

Date: 15th April 2026

DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION

**Sodium Chloride 0.9% solution for infusion(PL 08828/0084):
Interim Supply of USA Labelled Stock to Mitigate Supply Disruption**

Dear Healthcare Professional,

Summary: Fresenius Kabi is currently experiencing supply disruption with Sodium Chloride 0.9% solution for infusion in the UK.

To ensure continuity in supply, Fresenius Kabi has obtained approval from the MHRA to supply USA labelled stock Sodium Chloride 0.9% solution for infusion. The batch number concerned are listed in below Annex B which is expected to be on the UK market from May 2026 to expiry date mention in below Annex B for each batch no.

Please note the following:

- This product is considered licensed in the UK.
- The product from USA has the same formulation as the UK product.
- The product from USA is manufactured according to the same manufacturing process and quality controls as the UK product.
- There are minor differences between the USA and UK product information. Key differences between the USA and UK licensed product is the storage condition on labelling, In the US, the labelled storage conditions are: "Store at 20°C to 25°C. Protect from freezing." In the UK the labelled storage conditions are: "Store between 2°C and 25°C." the discrepancy is purely regulatory and not related to product performance or stability , so you can followed UK storage condition which is "Store between 2°C and 25°C." Please ensure the UK Summary of Product Characteristics (SPC) and Patient Information Leaflet (PIL) are followed.
- Please refer to the UK approved SPC and PIL supplied electronically with the USA packs. Discard the USA leaflet in the pack.
- For additional copies of the leaflet, please refer to <https://www.medicines.org.uk/emc/> or contact the company contact point (see below).
- The MHRA has agreed to an exemption granted in accordance with regulation 266(4)(a) and (b) of the Human Medicines Regulations (HMR) 2012, from the obligation that certain particulars should appear on the outer and immediate packaging of USA and that the information must be given in English .



Please ensure all relevant staff are made aware of the content of this letter and that the information is communicated to the patients.




Fresenius Kabi Limited
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Eastgate Way
Manor Park
Runcorn
WA7 1NT
United Kingdom
www.fresenius-kabi.co.uk

- The USA labelled product is shown below.


Outer label pack of 30 Of 250ml(Item code-0753881/00 US)

NDC 63323-623-74	623174	QTY 30
0.9% Sodium Chloride Injection, USP		
250 mL x 30		63592 0753881/00 US
Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Protect from freezing.		
Manufactured for:  FRESENIUS KABI Lake Zurich, IL 60047 Made in Germany		
 (01)30363323623747		
LOT		
EXP		

Inner label pack of 30 Of 250ml (Item code-0717121/01 US)



NDC 63323-623-74



free flex[®]

250 mL

0.9% Sodium Chloride Injection, USP
 For intravenous use. Rx only

50 Each 100 mL contains: Sodium Chloride 900 mg
 in water for injection.
 Electrolytes per 1,000 mL:

Sodium	154 mEq
Chloride	154 mEq
308 mOsmol/LITER (CALC.)	pH 4.5 to 7.0

100 Single Dose Only. Discard Unused Portion.


Additives may be incompatible. Consult with pharmacist. When introducing additives, use aseptic technique, mix thoroughly and do not store. Use only if solution is clear and container is undamaged. Must not be used in series connections.

Usual dosage: See package insert.

150 **STORE AT: 20° to 25°C (68° to 77°F)** [see USP Controlled Room Temperature]. Protect from freezing.


The container closure is not made with natural rubber latex. Non-PVC, Non-DEHP, Sterile.

200



(01)00363323623746

Mfd. for:




**FRESENIUS
KABI**

LOT


Lake Zurich, IL 60047
 Made in Germany EXP

www.fresenius-kabi.com/us

403383A



0717121/01 US





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Cestrian Court
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WA7 1NT
United Kingdom
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Outer label pack of 10 Of 1000ml (Iteam code – 0753781/00 US)


NDC 63323-623-76 623176

0.9% Sodium Chloride Injection, USP
1,000 mL x 10

Store at 20° to 25°C (68° to 77°F)
[see USP Controlled Room Temperature].
Protect from freezing.

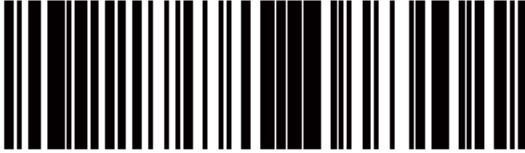
QTY 10

Manufactured for:

 **FRESENIUS
KABI**







Lake Zurich, IL 60047
Made in Germany

LOT
EXP



0753781/00 US (01)10363323623767

Inner label pack of 10 Of 1000ml (Item code- 0716951/00 US)

100								
	free flex[®]	1,000 mL						
	0.9% Sodium Chloride Injection, USP							
200	For intravenous use. Rx only							
300	<p>Each 100 mL contains: Sodium Chloride 900 mg in water for injection. Electrolytes per 1,000 mL:</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 80%;">Sodium Chloride</td> <td style="text-align: right;">154 mEq</td> </tr> <tr> <td></td> <td style="text-align: right;">154 mEq</td> </tr> <tr> <td>308 mOsmol/LITER (CALC.)</td> <td style="text-align: right;">pH 4.5 to 7.0</td> </tr> </table>		Sodium Chloride	154 mEq		154 mEq	308 mOsmol/LITER (CALC.)	pH 4.5 to 7.0
Sodium Chloride	154 mEq							
	154 mEq							
308 mOsmol/LITER (CALC.)	pH 4.5 to 7.0							
	Single Dose Only. Discard Unused Portion.							
400	Additives may be incompatible. Consult with pharmacist. When introducing additives, use aseptic technique, mix thoroughly and do not store. Use only if solution is clear and container is undamaged. Must not be used in series connections.							
	Usual dosage: See package insert.							
500	STORE AT: 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Protect from freezing.							
	The container closure is not made with natural rubber latex. Non-PVC, Non-DEHP, Sterile.							
600	 3 NDC 63323-623-76 0							
700	Mfd. for:  FRESENIUS KABI Lake Zurich, IL 60047 Made in Germany www.fresenius-kabi.us 403231	LOT EXP						
mL								
	0716951/00 US							

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 ▼

You can report via:

- the [Yellow Card website](#)
- the free Yellow Card app available from the Apple App Store or Google Play Store
- some clinical IT systems (EMIS/SystemOne/Vision/MiDatabank) for healthcare professionals

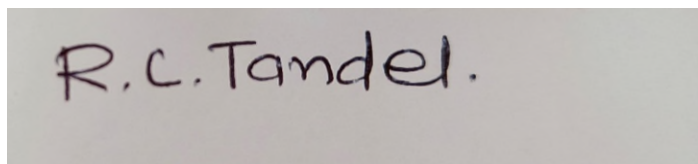
Alternatively, you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm.

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

Company contact point

If you have any questions about this letter or wish more information about Sodium Chloride 0.9% Solution for Infusion, please contact Fresenius Kabi Limited at medical.information-UK@fresenius-kabi.com.

Yours faithfully,



Riddhi Tandel
Regulatory Affairs Officer
Fresenius-Kabi Ltd

Annex-B

Product name	Batch	Expiry date
Sodium Chloride 0.9% Solution for Infusion 250ml	14TM7125	30/11/27
	14UA7125	31/12/27
	14UA7126	31/12/27
	14UA7127	31/12/27
	14UB7111	31/01/28
	14UB7112	31/01/28
	14UB7113	31/01/28
	14UB7114	31/01/28
	14UB7115	31/01/28
	14UB7116	31/01/28
	14UB7117	31/01/28
	14UB7118	31/01/28
	14UB7119	31/01/28

Product name	Batch	Expiry date
Sodium Chloride 0.9% Solution for Infusion 1000ml	14UG7113	30/06/2028
	14UG7112	30/06/2028
	14UG7114	30/06/2028
	14UG7115	30/06/2028
	14UG7116	30/06/2028
	14UG7117	30/06/2028
	14UG7118	30/06/2028
	14UG7119	30/06/2028
	14UG7120	31/07/2028