HALYCIL™ (propylthiouracil 50mg Tablets) Approved by Health Canada
November 4, 2021
Message from Accelera Pharma Canada Inc (APCI) to Health Care Professional

Accelera Pharma Canada Inc (APCI), in partnership with Halewood Chemicals Ltd., has received approval for HALYCIL™ (propylthiouracil 50mg Tablets) and will be available soon for the following adult Indications:

- *For the medical management of hyperthyroidism.*
- *In conjunction with radioiodine to hasten recovery while awaiting the effects of radiation.*
- *For the control of thyrotoxicosis prior to surgery.*
- *In the management of a thyroid storm in addition to other therapeutic measures.*

The DIN number is: 02521059.

The recommended dose and dose adjustment is as follows:

Adults (≥18 years of age): *The recommended initial dose is 50-100 mg (1 to 2 tablets of HALYCIL) every 8 hours, with increases as necessary up to a maximum of 500 mg/day.*
In some cases, initial doses as high as 900 mg/day may be required.

When doses larger than 300 mg/day of HALYCIL are needed, the drug should be administered every 4 to 6 hours.

The patient should be examined regularly by the physician and the dose of HALYCIL adjusted until the patient is euthyroid (usually after 6-8 weeks). At this stage, the dose should be reduced by 1/3 every 4-6 weeks to a maintenance dosage of one tablet of HALYCIL 2 or 3 times daily, administered at regular intervals.

Geriatric (>65 years of age): *Evidence from clinical studies and experience suggests that use in the geriatric population is associated with no differences in safety or effectiveness. Dose selection for an elderly patient should be cautious reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.*

Pediatric (<18 years of age): *Health Canada has not authorized an indication for pediatric use.*

Hepatic impairment: *No clinical studies have been performed with HALYCIL in patients with hepatic insufficiency. Since liver toxicity is associated with the use of propylthiouracil, caution is warranted in these patients. The dose should be kept as low as possible.*

Renal impairment: *No clinical studies have been performed with HALYCIL in patients with renal impairment. The following schedule is recommended by W.M. Bennett et al[1]:*

Glomerular Filtration Rate (creatinine clearance)	***10-50 mL/min***	***<10 mL/min***
Reduce dose by	*25% of the usual maintenance dose*	*50% of the usual maintenance dose*

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1. Bennett WM et al. Guidelines for drug therapy in renal failure. Ann Intern Med 1977; 86:754-83.

HALYCIL™ with Canadian labels approved by Health Canada will be *commercially available soon. Halewood Propylthiouracil (PTU) 50 mg tablets are currently available under an Interim Order* through pharmacies and covered by several provincial and private plans throughout Canada.*

Halewood Propylthiouracil will continue to be available in the interim until Halycil™ is commercially available. The PIN (Pseudo-Drug Identification Number) under the Interim Order is 09858135.

APCI Product Code	***Product Name***	***Size***	***GTIN***	***PIN***
ARX-43045	*Propylthiouracil (PTU) 50 mg Tablets (mfr Halewood Chemicals Ltd. (UK))*	*100 Tablets*	*5060306430456*	*09858135*

For further information about Halewood Propylthiouracil (PTU), including the Canadian Dear Health Care Practitioner letter, UK Summary of Product Characteristics, and the Package Leaflet please refer to:

http://apcipharma.com/products

**As an interim measure, Health Canada has approved APCI to import Propylthiouracil (PTU) 50 mg Tablets manufactured by Halewood Chemicals Ltd. of the UK. This product now appears on the List of Drugs for Exceptional Importation of Sale for the treatment of hyperthyroidism.*