Chief Medical Officer Directorate
Pharmacy and Medicines Division

Scottish Government
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IMMEDIATE MESSAGE TO:

1. Directors of Pharmacy
2. Medical Directors NHS Boards

22 May 2024

Dear Healthcare Professional,

DRUG ALERT CLASS 4 DRUG ALERT 17 2024 – CLASS 4 MEDICINES DEFECT INFORMATION CAUTION IN USE – FRESENIUS KABI LTD – SODIUM CHLORIDE 0.9% INTRAVENOUS INFUSION BP (FREEFLEX AND FREEFLEX PLUS)

Please see drug alert for onward transmission as below

Could all Directors of Pharmacy please forward this alert to:-

- Community Pharmacists
- Hospital Pharmacists
- Primary Care Pharmacists

Please could Medical Directors arrange to forward this alert on to:-

- General Practitioners
- Accident & Emergency Departments
- Directors of Public Health
- Relevant Clinics
- Chief Executives of NHS Board

Thank you for your co-operation.

Yours sincerely

IRENE FAZAKERLEY
Medicines Policy Team

Medicines & Healthcare products Regulatory Agency

M E D I C I N E S N O T I F I C A T I O N

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use
Distribute to Pharmacy / Wholesaler Level

Date: 22 May 2024 EL (24)A/17 Our Ref: MDR 035-05/24

Dear Healthcare Professional,

Fresenius Kabi Limited

Sodium Chloride 0.9% Intravenous Infusion BP [Freeflex] **PL 08828/0084**

SNOMED Code: 40546011000001103

Batch Number	Expiry Date	Pack Size	First Distributed	Error type
13SKL101	30/09/2026	20 x 500 ml	23/01/2024	No PIL in the box
13TAL213	31/12/2026	20 x 500 ml	06/03/2024	No PIL in the box

Sodium Chloride 0.9% Intravenous Infusion BP [Freeflex] **PL 08828/0084**

SNOMED Code: 40545411000001103

Batch Number	Expiry Date	Pack Size	First Distributed	Error type
13SMF061	30/11/2026	30 x 250 ml	Not yet distributed	No PIL in the box
13TBF281	31/01/2027	30 x 250 ml	Not yet distributed	No PIL in the box

Sodium Chloride 0.9% Intravenous Infusion BP [Freeflex Plus] **PL 08828/0084**

SNOMED Code: 42071711000001100

Batch Number	Expiry Date	Pack Size	First Distributed	Error type
13SLF242	31/10/2025	50 x 100 ml	17/01/2024	Outdated PIL
13TAF173	31/12/2025	50 x 100 ml	29/03/2024	Outdated PIL

Active Pharmaceutical Ingredient: Sodium Chloride 0.9% w/v

Brief description of the problem
Fresenius Kabi Limited have informed the MHRA of a packaging error with specific batches of Sodium Chloride Intravenous Infusion 0.9% Freeflex and Freeflex PLUS. Some batches were packaged without the patient information leaflet (PIL), and some were packaged with an older version of the PIL.

Although two of batches that have been packaged without a PIL have not yet been distributed, due to the consideration of supply and that Fresenius Kabi Limited will be providing printed copies of the correct PIL, these batches will not be repackaged and will continue to be distributed.

The current approved version of the PIL contains an additional product name (Freeflex ProDapt) and a 2D data matrix. Freeflex ProDapt is not marketed in the UK, however a common PIL is used for the various presentations of the product. The 2D matrix contains information about the product batch number, expiry dates and the GTIN reference, which are also present in human readable format on the product.

The affected texts in the older PIL (revised 09/2016) and the correct texts in the current approved PIL (revised 01/2022) are detailed below:

Affected texts in older PIL	**Corrected texts in current approved PIL**
Product name: Sodium Chloride 0.9% Intravenous Infusion BP as Steriflex No 1 or Freeflex or Freeflex Plus • Keep this leaflet. You may need to read it again. • If you have any further questions, ask your doctor or pharmacist. • This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours. • If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.	Product name: Sodium Chloride 0.9% Intravenous Infusion BP as Steriflex No 1 or Freeflex or Freeflex Plus or **Freeflex ProDapt** **Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.** • Keep this leaflet. You may need to read it again. • If you have any further questions, ask your doctor or pharmacist. • This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours. • If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. **See Section 4**
Section 4: If the side effects gets serious please tell your doctor or pharmacist.	Section 4: If the side effects gets serious please tell your doctor or pharmacist. **Reporting of side effects** **If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store** **By reporting side effects you can help provide more information on the safety of this medicine.**

Section 6: What Sodium Chloride 0.9% intravenous infusion looks like and contents of the pack. Sodium Chloride Intravenous Infusion BP is a clear solution of sodium chloride in water. The solution is contained in a sealed plastic container, known as a Steriflex® bag or freeflex bag, or freeflex bag	Section 6: What Sodium Chloride 0.9% intravenous infusion looks like and contents of the pack. Sodium Chloride Intravenous Infusion BP is a clear solution of sodium chloride in water. The solution is contained in a sealed plastic container, known as a Steriflex® bag or freeflex bag, or freeflex bag **or freeflex ProDapt.**

Advice for healthcare professionals
This notification is intended to inform healthcare professionals of the discrepancy with the PIL for specific batches of product. There is no product quality nor patient safety-related implications with this issue.

Fresenius Kabi Limited have confirmed that printed copies of the correct PIL will accompany the future delivery/order of these batches.

The current approved PIL is also available on the MHRA website which may be accessed here.

Advice for patients
The product quality and safety are not affected by this issue. Patients should continue using medicines from these batches as prescribed by your healthcare professional.

Patients who experience adverse reactions or have any questions about the medication, should seek medical attention. Any suspected adverse reactions should also be reported via the MHRA Yellow Card scheme.

Further Information
For more information or medical information queries please email Medical.Information-UK@fresenius-kabi.com or telephone +44 (0) 1928533575.

For stock control enquiries please contact FK.complaints-uk@fresenius-kabi.com or telephone +44 (0) 1928 533758.

Recipients of this Medicines Recall should bring it to the attention of relevant contacts by copy of this notice. NHS regional teams are asked to forward this to community pharmacists and dispensing general practitioners for information.

Yours faithfully

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