



Issue: Storage of Thyroxine bottles

Raised by: Sue Leverton (RAN, Yuendumu)

Background: There appears to be differing views on what is best practice on the management of bottles of thyroxine.

Discussion: There is a current lack of evidence to support an unquestionable directive on the correct storage of Thyroxine, although there has been some recent discussion in endocrinology and pharmacology circles which suggests a preferred method while research seeks to guide the current debate. Key points in the debate are:

- Thyroxine does degrade with up to 10% loss of potency in the first 6 months, when stored <25°C (potential to have clinical significance)
- The manufacturer supports that thyroxine is more stable when refrigerated (2-8°C), but this is challenged
- Moisture is also able to effect potency
- The TGA ruled that the manufacturer should issue Thyroxine with only a 12 month shelf life, and that it should be refrigerated, with a maximum un-refrigerated period of 4 weeks
- Australia is possibly the only country refrigerating thyroxine, following the TGA instruction
- Repeated opening of a Thyroxine bottle stored in a refrigerator will likely lead to a multiplied occurrence of condensation

The status of the current debate appears to support refrigerated storage of unopened bottles, and then a 40 day period of conventional storage, and does not contravene manufacturer or TGA instructions or manufacturer's storage instructions.

Consultation: Alan Evans (CA SDMO), Bhavini Patel (Chief Pharmacist RDH)
Peter Barrett (Pharmacist Palmerston Soul Pattinson Pharmacy)

References: "Should Thyroxine tablets be refrigerated?" Letter to the editor, MJA.
http://www.mja.com.au/public/issues/182_12_200605/letters_200605-1.html

"Changes to the shelf life of Thyroxine" Letter to the editor, AustralianPrescriber.
<http://www.australianprescriber.com/magazine/28/1/5/7/>

Consumer Medicine Information & outer packaging for Sigma product "Oroxine"

Outcome: Thyroxine bottles should be stored in the refrigerator while unopened.

Following opening, Thyroxine bottles should be dated with the date of opening and thereafter stored in the drug storage room (<25°C). Bottles are to be discarded after 40 days since opening (utilising the Return of Unwanted Medicines mechanism).

(The recently released Atlas item on Drug Administration Aids utilised Thyroxine as an example of a drug not suitable for inclusion in blister packing due to the requirement of refrigeration. In light of this communiqué, non refrigeration of Thyroxine following inclusion in a blister pack would be reasonable, subject to a shelf life of the blister pack not exceeding 40 days, and the blister pack being otherwise stored in reasonable conditions including <25°C. The Atlas item will be amended accordingly.)