FRESENIUS KABI

Fresenius Kabi
New Zealand Limited

ABN 39 109 383 593
60 Pavilion Drive

MANGERE 2022
AUCKLAND, NEW ZEALAND

T +64 9 925 2719
F +64 9 916 1025
www.fresenius-kabi.co/nz

Attn:Chief Executive Officer/Chief Pharmacist

12 September 2018

SAFETY INFORMATION UPDATE

Sub: VOLULYTE® 6% hydroxyethyl starch 130/0.4 in a balanced electrolyte solution 6% solution for infusion
VOLUVEN® 6% hydroxyethyl starch 130/0.4 500 mL solution for intravenous infusion

Dear Healthcare Professional,

Fresenius Kabi New Zealand Limited, in consultation with the New Zealand Medicines and Medical Devices Authority (MEDSAFE) would like to inform you about the outcome of a recently performed evaluation of the benefits and risks of Hydroxyethyl starch (HES)-containing solutions, which are currently used for the treatment and prophylaxis of hypovolemia. This evaluation was triggered by the results of two Drug Utilisation Studies (DUSs) conducted with HES-containing solutions in countries of the European Union. The objective of these DUSs was to investigate the adherence of the hospital physicians to the European Product Information for HES products. The DUS performed by Fresenius Kabi Deutschland is an observational, retrospective, anonymized study across EU (9 countries). 3,890 patients' charts were evaluated.

The results of these DUSs indicate to some extent a low adherence of the hospital physicians to the European HES Product Information (PI) and usage of HES solutions to some extent in patients with sepsis and renal impairment, a patient group in which the use of HES products is contraindicated.

Besides the apparent off-label use in these DUSs, the positive benefit-risk balance for HES-containing products is unchanged in their indicated use as supported by clinical studies, recent scientific literature, the expert group selected by the European Medicine Agency and several European Anesthesiology Societies.

Fresenius Kabi New Zealand Limited kindly requests you to ensure the proper and safe use of its Hydroxyethyl starch (HES)-containing infusion solutions such as Voluven 6% and Volulyte 6% solution for infusion according to their approved product information and taking the following contraindications into consideration:

Contraindications
Voluven/Volulyte should not be used, if any one or more of the following clinical conditions apply:
- Critically ill patients (typically admitted to intensive care unit), including those with sepsis

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- Fluid overload (hyperhydration), especially in cases of pulmonary oedema and congestive cardiac failure
- Patients with pre-existing coagulation or bleeding disorders
- Renal failure with oliguria or anuria not related to hypovolaemia
- Patients receiving dialysis treatment
- Intracranial bleeding
- Severe hypernatraemia or severe hyperchloraemia (Voluven)
- Patients with severe hyperkalaemia, severe hypernatraemia or severe hyperchloraemia (Volulyte)
- Known hypersensitivity to hydroxyethyl starches
- Patients with severe liver disease

You are requested to strictly consider the contraindications listed above. We particularly point out the contraindication for patients with sepsis and for patients with renal impairment or renal replacement therapy.

This letter is not intended to provide a complete description of the indications, dosage and administration, risks and benefits associated with the use of these products. Practitioners are advised to refer to the current approved product information and consider this safety information update, in addition to the current contraindications, warnings and precautions, when prescribing these products.

If you have any questions regarding this information, please contact Fresenius Kabi Medical Department at 0800-144-892 (toll-free) or e-mail Medical.Information@fresenius-kabi.com.

Please report any adverse reactions to HES solutions to CARM (https://nzphvc.otago.ac.nz/report/).

Sincerely,

Fresenius Kabi New Zealand Limited

Juan Villar
Managing Director

Ram Kamath
National Safety Officer