



Abbott Laboratories South Africa (Pty) Ltd
Reg. No. 1940/014043/07
Abbott Place, 219 Golf Club Terrace
Constantia Kloof 1709
P.O. Box 7208, Weltevredenpark 1715
South Africa
Tel: 011 858 2000
Fax: 011 858 2070

IMPORTANT
MEDICINE SAFETY INFORMATION

04 September 2023

Dear Healthcare Professional,

Abbott Laboratories SA (Pty) Ltd, as directed by the South African Health Products Regulatory Authority (SAHPRA), wish to inform you that it has obtained a Section 36 exemption to distribute a designated batch of Klacid XL[®] tablets registered for Vietnam market in South Africa. Abbott Laboratories are experiencing a delay in production from the manufacturing site and anticipate shortages of Klacid XL[®] in emerging markets. Given the advent of the influenza season in South Africa, with the potential for increased hospital admissions, Abbott Laboratories SA (Pty) Ltd sought to prevent stock shortages for those patients that require treatment with Klacid XL tablets. The approved Section 36 exemption allows for the distribution of Klacid MR[®] 500mg tablets packed for Vietnam, with **Batch number:** 1182082
Expiry date: 01 February 2026

Abbott Laboratories Pty(Ltd) would like to inform you that, as the outer carton, primary label, Professional Information (PI), and Patient Information Leaflet (PIL) will be those of Vietnamese pack, it is important to refer to the South African PI/PIL available on the SAHPRA PI/PIL repository and can be accessed on: <https://pi-pil-repository.sahpra.org.za>.

Summary

Klacid XL[®] is a medium to broad spectrum antibiotic indicated for the treatment of:

- Lower respiratory tract infections e.g., bronchitis, pneumonia.
- Upper respiratory tract infections e.g., pharyngitis, sinusitis.
- Skin and soft tissue infections e.g., folliculitis, cellulitis.

Advise to healthcare professionals.

- Healthcare professionals are alerted to note the difference in artwork between the Vietnamese pack and the South African registered pack in Table 1.
- Healthcare professionals are advised to refer to the PI/PIL from SAHPRA repository for dosing information approved by SAHPRA.
- As this is a scheduled substance, healthcare professionals must advise the patient during prescribing and/or dispensing of Klacid XL[®] 500mg on the packaging differences between the Vietnamese pack and the South African pack. With any uncertainty the healthcare professional may email medical queries to Medicalinfo.za@abbott.com or call +27 66 484 8543 to speak to medical officer.
- Healthcare professionals are urged to report adverse drug reactions (ADRs), or product quality issues (including batch details) related to Klacid MR[®] 500mg tablets to Abbott Laboratories (Pty) Ltd via email: pv.south-africa@abbott.com or call: 011 858 2000. Alternatively, healthcare



Abbott Laboratories South Africa (Pty) Ltd
Reg. No. 1940/014043/07
Abbott Place, 219 Golf Club Terrace
Constantia Kloof 1709
P.O. Box 7208, Weltevredenpark 1715
South Africa
Tel: 011 858 2000
Fax: 011 858 2070



professionals may complete the ADR reporting form accessible via the SAHPRA website and email it to adr@sahpra.org.za.

- Healthcare professionals may also use eReporting link available on SAHPRA website (www.sahpra.org.za). Additionally, reporting can be done via Med Safety App. The Application can be downloaded onto a smart phone via Google play or App store. For more information on ADR reporting of products listed below, please contact the SAHPRA Vigilance unit at pvqueries@sahpra.org.za.

Table 1: Noticeable labelling differences between Vietnamese Klacid MR[®] and South African Klacid XL[®] 500 mg Tablets

	South Africa (currently registered)	Vietnam (Alternative source)
Proprietary Name	Klacid XL [®]	Klacid MR [®]
Languages <ul style="list-style-type: none">LabelCartonProfessional Information	English/Afrikaans English/Afrikaans English/Afrikaans	English English/Vietnamese Vietnamese
Scheduling Status	S4	Prescription only
Registration Number	31/20.1.1/0379	VN-21161-18
Market Authorization Holder	Abbott Laboratories S.A.(Pty) Ltd	Abbott Laboratories (Singapore) Limited

Yours Faithfully,

DocuSigned by:

 Signer Name: Gugulethu Mabuza
Signing Reason: I approve this document
Signing Time: September 5, 2023 | 1:40:33 AM PDT
E216BA18D7DC40E1A1196E65C02CBE0B

Name: Gugulethu Mabuza

Head of Quality & Responsible Pharmacist English Africa Cluster

Directors: K. Mabaso, K. Peterson