

20 October 2022

URGENT MEDICINE RECALL

CLASS III Type C

Dear Healthcare Professional,

Pharma Dynamics (Pty) Ltd in collaboration with SAHPRA hereby, following the detection of non-conformances to the Medicines and Related Substances Act (Act 101 of 1965), in terms of the printed packaging material of LANCAP 15 mg (14 capsules) - Registration number: A40/11.4.3/0247, initiates an immediate recall of the following batches:

Product	Batch No	Expiry date	Batch quantity
Lancap 15 mg Capsules (14's)	SJ2758	01 March 2024	16 008
Lancap 15 mg Capsules (14's)	SJ3425	01 November 2023	171
Lancap 15 mg Capsules (14's)	SJ2652	01 March 2024	20 482
Lancap 15 mg Capsules (14's)	SJ8693	01 August 2024	81 239

Reason for recall:

- Incorrect information contained per the printed packaging components (carton and label) in terms of:
 - Scheduling status (S4)
 - Statement: "Available without a prescription for short term treatment." directly below the S4.
 - Indications

The non-conformance poses no risk to patient safety.

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DIRECTOR CF Roos (CEO) • **NON-EXECUTIVE DIRECTORS** TR Volle*, D Chakravorty*, S Makharia*, S Mumtaz*
Registration No. 2001/001124/07 *Foreign Resident

As a result, Pharma Dynamics (Pty) Ltd wishes to recall LANCAP 15 mg (14 capsules), [S4], Registration number: A40/11.4.3/0247 as indicated in the table above and will resume supply once all measures have been put in place to ensure the corrected packaging material is available.

Healthcare professionals are urged to return all inventory of LANCAP 15 mg (14 capsules), [S4] medication to their relevant distributor and/or wholesaler as soon as possible for reimbursement. We request you to retain this letter in a prominent position for one month in the event of stock being in transit.

We appreciate your cooperation and sincerely regret any inconvenience this may have caused.

For any further information please contact:

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Sincerely

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