

Dear Doctor / Pharmacist

Subject:- **Change in Pack Size to 5 bottles each containing 40 tablets (200's)**
OROXINE thyroxine sodium 50 µg, 100 µg & 200 µg AUST R 10984, 10985 & 10986
EUTROXSIG thyroxine sodium 50 µg, 100 µg & 200 µg AUST R 90765, 90766 & 90767
Eutroxsig is a clone or pseudo-generic brand of Oroxine.

Oroxine has been in the Australian market since the 1970's or earlier. Sigma acquired this product from the original manufacturer in December 1999. The formulation & manufacturing process has not been changed since its launch. A second brand, Eutroxsig, was launched on 1st Nov 2002. Eutroxsig & Oroxine are identical products.

In 2004 Sigma in consultation with the TGA introduced new storage conditions of 2°C to 8°C (Refrigerate. Do not freeze) to maximise product stability and potency. "Dear Doctor/Pharmacist" and "Dear Pharmacist" letters dated 4th & 27th May 2004, respectively were distributed as a notification of these changes.

The new stability studies support the storage of these products in the fridge. However, repeated in-use handling may result in an increase in condensation and microbial contamination. This may lead to changes in the physical characteristics of the tablets including the growth of mould. There may be a further increase in condensation if the lid is not tightly closed.

In order to overcome the above in-use problems identified in last few months, Sigma, in consultation with the TGA, will be introducing new storage conditions (see the Dear Doctor/Pharmacist letter/Advance Notices dated 27th June 2005) for in-use bottles and the following pack sizes in September/October 2005:-

- FIVE glass amber-coloured bottles, each containing 40 tablets (5 x 40 tablets). All five bottles will be shrink-wrapped together and packed into an outer carton. This will be the Pharmacy dispensing pack. There will be no change in the PBS dispensing quantity of 200's.
- All 5 bottles are to be kept in the refrigerator between 2°C to 8°C (Refrigerate. Do not freeze).
- Once a bottle has been opened for use, it can be stored outside the refrigerator, below 25°C for 40 days. This bottle must not be stored in the refrigerator while being used.
- All other bottles must remain in the refrigerator between 2°C to 8°C whilst unopened.
- Upon opening a bottle, patients will be able to write the date opened in the space provided on the bottle label ('Date opened') and 'Discard date' after adding 40 calendar days.
- Once the 'Discard date' is reached, any tablets remaining in the bottle must be disposed of.
- Opened or in-use bottles cannot be stored in the refrigerator for future use.

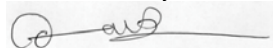
All of the above instructions will be printed on the inside top flap of the carton, in the PI and CMI. The CMI will be distributed as a pack insert. The new packs should continue to be stored at 2°C to 8°C (Refrigerate. Do not freeze) prior to the individual bottles of 40 tablets being opened.

All shipments should continue to be refrigerated when they arrive at your pharmacy. Please continue using the current stock on hand. Pharmacists should contact the wholesaler, if the storage conditions were not followed during transport.

Patients should be advised not to use tablets that show any signs of deterioration when stored at 2°C to 8°C (Refrigerate. Do not freeze) or within 40 days of opening the bottle. Please report and return such tablets to Sigma.

We trust that this change will benefit your patients, and thank you for your cooperation in this matter.

Yours Sincerely



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