Date: 29th May 2025

Moviprep powder for Oral Solution - PI1411/06901A

CLARIFICATION ON LABELLING

Dear Healthcare Professional,

EJ Busuttil, in agreement with the Medicines Authority, would like to inform you about the labelling information for Moviprep Powder for Oral Solution, authorised under PI1411/06901A.

SUMMARY

Kindly note that the following batches of Moviprep have been placed on the local supply chain. Following a review of molar calculations of ascorbate in this product, concentration of ascorbate was amended. The old (incorrect) concentration may still be present on the product.

BACKGROUND OF SAFETY CONCERN

The following batches may have Incorrect label/information of ascorbate (mmol/l)

Batch number	EXP date	ORIGINAL PACK in POLISH		OVER LABEL IN ENGLISH	
		OUTER PACK	PIL	OUTER PACK	PIL
430370	01/10/2026	29.8	29.8	56.5	56.5
430369	01/10/2026	29.8	29.8	56.5	56.5
430368	01/09/2026	29.8	29.8	56.5	56.5
432311	01/10/2026	29.8	29.8	56.5	56.5
432312	01/11/2026	29.8	29.8	56.5	56.5
437485	01/01/2027	56.5	56.5	29.8	56.5
437484	01/01/2027	56.5	56.5	29.8	56.5
432314	01/01/2027	56.5	56.5	29.8	56.5
432315	01/01/2027	56.5	56.5	29.8	56.5

CORRECT LABELLING

The correct amount of total ascorbate on both the PIL and on the Outer label should read 56.5 mmol/l. This has been corrected by a variation submitted by the manufacturer.

The approved labelling and PIL can be accessed from here or

The approved SPC can be accessed from here

Alternatively use this link: https://limewire.com/d/TyY4e#Ox0IlcqSlm

CALL FOR REPORTING

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via their national reporting system. Report forms can be downloaded from www.medicinesauthority.gov.mt/adrportal. Alternatively, this can be reported directly to EJ Busuttil on safety@ejbusuttil.com.

COMPANY CONTACT POINTS

Should you require further assistance, or require physical copies of the latest product information kindly contact us on 21447184 or safety@ejbusuttil.com.

This letter is being sent as a clarification measure following an exemption granted by from the competent authority to ensure patient safety .