26 June 2020

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Direct Healthcare Professional Communication (DHPC)

Incorrect Information on the Primary and Secondary Labels of Viaflex Specials Products containing Sodium Chloride, Heparin Sodium, Potassium Chloride and Magnesium Sulfate

Dear Healthcare Professional,

Baxter Healthcare Limited in agreement with the Medicines & Healthcare products Regulatory Agency (MHRA) would like to inform you of the following:

- There are minor errors in the labelling of the medicines in Table 1 whereby the labels do not accurately reflect the mmol and mOsm/l content of the solutions or the chemical name of the salt forms used.
- In all cases the contents of the solutions (expressed in %w/v) are correct, and the affected batches conform to manufacturing specifications.
- The labelling errors are not considered to be a risk to patients, and the medicines can be used as normal. Therefore Baxter is not recalling these medicines and they can be used as normal. Healthcare professionals should be aware but are not required to take any further action.

Table 1: Affected product codes and lot numbers

Product Code	Lot Number	Product Name	Incorrect Details on Label	Label Should Read
FKB2472	19I02BF	Potassium Chloride 0.15% w/v, Sodium Chloride 0.45% w/v and Glucose 2.5% w/v Solution for Infusion 3000ml	225mmol sodium	231mmol sodium
			285mmol chloride	291mmol chloride
			glucose (as monohydrate)	glucose (as anhydrous)
FKB2481	20D01BY	Sodium Chloride 0.9% w/v, Magnesium Sulphate 0.4% w/v Solution for Infusion 250ml	38mmol sodium	38.5mmol sodium (39 with rounding)
			38mmol chloride	38.5mmol chloride (39 with rounding)
			332mOsm/l (approx)	340mOsm/l (approx)
			magnesium sulphate	magnesium sulfate heptahydrate
			Product name on primary and secondary labels - Sodium Chloride 0.9% w/v, Magnesium Sulphate 0.4% w/v Solution for Infusion	Product name on primary and secondary labels - Sodium Chloride 0.9% w/v, Magnesium Sulfate Heptahydrate 0.4% w/v Solution for Infusion

Product Code	Lot Number	Product Name	Incorrect Details on Label	Label Should Read
FKB2482	19I13BE	Sodium Chloride 0.9% w/v, Magnesium Sulphate 0.2% w/v Solution for Infusion 500ml	75mmol sodium	77mmol sodium
			75mmol chloride	77mmol chloride
			316mOsm/l (approx)	324mOsm/l (approx)
			magnesium sulphate	magnesium sulphate heptahydrate
			Product name on primary and secondary labels - Sodium Chloride 0.9% w/v, Magnesium Sulphate 0.2% w/v Solution for Infusion	Product name on primary and secondary labels - Sodium Chloride 0.9% w/v, Magnesium Sulfate Heptahydrate 0.2% w/v Solution for Infusion
FKB2483	19G02BE 19K28BL	Sodium Chloride 0.9% w/v, Magnesium Sulphate 0.1% w/v Solution for Infusion 1000ml	150mmol sodium	154mmol sodium
			150mmol chloride	154mmol chloride
			308mOsm/l (approx)	316mOsm/l (approx)
			magnesium sulphate	magnesium sulphate heptahydrate
			Product name on primary and secondary labels - Sodium Chloride 0.9% w/v, Magnesium Sulphate 0.1% w/v Solution for Infusion	Product name on primary and secondary labels - Sodium Chloride 0.9% w/v, Magnesium Sulfate Heptahydrate 0.1% w/v Solution for Infusion
	19K11BM 20B24BF	Heparin Sodium 1000 IU/L in 0.45% w/v Sodium Chloride IV Infusion 500ml	disodium hydrogen phosphate	disodium hydrogen phosphate dodecahydrate

Please ensure that a copy of this letter is sent to all relevant departments within your institutions to ensure that staff are aware.

Call for reporting

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▼

It is easiest and quickest to report ADRs online via the Yellow Card website - https://yellowcard.mhra.gov.uk/ or via the Yellow Card app available from the Apple App Store or Google Play Store.
Alternatively, prepaid Yellow Cards for reporting are available:

- by writing to FREEPOST YELLOW CARD (no other address details necessary)
- by emailing yellowcard@mhra.gov.uk
- at the back of the British National Formulary (BNF)
- by telephoning the Commission on Human Medicines (CHM) free phone line: 0800-731-6789
- by downloading and printing a form from the Yellow Card website (see link above)

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, onset, treatment dates, and product brand name.

For general questions regarding this communication, contact Baxter at uk_shs_fca@baxter.com

Reporting product quality complaints UK:

- Call: 01604 704 603
- Email: uk_shs_qa_complaints@baxter.com

Reporting adverse events with drugs:

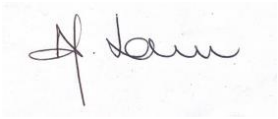
- Call: 01635 206 360
- Email: vigilanceuk@baxter.com

Reporting product quality complaints NI:

- Call**:** 00 353 1 206 5500
- Email**:** SHS_Complaints_Dublin@baxter.com

We apologise for any inconvenience this may cause you and your staff.

Sincerely,



Anna Lawson
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