



23th March 2011

Dear Healthcare Professional,

Perrigo on behalf of Aspen would like to provide you with information regarding the new formulation of Eltroxin™ Tablets (50mcg and 100mcg).

GlaxoSmithKline has reformulated Eltroxin™ to improve stability. Subsequently this product has been transferred to Aspen. Aspen have appointed Perrigo as the Distributor and Marketing Authorisation Holder in Israel. **The reformulated tablets satisfy all quality, safety and bioequivalence criteria and are approved by the Israeli MOH.** The reformulation involved only the excipients. All excipients and excipient quantities present in the new formulation are commonly used in medicines. The active ingredient (levothyroxine) in the reformulated tablets remains the same and in the same quantity as in the previous formulation.

The new formulation of Eltroxin™ 100 mcg and 50mcg tablets have been distributed since 16-Feb-2011.

Important Prescribing Information Regarding the New Formulation of Eltroxin™ (levothyroxine)

- Do not split tablets (**tablets are unscored**). Some patients may find that the new formulation tablet dissolves faster in their mouth. The new formulation tablets may crumble if a patient tries to split them, which has the potential to create inconsistent dosing. Therefore it is important to highlight that the **Eltroxin™ tablet should be taken whole.**
- Take on an **empty stomach.**
- **When switching to the new formulation, thyroid function blood tests (e.g. thyroid stimulating hormone [TSH] levels) should be obtained approximately 6 weeks after switching to the new formulation** to ensure that the dosage is appropriate to avoid the consequences of under- or over-treatment.
- **When initiating treatment with the new formulation, during the initial titration period, careful dosage titration and monitoring (e.g. TSH levels approximately every 6 weeks) is necessary** to avoid the consequences of under- or over-treatment.
- As is true for all levothyroxine products, **Eltroxin™ has a narrow therapeutic index.** Due to the subtle differences between levothyroxine formulations and pharmacokinetic variability between individuals, some patients may experience a change in clinical effect when switched to a different brand or formulation. Therefore, in addition to laboratory monitoring, **clinical monitoring** for symptoms suggestive of over- or under-treatment or other adverse reactions is advised, particularly in patients who are elderly or with underlying cardiac disease.



- Refer to Table 2 for dosing recommendations.

Table 1. Differences between both formulations are tabulated as follows:

	New Formulation tablets	Old Formulation tablets
Excipients	Microcrystalline cellulose Pre-gelatinised starch Talc Colloidal anhydrous silica Magnesium stearate	Lactose Starch corn Acacia powder Magnesium stearate
Appearance	<u>Eltroxin™ Tablet 50mcg:</u> Unscored (no breakline) round, Biconvex tablet, Marked 'GS 11E' on one face and '50' on the other. <u>Eltroxin™ Tablet 100mcg:</u> Unscored (no breakline) round, Biconvex tablet, Marked 'GS 21C' on one face and '100' on the other	<u>Eltroxin™ Tablet 50mcg:</u> Scored (with breakline) round, Biconvex tablet, Marked '50' above a breakline <u>Eltroxin™ Tablet 100mcg:</u> Unscored (no breakline) round, Biconvex tablet, Marked 100
Pack size	100 tablets	100 tablets

Table 2. Dosing recommendations using the reformulated 50mcg and 100mcg Eltroxin™

DAILY DOSE	DOSING REGIMEN
25 mcg	One 50 mcg tablet on alternate days
50 mcg	One 50 mcg tablet daily
75 mcg	One 50 mcg tablet daily and one additional 50 mcg tablet on alternate days
100 mcg	One 100 mcg tablet daily
125 mcg	One 100 mcg tablet daily and one 50 mcg tablet on alternate days
150 mcg	One 100 mcg tablet daily and one 50 mcg tablet daily
175 mcg	One 100 mcg tablet daily, one 50 mcg tablet daily and one additional 50 mcg tablet on alternate days

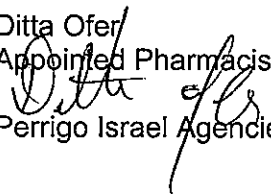


If any of your patients have a question about their response to Eltroxin™, they should consult you, their physician, in the first instance to confirm what treatment regimen is right for them. Please inform and advise your patients of this change in Eltroxin.

Healthcare professionals are encouraged to report any suspected adverse drug reactions associated with the use of Eltroxin™ to Perrigo or Israeli MOH.

In case of any further queries, please contact Medical Information Coordinator – Dganit Even Sapir, Perrigo Israel 052-3667586.

Yours sincerely,

Ditta Ofer
Appointed Pharmacist

Perrigo Israel Agencies Ltd.