

Propylthiouracil and reports of serious liver injury

Final SPC and PL wording agreed by the PhVWP in December 2009

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SUMMARY OF PRODUCT CHARACTERISTICS

Section 4.4

Some cases of severe hepatic reactions, both in adults and children, including fatal cases and cases requiring a liver transplant, have been reported with propylthiouracil. Time to onset has varied but in a majority of cases the liver reaction occurred within 6 months. If significant hepatic enzyme abnormalities develop during treatment with propylthiouracil the drug should be discontinued immediately (see 4.8).

Section 4.8

Frequency unknown: Hepatitis, Hepatic failure.

PACKAGE LEAFLET

Section 2. Before you take....

Check with your doctor if any of the following applies to you:

Some cases of severe liver reactions, including cases with fatal outcome or requiring liver transplant, have been reported in both children and adults treated with propylthiouracil. You should inform your doctor immediately if you develop symptoms of liver disease, such as nausea, feeling sick, diarrhoea, yellow discolouration of the skin or eyes, dark urine, pale stools, bleeding easily, itching or chills.

Section 4. Possible side effects

Frequency unknown: Liver failure, liver inflammation.