

Propylthiouracil Boxed Warning

Audience: Endocrine healthcare professionals, Pharmacists, Pediatricians

[Updated 04/21/2010] FDA has added a Boxed Warning to the label for propylthiouracil, to include information about reports of severe liver injury and acute liver failure, some of which have been fatal, in adult and pediatric patients using this medication.

[Posted 06/04/2009] FDA notified healthcare professionals of the risk of serious liver injury, including liver failure and death, with the use of propylthiouracil in adult and pediatric patients. Reports to FDA's Adverse Event Reporting System (AERS) suggest there is an increased risk of hepatotoxicity with propylthiouracil when compared to methimazole. FDA has identified 32 (AERS) cases (22 adult and 10 pediatric) of serious liver injury associated with propylthiouracil use. Although both propylthiouracil and methimazole are indicated for the treatment of hyperthyroidism due to Graves' disease, healthcare professionals should carefully consider which drug to initiate in a patient recently diagnosed with Graves' disease. Physicians should closely monitor patients on propylthiouracil therapy for symptoms and signs of liver injury, especially during the first six months after initiation of therapy. Propylthiouracil should not be used in pediatric patients unless the patient is allergic to or intolerant of methimazole, and there are no other treatment options available.