

Urgent Field Safety Notice

Rociale Healthcare Limited

RSET5003 Pack Minor Op (Bronze)

Date: 06/08/2025

FSN 2025-01

Details of affected devices:

Some individual packs of Rociale RSET5003 Pack Minor Op (Bronze), Lot no. W556093, have been mislabelled.

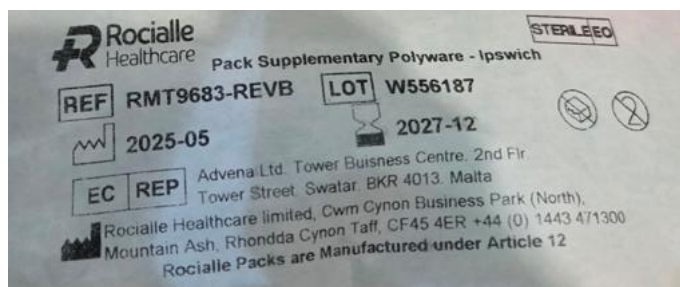
Description of the problem:

Some individual packs of Rociale RSET5003 Pack Minor Op (Bronze), Lot no. W556093 are labelled as RMT9683 Lot no. W556187. The case label for the products is correct but some of the packs within each case are incorrect.

Case Label - correct



Incorrect Pack Label



Correct Pack Label



Rear View of Pack – correct in all cases



Please note that this is a labelling issue only and that there is no impact on the contents of the pack. Approximately one third of all packs are affected.

Action to be taken by the user:

Rociale are kindly requesting that customers log this issue on the Rociale customer complaint portal here: [Report a Problem - Rociale AcuteCare](#), after which the customer services team will organise the uplift and replacement of any remaining stock of RSET5003 Pack Minor Op (Bronze), Lot no. W556093.

Transmission of this Field Safety Notice: (if appropriate)

This notice needs to be passed on all those who need to be aware within your organisation, or to any organisation where the potentially affected products may have been transferred (if appropriate).

Please transfer this notice to other organisations on which this action has an impact, if appropriate.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action, if appropriate.

Contact reference team:

If you have any queries regarding this Field Safety Notice, please contact:

Rociale Healthcare Limited
Regulatory Team
Ty Mynydd
Cwm Cynon Business Park (North)
Mountain Ash
Rhondda Cynon Taff
CF45 4ER

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