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
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**IMPORTANT**

**MEDICINE SAFETY INFORMATION**

18 May 2023

**RE: Synthroid® range of tablets: Typing error in the Professional Information (PI) and Patient Information Leaflet (PIL)**

Dear Healthcare Professional,

Abbott Laboratories SA (PTY) Ltd, as directed by the South African Health Products Regulatory Authority (SAHPRA), wish to inform you about the typing error in the PI and PIL of Synthroid® range of tablets, listed in the table below. The tablets are debossed on one side with the word "FLINT", while the PI and PIL indicates the word "SYNTHROID" instead of the correct word "FLINT" in the tablet description. The Synthroid® products with the PI and PIL typing error will not be distributed in the country for human use. Thus, Abbott applied for a Section 36 exemption which allows supply of Synthroid® range of tablets sourced outside of South Africa (SA). To prevent treatment interruptions in patients on Synthroid® tablets and allow distribution of the products, SAHPRA has granted Abbott's request for Section 36 exemption.

The PI and PIL are currently being updated for the next batches. The correct PI and PIL can be accessed from SAHPRA PI/PIL repository (https://pi-pil-repository.sahpra.org.za)

**Summary**

- Synthroid® is a prescription medicine (Schedule 3) and is indicated for hypothyroidism and pituitary thyroid stimulating hormone suppression.
- The are packs of Synthroid® range of tablets in which the tablets are debossed on one side with "FLINT", however the PI and PIL do not indicate this information.
- There is no patient impact in terms of safety and efficacy, as all clinical and safety related information on the PI and PIL are correct.
- Abbott has obtained a batch specific, Section 36 exemption to supply Synthroid® range of tablets sourced outside of South Africa.

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**Advise to healthcare professionals.**

- Healthcare professionals are alerted to note the difference in artwork between Synthroid® tablets sourced outside of SA to those registered in the country.
- Healthcare professionals are advised to refer to the PI/PIL from SAHPRA repository for dosing information approved by SAHPRA.
- Healthcare professionals are urged to report any adverse drug reactions (ADRs), or product quality issues (including batch details) related to Synthroid® range to Abbott Laboratories SA (PTY) Ltd via email: pv.south-africa@abbott.com or call: 011 858 2000. Alternatively, healthcare 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 App 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: List of Synthroid® range registered in SA.

| Product name | Registration No | Batch Number | Expiry Date |
|---|---|---|---|
| Synthroid 25µg Tabs | 42/21.3/0670 | 1190603 | 31-Jul-2024 |
| Synthroid 50µg Tabs | 42/21.3/0671 | 1191644 | 31-Jul-2024 |
| | | 1192796 | 30-Sept-2024 |
| Synthroid 75µg Tabs | 42/21.3/0672 | 1191645 | 31-Jul-2024 |
| Synthroid 100µg Tabs | 42/21.3/0674 | 1191646 | 31-Jul-2024 |
| | | 1193683 | 30 Sept-2024 |

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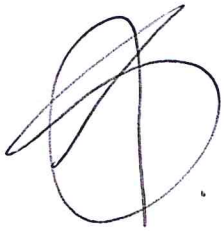
For any queries, please contact pv.south-africa@abbott.com or call 011 858 2034.

Sincerely,



Name: Gugulethu Mabuza

Head of Quality & Responsible Pharmacist English Africa Cluster