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**Endocrine Society of Australia statement**

**Thyroxine preparations available in Australia**

For many years, two thyroxine preparations have been marketed in Australia, Oroxine and Eutroxsig (both marketed by Aspen Pharmaceuticals), available in 50, 75, 100 and 200 μg tablets. These preparations are identical, and so it has been immaterial which is dispensed to patients, and brand switching has not been problematic. A new preparation , Eltroxin (also marketed by Aspen) is now available which features a wider range of tablet strengths (25, 50, 75, 100, 125, and 200 μg) and (unlike Oroxine/Eutroxsig) does not require refrigeration. This may allow more accurate daily dosing for patients and may be more convenient.

The product information for Eltroxin states that it is not bioequivalent to Oroxine and Eutroxsig. This is based on a bioequivalence study using an FDA-approved protocol in which single doses of 600 μg of Eltroxin and Oroxine were administered in turn to to healthy volunteers and serum total T4 concentrations measured. For Eltroxine, the uncorrected area under the curve was 89.1% of that for Oroxine (90% CI: 84.7%, 93.7%), whereas for peak concentration (Cmax) it was 86.2% (82.1%, 90.6%). This suggests that Eltroxin may be less bioavailable than Oroxine/Eutroxsig.

This approach to determining bioequivalence of thyroxine preparations has been criticised (1, 2). It takes no account of baseline serum T4 concentrations (an important confounder, since participants have intact thyroids), involves a single dose of T4 rather than steady state pharmacokinetics, and takes no account of serum TSH, the usual clinical measure of thyroxine action. There are conflicting data as to whether bioequivalence differences found using this approach predict clinically relevant differences during steady state treatment of hypothyroid patients (1).

Based on the available data, and clinical experience from countries where different thyroxine brands are available, the ESA recommends the following:

1. Patients who are established on stable Eutroxsig/Oroxine dosage with serum TSH at target and who do not wish to change preparation should continue it unchanged.
2. Patients should not be switched between Eutroxsig/Oroxine and Eltroxin (eg by pharmacists) without the consent of the patient and the prescribing doctor.
3. If patients are switched between Eutroxsig/Oroxine and Eltroxin, thyroid function should be assessed six weeks later, and dosage adjusted if necessary.

References

1. Jonklaas J, Bianco AC, Bauer AJ, Burman KD, Cappola AR, Celi FS, Cooper DS, Kim BW, Peeters RP, Rosenthal MS, Sawka AM; American Thyroid Association Task Force on Thyroid Hormone Replacement. Guidelines for the treatment of hypothyroidism: prepared by the American Thyroid Association task force on thyroid hormone replacement. Thyroid. 2014; 24:1670-751.
2. American Association of Clinical Endocrinologists, the Endocrine Society, and the American Thyroid Association Joint Position Statement on the Use and Interchangeability of Thyroxine Products, 2004. [www.thyroid.org/thyroxine-products-joint-position-statement](file:///C:\Users\he45245\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.Outlook\W25E1FYB\www.thyroid.org\thyroxine-products-joint-position-statement) (accessed 3 December 2014).

Taken from: http://www.endocrinesociety.org.au/position-statements.asp