

Summary Safety Review - Mesalazine-containing products - Assessing the Potential Risk of Birth Defects

Product: Mesalazine-containing products

Potential Safety Issue: Birth defects

Key Messages

- **Mesalazine-containing products are authorized for sale in Canada for the treatment and/or prevention of symptoms of inflammatory bowel disease, including ulcerative colitis and Crohn's Disease.**
- **Health Canada reviewed the potential risk of birth defects in babies with the use of mesalazine in pregnant women. The review was triggered by international reports of birth defects in babies whose mothers were treated with mesalazine during pregnancy.**
- **Health Canada's review of the available information did not confirm a link between the risk of birth defects in babies and the use of mesalazine in pregnant women.**
- **Health Canada will continue to monitor safety information involving mesalazine-containing products, as it does for all health products on the Canadian market.**

Overview

Health Canada reviewed the potential risk of birth defects in babies with the use of mesalazine-containing products in pregnant women. The safety review was initiated following international reports received from a manufacturer of birth defects in babies whose mothers were treated with mesalazine during pregnancy.

Use in Canada

- Mesalazine-containing products are prescription drugs for the treatment and/or prevention of symptoms caused by inflammatory bowel disease including ulcerative colitis and Crohn's Disease. Mesalazine is also known as mesalamine, 5-aminosalicylic acid, and 5-ASA.
- Mesalazine-containing products have been marketed under different brand names in Canada since 1993. In 2019, mesalazine-containing products were marketed in Canada in many strengths and dosage forms for oral and rectal use under the brand names: Asacol, Asacol 800, Mezavant, Mezera, Pentasa, Salofalk and Teva-5 ASA
- There are about 125,000 prescriptions filled per year for all mesalazine-containing products by women who could become pregnant.

Safety Review Findings

- Health Canada reviewed the scientific and medical literature, Canadian and international information, including case reports in the Canada Vigilance database^a as well as information received from manufacturers.
- This safety review assessed 43 case reports (41 international and 2 Canadian) of birth defects in babies whose mothers were treated with mesalazine during pregnancy. Of the 43 case reports, 14 reports were found to be possibly linked to the use of mesalazine-containing products during pregnancy, 8 reports were not likely to be linked and 21 reports (including 2 Canadian case reports) did not have enough information to be assessed.
- Assessing the risk of birth defects in babies related to the use of mesalazine-containing products during pregnancy in these reports was challenging because of incomplete case details and other contributing factors, such as women taking other medications beside mesalazine during pregnancy or having other existing medical conditions. The review of these cases did not support a link between the birth defects in babies and the use of mesalazine-containing products in pregnant women.
- Health Canada also looked at additional information available from 12 studies in published literature (11 international and one Canadian). The review of these studies did not find a link between the risk of birth defects in babies and the use of mesalazine during pregnancy.
- Based on all of the available scientific and medical evidence, the lack of a known cause for birth defects, and no observation of a clear pattern of birth defects related to the use of mesalazine in pregnant women, the benefits of treatment with mesalazine continue to outweigh this risk. The current clinical guidelines also recommend the continued use of mesalazine during pregnancy as the underlying disease suffered by the pregnant women (inflammatory bowel disease) may harm the unborn child.

Conclusions and Actions

- Health Canada's safety review of the available information could not confirm a link between the risk of birth defects in babies and the use of mesalazine-containing products during pregnancy.
- Health Canada encourages consumers and healthcare professionals to [report](#) any side effects related to the use of mesalazine-containing products.
- Health Canada will continue to monitor safety information involving mesalazine-containing products as it does for all health products on the Canadian market. Health Canada will take appropriate and timely actions 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 adverse reaction reports and what is known about the use of mesalazine-containing products 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](#)