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Dear Doctor

GlaxoSmithKline NZ (GSK) has recently received an increased number of Eltroxin® (levothyroxine) related queries to its Medical Information Department; however, this is often the case with reformulated products and can be associated with closer monitoring by healthcare professionals and reporting by patients that is undertaken during such changes. GSK has provided the following information for Doctors to be able to address some of the queries you may be receiving from your patients.

GSK has distributed since July 2007 a new formulation of Eltroxin® 50 and 100mcg tablets. As outlined in the patient information materials distributed at that time, the size and colour of the tablets were changed and the score line across the tablet was also removed. GSK believes that the dosing performance of the new formulation tablets will be better if they are not broken; hence the score line has been removed.

In December 2007, GSK also changed the generic name of Eltroxin from "Thyroxine" to "Levothyroxine". This was done to align with changes made to the British National Formulary, where the British Approved Name (BAN) "thyroxine" was required by law to align with the Recommended International Nonproprietary Name (rINN) "levothyroxine". **Patients who might be confused about the name change should be reassured that "levothyroxine" is the same medicine as "thyroxine."**

With regard to the new formulation, Eltroxin tablets for the New Zealand market are manufactured at the GSK factory in Germany. The active ingredient in the reformulated tablets remains the same and in the same quantity as in the 'old' tablets. Due to changes made in the manufacturing process of Eltroxin tablets, the excipients in the tablet have changed as follows:

> New formulation tablet excipients: Microcrystalline cellulose, Pregelatinised starch, Talc, Colloidal anhydrous silica, Magnesium stearate.
>
> Old formulation tablet excipients: Lactose monohydrate, Maize starch, Acacia powdered, and Magnesium stearate.

What do the changes mean for your patients?

As a result of the changes to the tablet excipients, patients may find that the tablet dissolves faster in their mouth, possibly making it more difficult to swallow, sticking to their tongue, or leaving a different taste in their mouth. The tablet may also crumble if the patient tries to split the tablet, which has the potential to create dosing consistency issues if patients attempt to use split tablets.

In order to ensure consistent absorption of the drug from the tablet, it is important that your patients take their Eltroxin tablets as outlined in the product's Data Sheet and Consumer Medicine Information, and **most importantly** that they **take Eltroxin on an empty stomach**, and that they **do not split Eltroxin tablets (see below for 25mcg increment dosing recommendations).**

Summary of Important Information for Health Care Practitioners:

1. **Eltroxin tablets should be taken on an empty stomach, preferably 30 minutes before breakfast.**
Following oral administration, the absorption of levothyroxine is incomplete and variable especially when taken with food. The amount absorbed increases during fasting conditions. To ensure that Eltroxin is taken on an empty stomach, it is recommended that it be taken at least one-half hour before breakfast.

2. **Eltroxin tablets should be swallowed whole, and taken with a full glass of water.** Due to a lack of data to support the use of split or crushed tablets, it is recommended that Eltroxin tablets are swallowed whole. Taking the tablet with a full glass of water will also ensure that the tablet is more easily swallowed before it can unintentionally dissolve in the mouth.

3. **Doses requiring 25mcg increments should be administered using alternate day dosing of 50mcg tablets (as described in the following table).**

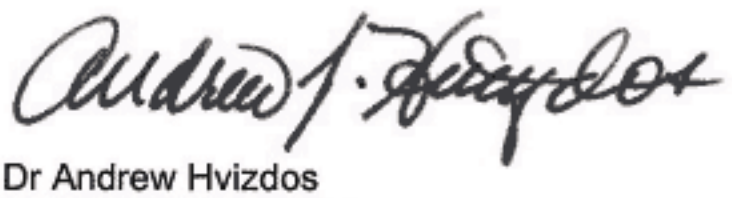
DAILY DOSE	DOSING REGIMEN
25 microgram	One 50 microgram tablet on alternate days
50 microgram	One 50 microgram tablet daily
75 microgram	One 50 microgram tablet daily and one additional 50 microgram tablet on alternate days
100 microgram	One 100 microgram tablet daily
125 microgram	One 100 microgram tablet daily and one additional 50 microgram tablet on alternate days

If any of your patients has a question about their response to Eltroxin, or is currently on a dosing regimen that differs from those outlined above (e.g. taking their Eltroxin with food), they should consult with you, their doctor, in the first instance to confirm what treatment regimen is right for that specific patient. GSK will also be placing a notice in the newspaper to address the issue for consumers.

If you have any other questions on the use of Eltroxin, please contact GSK on 0800 808 500 and ask for the Medical Information Department. You may also report adverse events involving Eltroxin to GSK Medical Information on the same number.

Investigations by GSK into the adverse events reported to the company following the switch to the reformulated product have not identified any quality issues and GSK remains confident that Eltroxin tablets are safe to use as prescribed and directed in the prescribing information. GSK will continue to monitor this situation closely and will continue to consult with Medsafe, healthcare professionals, and patients regarding any necessary actions going forward.

Yours sincerely,



Dr Andrew Hvizdos
Head of Medical Affairs

Eltroxin (levothyroxine sodium; 50 and 100 microgram tablets). Eltroxin is a **fully funded** Prescription Medicine for the treatment of hypothyroidism. Eltroxin should be taken on an empty stomach, at least 30 minutes before breakfast. Eltroxin tablets should be swallowed whole with a full glass of water; do not split tablets. **Contraindications:** hypersensitivity to any components of the preparation; thyrotoxicosis. **Warnings and Precautions:** panhypopituitarism or adrenal insufficiency, myocardial insufficiency, ECG evidence of MI or ischaemia, diabetes, pregnancy and breastfeeding. **Adverse Events:** The following may indicate excessive dosage: angina, arrhythmias, palpitation, skeletal muscle cramps, tachycardia, diarrhoea, vomiting, tremors, restlessness, insomnia, headache, flushing, sweating, excessive weight loss, and muscle weakness. Before prescribing Eltroxin, please review the full Data Sheet available at www.medsafe.govt.nz. Eltroxin is a trade mark of the GlaxoSmithKline group of companies. Marketed by GlaxoSmithKline NZ Limited, Auckland. TAPS DA89KH/08JU/080.