyte 6% solution for infusion (500ml)	PL 08828/0174

All unexpired stock of these products is being recalled to pharmacy, clinic and wholesaler level irrespective of batch number and expiry date.

These products are being withdrawn after results from large randomised clinical trials have reported an increased risk of renal dysfunction and mortality in critically ill or septic patients who received hydroxyethyl starch (HES) compared with crystalloids (simple salt solutions). The UK Commission on Human Medicines (CHM) has concluded that the benefits no longer outweigh the risks.

No further hydroxyethyl starch (HES) products should be dispensed. An alternative resuscitation fluid should be selected according to clinical guidelines.

Remaining stocks of the affected batches should be quarantined and returned to the original supplier for credit. For enquiries relating to stock returns please contact:

B Braun Medical Limited (UK) on 01142 259 155
Fresenius Kabi Limited Customer Services on 01928 533 697

Contd/...

For medical information enquiries please contact:

B Braun Medical Limited (UK) Medical Information on 01142 259 159
Fresenius Kabi Limited Medical Information on 01928 533 612 or email
pharmacovigilance.GB@fresenius-kabi.com.

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
Defective Medicines Report Centre
151 Buckingham Palace Road
London
SW1W 9SZ
Telephone +44 (0)20 3080 6574