



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.

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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

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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 |

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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

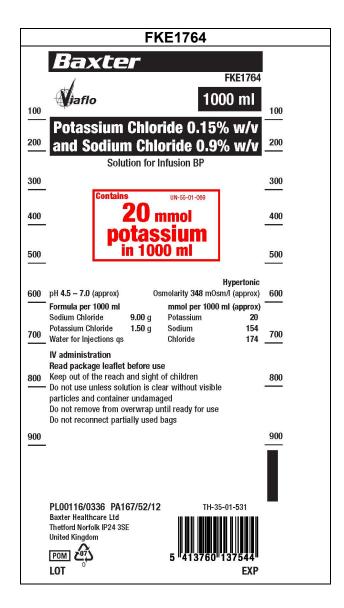
| Batch | Manufacture | Expiry |
|-----------|-------------|--------|
| | Date | Date |
| 16H02T1B | 02/08/2016 | Jul-19 |
| 16I15T1B | 15/09/2016 | Aug-19 |
| 16J18T1A | 18/10/2016 | Sep-19 |
| 16K21T1D | 21/11/2016 | Oct-19 |
| 16L19T2G | 19/12/2016 | Nov-19 |
| 17B03T1D | 03/02/2017 | Jan-20 |
| 17B03T1DA | 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 |

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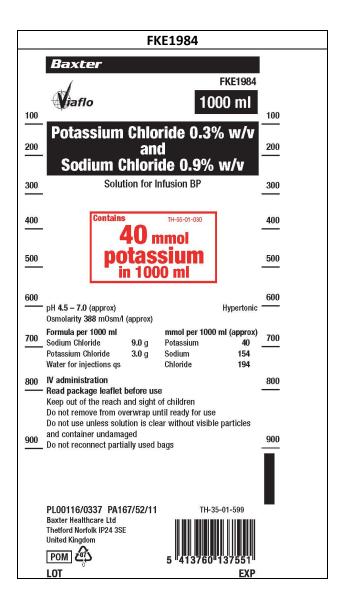
Appendix 2: Label texts showing red text highlighting the presence of potassium chloride in the products.



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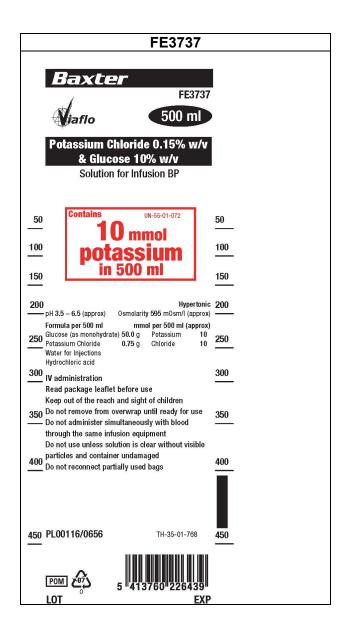
Appendix 2 cont.



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Appendix 2 cont.



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