

**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 [Dose 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.)