



DRUG ALERT

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use
Distribute to Hospital Pharmacy Level

Date: 03 June 2019

EL (19)A/13

Our Ref: MDR 62-05/19

Dear Healthcare Professional,

Baxter Healthcare Limited

Potassium Chloride 0.15% w/v and Sodium Chloride 0.9% w/v PL 00116/0336
Solution for Infusion – BP, 1000ml, Product code FKE1764

Potassium Chloride 0.3% w/v and Sodium Chloride 0.9% w/v PL 00116/0337
Solution for Infusion, 1000ml, Product Code FKE1984

Potassium Chloride 0.15% w/v and Glucose 10% w/v Solution PL 00116/0656
for Infusion, 500ml Product Code FE3737

See Appendix 1 for tables showing potentially affected batches.

Brief description of the problem

Baxter Healthcare Limited has informed us that a quality defect has been identified with the above products where the front panel of a small number of infusion bags was found to be missing the red text.

The red text highlights the presence of potassium chloride in the product formulation which is a risk-mitigating factor in the prevention of a potential mix-up with other solutions for infusion. See Appendix 2 for correct label texts..

Advice for healthcare professionals

- Please check your complete inventory of the above products and inspect the print on each bag to ensure the presence of the red print. This includes stock within your pharmacy, on wards and at any other relevant location within your hospital'
- Please consider the possibility that the absence of red text may have resulted in units being stored in the incorrect location so please ensure that all locations where infusion bags are stored are checked.
- If units have been supplied to any other facilities or departments within your institution, please forward a copy of this letter to them.
- If you have any home patients who use these products, please notify them.



Should any units be identified without the red print, please place those units in quarantine and notify Baxter by email: uk_shs_qa_complaints@baxter.com or by telephone: 01604 704 603 (Baxter reference number: FA-2019-026).

Recipients of this Drug Alert should bring it to the attention of relevant contacts by copy of this letter.

Yours faithfully

**Defective Medicines Report Centre
10 South Colonnade
Canary Wharf
London
E14 4PU
Telephone +44 (0)20 3080 6574**



Appendix 1: Tables of affected batches

Potassium Chloride 0.15% w/v and Glucose 10% w/v Solution for Infusion, 500ml, PL 0116/0656, Product Code FE3737. Distributed from August 2017

Batch	Manufacture Date	Expiry Date
17H11T2G	11/08/2017	Jul-19
17L01T2F	01/12/2017	Nov-19
18C26T2C	26/03/2018	Feb-20
18C26T2CA	26/03/2018	Feb-20
18C26T2CB	26/03/2018	Feb-20
18I24T2H	24/09/2018	Aug-20
18J08T2A	08/10/2018	Sep-20
19D10T2C	10/04/2019	Mar-21

Potassium Chloride 0.15% w/v and Sodium Chloride 0.9% w/v Solution for Infusion – BP, 1000ml, PL 00116/0336, Product Code FKE1764. Distributed from August 2016

Batch	Manufacture Date	Expiry Date
16G13T2C	13/07/2016	Jun-19
16H03T1F	03/08/2016	Jul-19
16J10T1B	10/10/2016	Sep-19
16L12T1D	12/12/2016	Nov-19
17A26T2D	26/01/2017	Dec-19
17D25T1G	25/04/2017	Mar-20
17E31T1B	31/05/2017	Apr-20
17H22T2G	22/08/2017	Jul-20
17I28T2C	28/09/2017	Aug-20
17L02T1B	02/12/2017	Nov-20
17L22T2G	22/12/2017	Nov-20
18B02T1B	02/02/2018	Jan-21
18B02T1B	02/02/2018	Jan-21
18B03T1H	03/02/2018	Jan-21
18D06T1G	06/04/2018	Mar-21
18E15T2E	15/05/2018	Apr-21
18E15T2EA	15/05/2018	Apr-21
18G05T1C	05/07/2018	Jun-21
18H21T2D	21/08/2018	Jul-21
18I18T1E	18/09/2018	Aug-21
18J03T1F	03/10/2018	Sep-21
18K05T2C	05/11/2018	Oct-21
18K21T2H	21/11/2018	Oct-21
18L20T1D	20/12/2018	Nov-21
19B03T1E	03/02/2019	Jan-22
19D05T2A	05/04/2019	Mar-22





Potassium Chloride 0.3% w/v and Sodium Chloride 0.9% w/v Solution for Infusion, 1000ml, PL 00116/0337, Product Code FKE1984. Distributed from September 2016

Batch	Manufacture Date	Expiry Date
16H02T1B	02/08/2016	Jul-19
16I15T1B	15/09/2016	Aug-19
16J18T1A	18/10/2016	Sep-19
16K21T1D	21/11/2016	Oct-19
16L19T2G	19/12/2016	Nov-19
17B03T1D	03/02/2017	Jan-20
17B03T1DA	03/02/2017	Jan-20
17C15T2E	15/03/2017	Feb-20
17D18T1B	18/04/2017	Mar-20
17D18T1BA	18/04/2017	Mar-20
17E09T1B	09/05/2017	Apr-20
17F06T1F	06/06/2017	May-20
17G11T2A	11/07/2017	Jun-20
17I19T2A	19/09/2017	Aug-20
17K08T1H	08/11/2017	Oct-20
17L13T2B	13/12/2017	Nov-20
18A05T2B	05/01/2018	Dec-20
18A31T1B	31/01/2018	Dec-20
18B14T2C	14/02/2018	Jan-21
18C09T1G	09/03/2018	Feb-21
18D19T2B	19/04/2018	Mar-21
18D30T1F	30/04/2018	Mar-21
18E21T2C	21/05/2018	Apr-21
18F12T1G	12/06/2018	May-21
18F12T1GA	12/06/2018	May-21
18F19T1F	19/06/2018	May-21
18G19T1F	19/07/2018	Jun-21
18H29T2C	29/08/2018	Jul-21
18I19T1C	19/09/2018	Aug-21
18J17T2H	18/10/2018	Sep-21
18J24T2H	24/10/2018	Sep-21
18K20T2H	20/11/2018	Oct-21
18K25T2G	25/11/2018	Oct-21
19A07T1C	07/01/2019	Dec-21
19B04T2E	04/02/2019	Jan-22
19B18T2C	18/02/2019	Jan-22
19C19T2A	19/03/2019	Feb-22
19D07T2H	07/04/2019	Mar-22



Appendix 2: Label texts showing red text highlighting the presence of potassium chloride in the products.

FKE1764	
Baxter	
FKE1764	
	1000 ml
Potassium Chloride 0.15% w/v and Sodium Chloride 0.9% w/v	
Solution for Infusion BP	
Contains UN-55-01-069	
20 mmol potassium in 1000 ml	
Hypertonic	
pH 4.5 – 7.0 (approx)	Osmolarity 348 mOsm/l (approx)
Formula per 1000 ml	
Sodium Chloride 9.00 g	Potassium 20
Potassium Chloride 1.50 g	Sodium 154
Water for Injections qs	Chloride 174
IV administration	
Read package leaflet before use	
Keep out of the reach and sight of children	
Do not use unless solution is clear without visible particles and container undamaged	
Do not remove from overwrap until ready for use	
Do not reconnect partially used bags	
PL00116/0336 PA167/52/12	
Baxter Healthcare Ltd	
Thetford Norfolk IP24 3SE	
United Kingdom	
TH-35-01-531	
	
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LOT	
EXP	



Appendix 2 cont.

FKE1984	
Baxter	
Viaflo	
FKE1984	
1000 ml	
100	100
200	200
300	300
400	400
500	500
600	600
700	700
800	800
900	900

**Potassium Chloride 0.3% w/v
and
Sodium Chloride 0.9% w/v**

Solution for Infusion BP

Contains TH-55-01-030
**40 mmol
potassium
in 1000 ml**

pH 4.5 – 7.0 (approx)
Osmolarity 388 mOsm/l (approx)


Hypertonic


Formula per 1000 ml		mmol per 1000 ml (approx)	
Sodium Chloride	9.0 g	Potassium	40
Potassium Chloride	3.0 g	Sodium	154
Water for injections qs		Chloride	194

IV administration
Read package leaflet before use
Keep out of the reach and sight of children
Do not remove from overwrap until ready for use
Do not use unless solution is clear without visible particles
and container undamaged
Do not reconnect partially used bags

PL00116/0337 PA167/52/11
Baxter Healthcare Ltd
Thetford Norfolk IP24 3SE
United Kingdom

TH-35-01-599





POM 

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Appendix 2 cont.

FE3737	
Baxter	
FE3737	
	500 ml
Potassium Chloride 0.15% w/v & Glucose 10% w/v	
Solution for Infusion BP	
50	50
Contains 10 mmol potassium in 500 ml UN-55-01-072	
100	100
150	150
200	200
pH 3.5 – 6.5 (approx)	Hypertonic Osmolarity 595 mOsm/l (approx)
Formula per 500 ml mmol per 500 ml (approx)	
250	250
Glucose (as monohydrate) 50.0 g	Potassium 10
Potassium Chloride 0.75 g	Chloride 10
Water for Injections	
Hydrochloric acid	
300	300
IV administration	
Read package leaflet before use	
Keep out of the reach and sight of children	
350	350
Do not remove from overwrap until ready for use	
Do not administer simultaneously with blood	
through the same infusion equipment	
Do not use unless solution is clear without visible	
400	400
particles and container undamaged	
Do not reconnect partially used bags	
450	450
PL00116/0656	TH-35-01-768
	
	
LOT	EXP