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IMPORTANT MEDICINE SAFETY INFORMATION
SECTION 36 APPROVAL - PHENYLEPHRINE HYDROCHLORIC INJECTION™

25 April 2024

Dear Healthcare Professional,

In collaboration with the South African Health Products Regulatory Authority (SAHPRA), Abbott Laboratories SA (Pty) Ltd, would like to inform you that Phenylephrine hydrochloric injection™ has been up scheduled from **Schedule 1** to **Schedule 4** status. However, Abbott is experiencing unforeseen delays in the implementation of the artwork following the up scheduling of this product.

In order to ensure seamless continuity of treatment with Phenylephrine hydrochloric injection™ and allow for the packaged product to be distributed in the market, SAHPRA granted all batches produced until **30 June 2024** an exemption from the assigned **Schedule 4** status. Phenylephrine hydrochloric injection™ stands as an essential medicine, indicated to raise blood pressure in adults with clinically significant hypotension primarily stemming from vasodilation, as witnessed in contexts such as septic shock or anaesthesia.

Advice to Healthcare professionals

- Healthcare professional should take note of the current labelling on the outer carton of Phenylephrine hydrochloric injection™, reflecting a scheduling status of Schedule 1 as opposed to the intended Schedule 4 status. Healthcare professionals should further note that, SAHPRA has granted Phenylephrine hydrochloric injection™ batches produced until 30 June 2024 an exemption from the assigned Schedule 4 status.
- Healthcare professionals are encouraged to refer to the approved Phenylephrine hydrochloric injection™ Patient Information Leaflet (PIL) and Professional Information (PI) available on the SAHPRA repository via this link: https://pi-pil-repository.sahpra.org.za.
- Healthcare professionals are urged to report adverse drug reactions (ADRs), or product quality issues related to Phenylephrine hydrochloric injection™ to SAHPRA via the following eReporting link https://primaryreporting.who-umc.org/ZA or to Abbott Laboratories (Pty) Ltd via email: pv.south-africa@abbott.com, QualityAssurance.ZA@abbott.com or call: **011 858 2000**.
- Alternatively, healthcare professionals may complete the ADR reporting form accessible via this link: https://www.sahpra.org.za/document/adverse-drug-reactions-and-quality problemreportingform/ and email it to adr@sahpra.org.za.
- Additionally, reporting can be done via the Med Safety App. The App can be downloaded into a smart mobile phone through Google Play or App Store. For more information on Med Safety App, please visit the following link: https://medsafety.sahpra.org.za/.
- For more information on ADR reporting of Phenylephrine hydrochloric injection™, please contact the SAHPRA Pharmacovigilance unit at pvqueries@sahpra.org.za.

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