

Summary Safety Review - Propyl-Thyracil (propylthiouracil): Assessing the Potential Risk of Birth Defects

Products: Propyl-Thyracil (propylthiouracil)

Potential Safety Issue: Birth defects

Key Messages

- **Propyl-Thyracil (propylthiouracil) is a prescription drug authorized for sale in Canada to treat various conditions where too much thyroid hormone is produced.**
- **Health Canada reviewed the potential risk of birth defects in babies whose mothers were treated with propylthiouracil (PTU) during pregnancy. This review was triggered by international reports of birth defects linked with PTU use in pregnant women.**
- **Health Canada's review of the available information could not confirm or exclude a link between the risk of birth defects in babies and use of PTU in women during pregnancy.**
- **Health Canada is working with the manufacturers to update the Canadian product safety information for PTU products to inform health care professionals and patients about this potential risk.**

Overview

Health Canada reviewed the potential risk of birth defects in babies whose mothers used PTU during pregnancy after becoming aware of international reports that suggested that such a link existed.

Use in Canada

- **Propyl-Thyracil (propylthiouracil) is a prescription drug authorized for sale in Canada to:**
 - **treat hyperthyroidism, a condition where too much thyroid hormone is produced in the body.**
 - **treat patients following radioiodine therapy, while waiting for the effects of radiation to start working.**
 - **control an overactive thyroid gland (thyrotoxicosis), which produces too much thyroid hormone, while waiting for surgery.**
 - **treat "thyroid storm", a life threatening thyroid gland disease where the heart rate, body temperature and blood pressure can be very high.**

- PTU has been marketed in Canada since 1945 under the brand name Propyl-Thyracil and is available as 50 mg and 100 mg oral tablets. A generic version of PTU (Apo-Propylthiouracil) was authorised for sale in 2010, however it has never been marketed in Canada.
- There were about 36,000 prescriptions for Propyl-Thyracil filled in 2018.

Safety Review Findings

- At the time of the review, Health Canada had received 12 reports (4 Canadian^a and 8 international) of birth defects in babies whose mothers were treated with PTU during pregnancy. Of these 12 reports, 7 were found to be possibly linked to PTU use; 4 were not likely to be linked; and one report did not have enough information to be assessed. No definitive link was found between the birth defects in these cases and use of PTU in pregnant women .
- Health Canada also looked at the published literature and found a total of 22 relevant studies where PTU was used during pregnancy. Eighteen studies were in people and 4 were in animals. These studies had opposing results as to whether PTU was linked with birth defects. The review of these studies did not find sufficient evidence that there is a risk of birth defects with the use of PTU during pregnancy.

Conclusions and Actions

- Health Canada's review of the available information could not confirm or exclude a link between the risk of birth defects in babies and use of PTU in women during pregnancy. However, health care professionals and patients should know of this potential risk.
- Health Canada is working with the manufacturers to update the Canadian product safety information for PTU products to inform health care professionals and patients about this potential risk.
- Health Canada will continue to monitor safety information involving PTU, as it does for all health products on the Canadian market, to identify and assess potential harms and will take appropriate and timely action if and when any new health risks are identified.

Additional Information

The analysis that contributed to this safety review included scientific and medical literature, Canadian and international information and what is known about the use of PTU during pregnancy both in Canada and internationally.

For additional information, contact the [Marketed Health Products Directorate](#)

^a Canadian reports can be accessed through the [Canada Vigilance Online Database](#).