15 April 2024

Dear Healthcare Professional,

RE: IMPORTANT ELTROXIN® (levothyroxine) UPDATE

1. **REFORMULATION and APPEARANCE CHANGES of the 100 microgram tablet**
2. **APPEARANCE CHANGES to the 50 microgram tablet**
3. **MONITORING RECOMMENDATIONS FOR PATIENTS**
4. **ADVERSE EVENT REPORTING and FURTHER INFORMATION**

Aspen New Zealand (Aspen) would like to advise you of upcoming changes to Eltroxin 50 microgram and 100 microgram tablets. Aspen will be moving to the same supply and packaging (product harmonisation) as Aspen Australia which will assist with continuity of supply for New Zealand.

Aspen anticipates supply of the new Eltroxin 50 microgram and 100 microgram tablets will commence **from June 2024** as the current stock becomes depleted.

Please see below for important information:

1. REFORMULATION and APPEARANCE CHANGES of the ELTROXIN 100 MICROGRAM TABLET

A reformulated Eltroxin 100 microgram tablet will be introduced which has:

- Exactly the same active and excipient ingredients with reduced amounts of each excipient (excipient ingredients are the same but in reduced quantities).
- The source of the active ingredient and the manufacturing site is the same.
- The tablet size will be smaller, the tablet shape and tablet imprint will change as outlined in the enclosed Eltroxin Tablet Guide.
- The outer carton will include the words 'New Formulation' for a period of one year.

2. APPEARANCE CHANGES to the ELTROXIN 50 MICROGRAM TABLET

A new Eltroxin 50 microgram tablet will be introduced which has:

- No formulation changes (same active and excipient ingredients and quantity of these).
- The source of the active ingredient and the manufacturing site is the same.
- Visual changes to the tablet imprint and tablet shape as outlined in the enclosed Eltroxin Tablet Guide.

3. MONITORING RECOMMENDATIONS FOR PATIENTS

Levothyroxine has a narrow therapeutic index.[1,2] Appropriate levothyroxine dosage is based upon clinical assessment and laboratory monitoring of thyroid function tests. During the initial titration period, **careful dosage titration and monitoring is necessary to avoid the consequences of under- or over-treatment.** The symptoms of excessive levothyroxine dosage are the same as many features of endogenous thyrotoxicosis. Please refer to the Eltroxin data sheet for all prescribing information, available at www.medsafe.govt.nz.[1]

In addition, the different brands of levothyroxine are not interchangeable.[3] A change in brand will require thyroid function monitoring, and in some cases dosage adjustment.[3] Prescribers are also reminded to specify the brand of levothyroxine on each prescription to ensure the correct brand is dispensed for each patient.[3]

To assist with the management of your patients over this transition period, the following guidance may be used at your clinical discretion:[4]

Patients new to Eltroxin:

For new patients starting on Eltroxin treatment, monitor your patient as per usual practice and obtain a thyroid function test, typically at 6 to 8 weeks after the start of treatment.

Patients taking 50 microgram Eltroxin Tablets:

For patients that are currently taking the Eltroxin 50 microgram tablet and changing to the new Eltroxin 50 microgram tablet, no additional thyroid function testing unless required, as there are no changes to the formulation (the tablets are only visually different). However, this is at your clinical discretion.

Patients taking 100 microgram Eltroxin Tablets:

For patients that are currently taking the 100 microgram tablet and changing to the reformulated Eltroxin 100 microgram tablet, a thyroid function test is recommended 6 weeks after the transition.

Patients requiring dosage adjustments:

For patients that require dosage adjustments, a thyroid function test is recommended after approximately 6 to 8 weeks.

4. ADVERSE EVENT REPORTING AND FURTHER INFORMATION

To report an adverse event or medication error related to your patient, please submit directly to **CARM** at **https://nzphvc.otago.ac.nz/reporting/**

For Eltroxin medical information enquiries, please email the Aspen Medical Information Department on **medical@aspenpharmacare.com.au**

To contact the Aspen New Zealand Head Office, please call **09 220 5399** or **0800 858 377** or via email at **aspen@aspenpharma.co.nz**

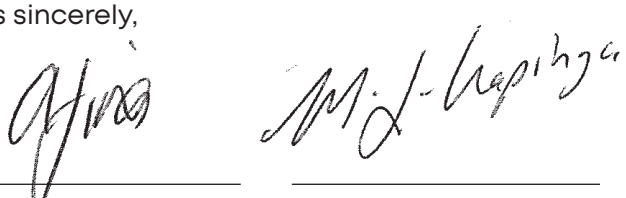
Please find enclosed the following resources:

- 'Eltroxin Tablet Guide for Healthcare Professionals' which outlines the tablet changes and includes tablet images.
- 'Your Eltroxin is changing' Patient Pad to assist you with informing your patients. There is a space on the reverse side to write specific instructions for your patient as required.

Pharmac have also published information on their website under the Medicines Notices section, located at **www.pharmac.govt.nz/eltroxin**.

Thank you for your understanding and support over this transition period.

Yours sincerely,



Anita Jina
Medical Manager

Michelle Kapinga
General Manager

References: 1. Eltroxin® New Zealand Data Sheet. Available at www.medsafe.govt.nz. 2. Medsafe Prescriber Update 40(4):68-69 Some medicines need to be prescribed by brand, December 2019. https://www.medsafe.govt.nz/profs/PUArticles/December2019/Some-medicines-need-to-be-prescribed-by-brand.htm Accessed February 2024. 3. Medsafe, Prescriber Update 30(1):1 Eltroxin Update, February 2009. https://www.medsafe.govt.nz/profs/PUArticles/Eltroxin-feb09.htm Accessed February 2024. 4. Management of thyroid dysfunction in adults. BPJ Issue 33. www.bpac.org.nz.

Eltroxin® (levothyroxine sodium) 50 microgram & 100 microgram tablets is a fully funded Prescription Medicine for the treatment of hypothyroidism. **Dosage & Administration:** Thyroxine has a narrow therapeutic index. Appropriate thyroxine dosage is based upon clinical assessment and laboratory monitoring of thyroid function tests. During the initial titration period, careful dosage titration and monitoring is necessary. See data sheet for dosage. Tablets should be swallowed whole preferably on an empty stomach. **Contraindications:** Hypersensitivity to any component of the product, thyrotoxicosis, acute myocardial infarction, acute myocarditis, acute pancarditis. **Adverse effects:** Hypersensitivity reactions such as skin rash, pruritis, anaphylactic reactions, increased appetite, excessive weight loss, abdominal cramps, nausea, vomiting, diarrhoea, headache, tremors, seizure, anxiety, emotional lability, nervousness, excitability, insomnia, restlessness, psychotic depression, cardiac arrhythmias, angina, palpitations, heart failure, myocardial infarction, hypertension, tachycardia, hyperthyroidism, dyspnoea, hair loss, sweating, flushing, muscle cramps, muscle weakness, decreased bone mineral density, menstrual irregularity, impaired fertility, fatigue, fever, heat intolerance. **Precautions:** Adrenal insufficiency, elderly, patients with symptoms of myocardial insufficiency/ ECG evidence of myocardial infarction or ischaemia, diabetes, bone mineral density in women, partial hair loss in children during first few months of treatment, malabsorption syndromes, myxoedema, pregnancy, neonates. A number of other drugs may cause an increase or decrease in the effect of thyroxine, and the dosage of either drug may need to be altered, see data sheet for full list of interactions. Before prescribing, please review data sheet available at www.medsafe.govt.nz

aspen NEW ZEALAND