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Advice from Medsafe – 26 June 2008

MEDSAFE
NEW ZEALAND MEDICINES AND MEDICAL DEVICES SAFETY AUTHORITY
A BUSINESS UNIT OF THE MINISTRY OF HEALTH
www.medsafe.govt.nz

Eltroxin formulation change – Monitor patients and adjust dosing if necessary

Medsafe is writing to provide information and advice on the change in formulation of Eltroxin (levothyroxine, also known as, thyroxine) tablets which has led to a number of patients reporting problems such as sore eyes, palpitations, and headaches.

In response to these reports, Medsafe has reassessed the change in Eltroxin formulation and can confirm that the new formulation satisfies all quality, safety, and bioequivalence criteria. In addition, all excipients and excipient quantities present in the new formulation are commonly used in medicines.

Treatment of thyroid dysfunction is subject to significant inter-patient variability. Therefore, when patients are changed to new formulations or brands of levothyroxine**, thyroid function monitoring is required** to ensure the correct dose is being prescribed. Small changes in dosing of levothyroxine can affect serum thyroid hormone levels.

When changing a patient to the new Eltroxin formulation, Medsafe advises that:

- **Thyroid function should be monitored** to ensure each patient is being prescribed the correct dose. This is particularly important for patients who have noticed symptoms since changing to the new formulation. Recent adverse reaction reports have shown raised TSH levels in some patients, confirming the need for monitoring.
- **When monitoring Thyroid function**:
    - Thyroid Stimulating Hormone (TSH) levels are the best indicator of thyroid function. If there are particular concerns about thyroid function, free T4 and free T3 levels should also be monitored.
    - Thyroid function tests can be performed at any time of the day.
    - Due to the long half life of levothyroxine (5 - 7 days), Thyroid function tests should be conducted no earlier than 4 – 6 weeks following a change in dose, or a change in formulation.
- **Dose adjustments** should not usually exceed 50 micrograms per day. Dose adjustments in the elderly, in patients with pre-existing heart disease, or in patients with diabetes should not exceed 50 micrograms on alternate days.
- **Specialist advice** should be sought if dose adjustments are required in children.

Additional factors to consider when prescribing Eltroxin tablets:

- Poor patient compliance should be considered as a possible cause of adverse effects. Compliance may be affected by the need to take Eltroxin tablets on an empty stomach, or the need for alternate day dosing in some patients.
- Adverse reactions should be reported to the Centre for Adverse Reactions Monitoring (CARM, Box 913, Dunedin. carmnz@otago.ac.nz. Fax 03 479 7150). Please include, where possible, the patient's TSH, T3, and T4 results, the current dosing regimen, and if and when the patient was changed to the new formulation.
- The Eltroxin data sheet includes dosing guidelines for transferring patients to the new Eltroxin formulation (http://www.medsafe.govt.nz/profs/Datasheet/e/Eltroxin(new)tab.htm).

- The GlaxoSmithKline letter dated 18 June 2008 provides further information on changing patients to the new formulation (http://www.medsafe.govt.nz/hot/alerts.asp).

For further advice relating to Eltroxin tablets, please contact the manufacturer (GSK) on 0800 808 500 (Monday to Friday 11 am – 6pm).

The new formulation of Eltroxin is the only brand of levothyroxine that has ministerial consent for distribution in New Zealand. Medsafe does not have any applications for levothyroxine tablets from any other pharmaceutical companies. Unapproved medicines (which includes other brands of levothyroxine) can only be supplied under provisions in the Medicines Act (Section 25 and 29) that require an authorised prescriber to request or obtain the medicine for a specific patient under their care. For further information on the use of unapproved medicines in New Zealand, please see: http://www.medsafe.govt.nz/regulatory/unapproved.asp.

Medsafe's media release is available at: www.medsafe.govt.nz/hot/MediaContents.asp