

Field Safety Notice

Product Codes: IVS01 (INS)
Brand: 1ml Luer Slip IV Syringe Insulin
Batch: 19070104, 21030104 and 22010103
MHRA ref: 2024/004/003/601/090
Ref: FSN-010
Date: 16 April 2024

Field Safety Notice: IV syringe Luer Slip for Insulin Use

Attention

All users of 1ml Luer Slip IV Syringe Insulin

Device Description

Medicina IVS01 (INS), 1ml Luer Slip IV Syringe Insulin for insulin usage only.

Product Code, Description and Batch Numbers

Code	Description	Batch
IVS01 (INS)	1ml Luer Slip IV Syringe Insulin	19070104 21030104 22010103

Reason for Field Safety Notice

This notice is issued to inform users that whilst the primary packaging of the batches of syringes listed above is orange, the printing of the barrel is black. Only the batches listed above are affected.

This is not in line with our specification for this product. However, the graduation markings on the syringe accurately display measurements suitable for insulin administration (units), aligning with insulin dosing requirements. This notice is to highlight to users that extra care should be taken to ensure that syringe graduation markings with 'units' not 'ml' should be used to administer insulin, and that this should always be checked prior to administration.

This notice aims to ensure transparency and uphold our commitment to maintaining product quality and safety standards.



Hazards associated with use of the recalled product

Detectability:	Visible during use of the device
Probability of adverse health impact	Not likely
Immediate Risk:	None
Long Term Risk:	None
Potential Harm:	There is no risk of harm when used as intended, the primary packaging features the appropriate colour coding. The graduation markings display accurate measurements suitable for insulin use.

Action to be taken

- Please carefully read this Field Safety Notice and return the Acknowledgement Form
- Please distribute throughout your organisations and to relevant personnel
- If you have any questions or queries in relation to this notice, please contact us using the information below

Contact information regarding FSN

Maria Ziden - QMS Manager
Unit 2, Rivington View Business Park, Station Road, Blackrod, Bolton BL6 5BN
Email: quality.administrator@medicina.co.uk Tel: 01204 695050 Fax: 01204 697755



Acknowledgement Form: FSN-010 Field Safety Corrective Action

Product Codes: IVS01 (INS)

Brands: 1ml Luer Slip IV Syringe Insulin

Please confirm you have received the notice by completing this form and returning it to us by post or email as soon as possible.

Acknowledgement

We confirm receipt of this Field Safety Notice FSN-010 and that this is received, read, and distributed to anyone it may concern within our organisation and/or to our customers (for distributors).

Organisation Name:	
Department:	
Representative Name and Signature:	
Date:	

Please return the Acknowledgement Form to:

Maria Ziden - QMS Manager
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