



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 Solution for Infusion – BP, 1000ml, Product code FKE1764 **PL 00116/0336**

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

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

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 | |
| 600 pH 4.5 – 7.0 (approx) | Osmolarity 348 mOsm/l (approx) | 600 |
| Formula per 1000 ml | | |
| Sodium Chloride 9.00 g | Potassium 20 | |
| Potassium Chloride 1.50 g | Sodium 154 | |
| 700 Water for Injections qs | Chloride 174 | 700 |

IV administration
Read package leaflet before use

800 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


900

PL00116/0336 PA167/52/12 TH-35-01-531

Baxter Healthcare Ltd
Theford Norfolk IP24 3SE
United Kingdom



LOT EXP


5 413760 137544



Appendix 2 cont.

FKE1984

FKE1984

1000 ml

**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)

Hypertonic

Osmolarity 388 mOsm/l (approx)

| 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

POM 

LOT

TH-35-01-599




5 413760 137551

EXP




Appendix 2 cont.

FE3737



FE3737



500 ml

**Potassium Chloride 0.15% w/v
& Glucose 10% w/v**
Solution for Infusion BP

50

100

150

200

250

300

350

400

450

Contains UN-55-01-072

**10 mmol
potassium
in 500 ml**

50

100

150

200

250

300

350

400

450

| | |
|---|---|
| <p>pH 3.5 – 6.5 (approx)</p> | <p>Hypertonic Osmolarity 595 mOsm/l (approx)</p> |
| <p>Formula per 500 ml mmol per 500 ml (approx)</p> | |
| Glucose (as monohydrate) 50.0 g | Potassium 10 |
| Potassium Chloride 0.75 g | Chloride 10 |
| <p>Water for Injections Hydrochloric acid</p> | |



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 administer simultaneously with blood through the same infusion equipment
Do not use unless solution is clear without visible particles and container undamaged
Do not reconnect partially used bags


450 PL00116/0656

TH-35-01-768

450

LOT



5 413760 226439

EXP