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IMPORTANT MEDICINE SAFETY INFORMATION

24 December 2020

Dear Healthcare Professional

Re: ELTROXIN NEW FORMULATION (25 mcg, 50 mcg, 75 mcg, 100 and 200 mcg TABLETS: INCREASED ADVERSE EVENTS REPORTS AND REQUIREMENT FOR PATIENT THERAPEUTIC MONITORING BY HEALTHCARE PROFESSIONALS.

Pharmacare, in consultation with the South African Health Products Regulatory Authority (SAHPRA) would like to warn healthcare professionals about an increase of adverse events/side effects associated with the introduction of Eltroxin New Formulation® and a call for therapeutic drug monitoring in patients using or switched to the agent.

Eltroxin New Formulation® has been on the South African market since July 2017; in place of Eltroxin®. The new formulation involved a change in one of the excipients. Lactose was removed from the Eltroxin® formulation and replaced by microcrystalline cellulose to make Eltroxin New Formulation®; without a change in the levothyroxine content. Therefore, both Eltroxin® and Eltroxin New Formulation® contain levothyroxine used for the treatment of hypothyroidism.

Prior to the launch of the Eltroxin New Formulation® in South Africa, it had been introduced in some parts of Europe, Africa and Asia. Following the introduction of Eltroxin New Formulation®, outside of SA, some markets experienced an increase in adverse events reports from healthcare professionals and patients. Most adverse event reports received have been previously documented in the professional information leaflet for Eltroxin New Formulation®. This unexpected increase in adverse event reports is of concern and healthcare professionals are hereby advised to perform therapeutic monitoring and regular clinical management of patients on Eltroxin New Formulation® ; until patients are stable.

There is evidence that some group of patients (e.g. those with thyroid cancer, heart disease or are pregnant) may be particularly sensitive to changes in thyroid hormone concentration;

and thus require close monitoring by their doctors. While most patients seem to tolerate slight changes in levothyroxine levels, or slight changes in their circulating hormone levels without any ill effects, there is evidence that in some patients, this slight change may alter their sense of well-being and possibly require their dose of levothyroxine to be altered.

Advice to Healthcare Professionals

1. New Patients
    a. At the start of treatment, a patient does not need measurement of their TSH until they have been on their predicted dose of Eltroxin New Formulation® for 4 to 8 weeks (unless symptoms of thyrotoxicosis dictate otherwise).

2. Switching from Eltroxin® to Eltroxin New Formulation® or other levothyroxine formulations
    a. During the initial titration period, or in the event of switching from another levothyroxine formulation, careful dosage titration and therapeutic drug monitoring is required.
    b. It is recommended that patients switching to Eltroxin New Formulation® commence at the same dose as Eltroxin® previous formulation, with regular TSH and T4 monitoring.

3. Thyroid Stimulating Hormone (TSH) test
    a. Repeat testing every four to eight weeks is recommended until the patient dose is stabilised.

Importantly, clinical monitoring for symptoms suggestive of over- or under-treatment or other adverse reactions is advised, particularly in patients who are elderly, pregnant or with underlying cardiac disease. Children and pregnant women may require more frequent monitoring of thyroid function.

Healthcare professionals are encouraged to report any adverse events/ adverse drug reactions associated with the use of Eltroxin New Formulation® to Aspen Pharmacare via email: Drugsafety@aspenpharma.com, tel: 0800 118 088 or fax: 011 239 6306.

OR

To SAHPRA via the eReporting link available on the SAHPRA website (www.sahpra.org.za). Alternatively, please complete the ADR reporting form available on the SAHPRA website and email it to adr@sahpra.org.za or fax to (021) 448 6181.

Yours sincerely

Lorraine Hill

Group Operating Officer and Responsible Pharmacist

Aspen Pharmacare Holdings Limited

Reference:

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