

Product Alert: Labelling of Eltroxin 50mcg and 100mcg

19 September 2007

Dear Pharmacist:

GlaxoSmithKline (GSK) would like to inform you of a labelling error affecting recently released batches of Eltroxin™ Tablets (levothyroxine sodium) 50 micrograms and 100 micrograms. As you are aware GSK recently introduced a new formulation of Eltroxin tablets that affected the appearance and excipients of both 50mcg and 100mcg tablets.

The first batches of new formulation were clearly identified on the label with the words "New Formulation" in red text highlighted in yellow. It was our intention and a requirement by Medsafe that packs distributed for a minimum of six months be labeled in this way to assist pharmacists in identifying which formulation they had in stock. The batches listed below are not labelled as "New Formulation", however we wish to confirm that these are in fact the new formulation that has been available since June 2007.

Pharmacodes and affected batch numbers

Eltroxin Presentation	Pharmacode	Batch Number	Expiry Date
Eltroxin tablets 50mcg x 1000	250287	7D005	Apr 2009
Eltroxin tablets 100mcg x 1000	250295	7F004	Jun 2009

Further batches of Eltroxin Tablets entering the distribution chain until the end of 2007 will carry the label that identifies it as "New Formulation".

Eltroxin Tablets Appearance

As previously communicated to you in our letter of 29 June 2007:

- The new 50 mcg tablets is white, round, biconvex, but not scored, imprinted with 'GS 11E' on one face and '50' on the other. The size of this tablet is 6.0 to 6.2mm in diameter and the height is 2.7 to 3.2mm.
- The new 100 mcg tablets is also white, round, biconvex, but not scored, imprinted with 'GS 21C' on one face and '100' on the other. The size of this tablet is 8.0 to 8.2mm in diameter and the height is 3.2 to 3.7mm.

An Eltroxin Tablet visual identification guide is still available. This guide shows the difference in appearance between the previous and new formulations of the 50 mcg and 100 mcg tablets. These tablet identification guides were distributed to all community and hospital pharmacies during July. A copy of the 29 June 2007 letter and further stocks of the tablet guide are available and can be ordered through GSK Customer Services at the telephone number indicated below.

GSK regrets this error in labelling and apologises for any inconvenience caused.

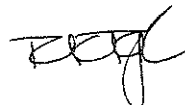
This action is being taken in consultation with Medsafe, Ministry of Health.

If you have any further questions or wish to discuss this letter, please contact **GSK Customer Services on 0800 500 010**.

Yours sincerely,



Ashley Witheford
 Product Manager
 GlaxoSmithKline NZ



Rachel Taylor
 Quality Systems Manager
 GlaxoSmithKline NZ

Before prescribing Eltroxin, please review the full Data Sheet available at www.medsafe.govt.nz. Eltroxin is a trademark of the GlaxoSmithKline group of companies. Marketed in New Zealand by GlaxoSmithKline NZ Limited, Auckland.