

16th February 2011

RE: Update on Thyrogen (thyrotropin alfa) Prescribing Information

Dear Sir/Madam

During a recent internal review of our documents on Thyrogen it has come to our notice that there was an error in the indication section of the Prescribing Information attached to two recent documents. We are writing to you to update you regarding this error and to request return or destruction of either item of Thyrogen communication you may still have in your clinic.

The current indications for Thyrogen are:

1. For use with serum thyroglobulin (Tg) testing with or without radioiodine imaging for the detection of thyroid remnants and well-differentiated thyroid cancer in post-thyroidectomy patients maintained on hormone suppression therapy (THST). Low risk patients with well-differentiated thyroid carcinoma who have undetectable serum Tg levels on THST and no rh(recombinant human) TSH-stimulated increase of Tg levels may be followed-up by assaying rh TSH-stimulated Tg levels.
2. For pre-therapeutic stimulation in combination with 100 mCi (3.7 GBq) radioiodine for ablation of thyroid tissue remnants in patients who have undergone a near-total or total thyroidectomy for well-differentiated thyroid cancer and who **do not** have evidence of distant metastatic thyroid cancer.

The error identified omits the words “do not” from the phrase in the final sentence of the indications.

The erroneous prescribing information has been used in 2 items; a letter regarding the product support team re-structuring sent to clinicians in December 2010 (THYR-UK-11/10-2337 and 2337a) and the Thyrogen promotional leavepiece (THYR-UK-7/10-2131) distributed during September and October 2010.

The risk for patients with metastatic disease given Thyrogen in error would be:

“Due to elevation of TSH levels after Thyrogen administration patients with metastatic thyroid cancer particularly in confined spaces such as the brain, spinal cord and orbit or disease infiltrating the neck, may experience local oedema or focal haemorrhage at the site of these metastases resulting in increased tumour size. This may lead to acute symptoms, which depend on the anatomical location of the tissue e.g. hemiplegia, hemiparesis, loss of vision have occurred in patients with CNS metastases. Laryngeal oedema, respiratory distress requiring tracheotomy, and pain at the site of metastasis have also been reported after Thyrogen administration. It is recommended that pre-treatment with corticosteroids be

considered for patients in whom local tumour expansion may compromise vital anatomic structures.”

All incorrect promotional material has been withdrawn from further use and we would appreciate if you could return or confirm destruction of the Thyrogen letter and the Thyrogen leave piece if they are still in your possession. Please also report any adverse events you have seen with the use of Thyrogen in your practice and especially if you believe this erroneous prescribing information may have contributed to the event to Genzyme Drug Safety on +44 (0)1865 405200.

Please do not hesitate to contact our Medical Information team on +44 (0)1865 405283 if you need additional information.

Yours Sincerely



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