

May 2025

Direct Healthcare Professional Communication

ACCUSOL 35 Potassium 4 mmol/L solution for haemofiltration (BWPE04): labelling defect

Dear Healthcare professional,

Nikkiso Belgium in agreement with The Medicines and Healthcare products Regulatory Agency (MHRA) would like to inform you of a labelling defect of the Accusol 35 Potassium 4 mmol/L solution bag. We are sending you this communication as a precaution since the mislabeling may cause confusion. **PLEASE NOTE: the below detailed mislabeling has no impact on the product quality and there is no safety risk to the patient or healthcare professional.**

Summary

During a quality check of the Accusol 35 Potassium 4 mmol/L bag label inconsistencies were found (Picture A):

- Presence of 2 additional storage conditions which are incorrect: 'Store below 30 °C' and 'Keep in dry place'
- Absence of POM (Prescription Only Medicine) icon
- Absence of Marketing Authorization license number (PL44204/0003)

The additional storage conditions on the bag label are incorrect and should not be followed. The remaining conditions are correct.

The impacted products can continue to be used as per usual practice.

PM-0245-04/2025-1

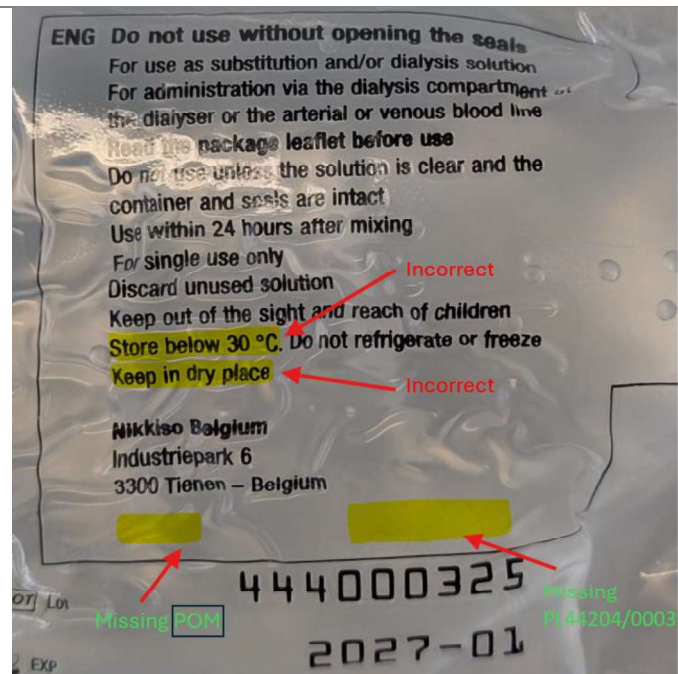
Nikkiso America, Inc.
7676 Hazard Center Drive, Suite 40
San Diego CA 92121,
United States
+1-858-222-6300

Nikkiso Europe GmbH
Desbrocksriede 1
30855 Langenhagen
Germany
+49-511-6799990

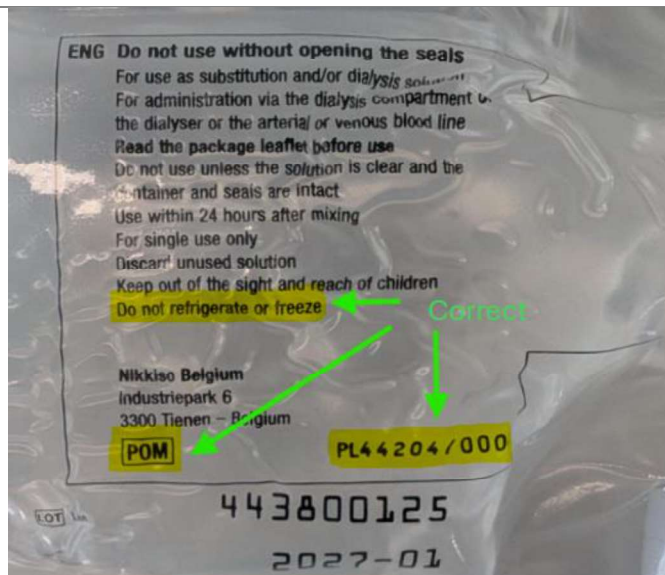
Nikkiso Belgium bv
Industriepark 6
3300 Tienen
Belgium
+32-16-781-771

Nikkiso Co., Ltd.
20-3, E bisu 4C home, Shibuya-ku,
Tokyo 1506022
Japan
+81-3-3443-3727

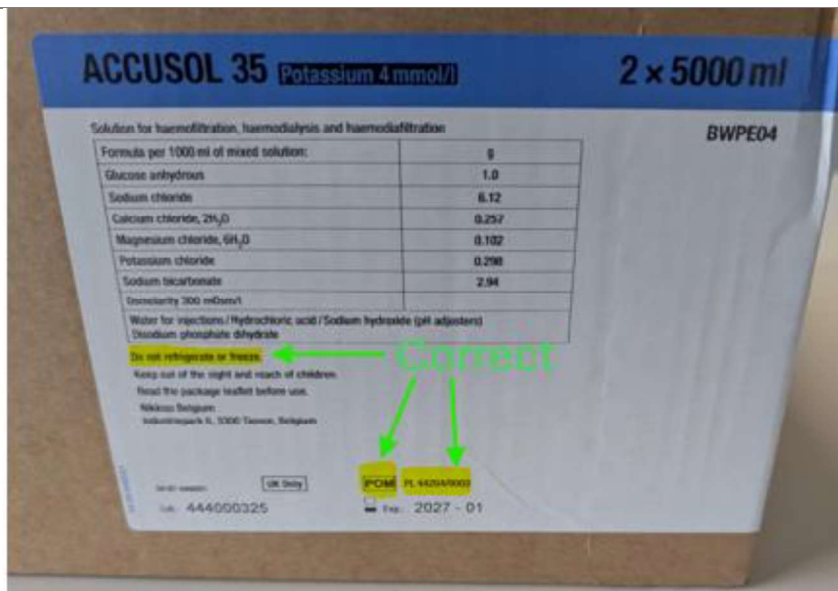
A. Picture of Mislabelled Accusol bag



B. Picture of Correctly labelled Accusol bag



C. Picture of Correctly labelled Accusol box



PM-0245-04/2025-1

Nikkiso America, Inc.
7676 Hazard Center Drive, Suite 40
San Diego CA 908,
United States
+1-858-222-6300

Nikkiso Europe GmbH
Desbrocksriede 1
30855 Langenhagen
Germany
+49-511-6799990

Nikkiso Belgium bv
Industriepark 6
3300 Tienen
Belgium
+32-16-781-771

Nikkiso Co., Ltd.
20-3, E bisu 4C home, Shibuya,
Tokyo 156022
Japan
+81-3-3443-3727

Please note that the storage conditions mentioned on the Accusol 35 Potassium 4 mmol/L **box label** (Picture C) and **the Patient Information Leaflet** are correct and should be followed. The Accusol 35 Potassium 4 mmol/L box label also has the POM icon and Marketing Authorization license number (PL44204/0003) present (Picture C).

Impacted Product Information

Product name:	ACCUSOL 35 Potassium 4 mmol/L	
Product code:	BWPE04	
Product description:	Solution for haemofiltration, haemodialysis and haemodiafiltration	
Impacted Batch numbers:	444000125 444000225 444000325 444000425 444000525	444000625 444000725 444000825 444000925 444001025

Accusol 35 is indicated for the treatment of acute and chronic renal failure, as substitution solution in haemofiltration and haemodiafiltration, and as dialysis solution in haemodialysis and haemodiafiltration.

Accusol 35, Potassium 4 mmol/L is primarily intended for use in patients with hypokalaemia and normokalaemia.

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](https://www.yellowcard.gov.uk/)
- the free Yellow Card app available from the Apple App Store or Google Play Store
- some clinical IT systems (EMIS/SystmOne/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.

PM-0245-04/2025-1

Nikkiso America, Inc.
7676 Hazard Center Drive, Suite 40
San Diego CA 92161
United States
+1-858-222-6300

Nikkiso Europe GmbH
Desbrocksriede 1
30855 Langenhagen
Germany
+49-511-6799990

Nikkiso Belgium bv
Industriepark 6
3300 Tienen
Belgium
+32-16-781-771

Nikkiso Co., Ltd.
20-3, Ebisu 4-chome, Shibuya-ku,
Tokyo 150-0022
Japan
+81-3-3443-3727

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 or concerns arising from this customer communication, please contact your direct Nikkiso contact or send an email to Quality@nikkisomedical.com.

Thank you in advance for your support on this important matter.

Respectfully,

Kieron O'Neil,

UK national PV contact
Sr. Director, Global Sales &
Marketing
KONeil@nikkisomedical.com



Jöelle Abi Char,

Responsible Person
Sr. Quality Manager
JAChar@nikkisomedical.com



Anik Hermans,

Deputy EU/UK QPPV
MA/Vigilance Manager
Ahermans@nikkisomedical.com

