



Generic “Diclectin” and Mannitol Statement

There has been concern regarding the safety of the newly approved generic doxylamine/pyridoxine products following a [letter](#) written by the Society of Obstetricians and Gynaecologists of Canada (SOGC) to Health Canada warning of the mannitol content in the generic tablets. In this letter, the SOGC claims the generic products should not have been approved in Canada because they contain mannitol, a substance “contra-indicated for pregnancy by the FDA”.¹

Mannitol was labelled as a class C pregnancy drug² (not contraindicated by the FDA) which means, in this case, there are no pregnancy data available. Note in the new system being used to evaluate the safety of drug use in pregnancy, mannitol is rated as “No Human Data - Probably Compatible”.³

Although mannitol has not been directly studied in any pregnancy trials, there is some information about the drug which can be used to evaluate safety:

- **Mannitol is very poorly absorbed when administered orally**⁴, therefore exposure of the fetus to ingested mannitol would be minimal.
- Use in rats at very high doses (1.6 g/kg/d for 10 days, about half of a rat’s gestation period) has shown no reproductive effects.⁵
- Perhaps most reassuring is that **mannitol is naturally present in many fruits and vegetables**.⁶ For instance, the mannitol content per 100 g servings are: celery 1.5 g; cauliflower 2.6 g; mushrooms 2.6 g; snow peas 1.2 g.
- Many sugarless gums contain 1-2 g sugar alcohols, including mannitol, per piece.⁶
- For context, one tablet of the Apotex brand of doxylamine/pyridoxine contains 137.2mg mannitol.⁷ If using the maximum dose of 4 tablets per day, this represents a daily mannitol intake of 548 mg, far less than the amount in a serving of the vegetables listed above or one piece of sugarless gum.

The warning from SOGC also contains some questionable logic. Their letter implies that medications with a category A pregnancy rating should not retain that level of safety if they contain a category C additive, such as mannitol. The Diclectin tablet contains n-butanol and isopropyl alcohol,⁸ both of which are also category C^{9,10} — should Diclectin’s safety rating be downgraded as well?

Additionally, **SOGC receives an undisclosed amount of funding from Duchesnay**,¹¹⁻¹³ the manufacturer of Diclectin, representing a potential conflict of interest with their recommendation. Health Canada has also issued an Information Update that counters the SOGC claims.¹⁴

In summary, mannitol, as a food additive — especially in the quantities present in generic doxylamine/pyridoxine tablets — **is very unlikely to pose a problem in pregnancy**. The potential for harm instead would be limiting women’s access to a less expensive treatment for morning sickness.

References:

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