

06 March 2024

URGENT MEDICINE RECALL – CLASS II – TYPE B

Dear Healthcare Professional

Pharma Dynamics (Pty) Ltd, in collaboration with SAHPRA and following the detection of discoloured ampoule content, initiates an immediate recall of the following product:

Product Name	Dosage Form	Registration Number	Pack Size	Batch Number
Emistop 4 mg	Solution for injection (2 ml)	A45/5.10/0386	Five ampoules packed in an outer carton	B5G0138A

Elevated levels of an unknown impurity were detected in the affected product and the ampoule appearance deviates from the Professional Information indicating a clear and colourless solution.

Healthcare Professionals are urged to return all inventory of the affected EMISTOP 4 mg batch to their relevant distributor and/or wholesaler as soon as possible for reimbursement.

For further product information or medical queries, please call Pharma Dynamics (Pty) Ltd (021 707 7000) or email pharmacovigilance@pharmadynamics.co.za.

We appreciate your co-operation and sincerely regret any inconvenience this may have caused.

Yours sincerely



Celeste Naude

Responsible Pharmacist

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