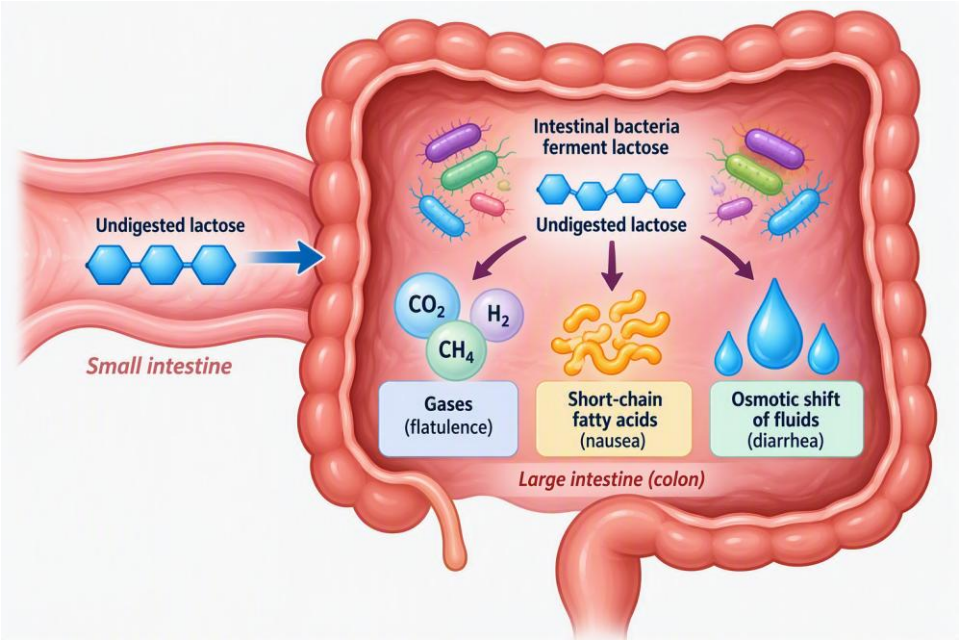
Pharmacy FAQ

Lactose Intolerance and Pharmaceutical Excipient Lactose

1. What is lactose intolerance?

Lactose intolerance (LI) is defined as the presence of symptoms, such as abdominal pain, bloating, diarrhea, flatulence, and headache, occurring within 30 minutes to 12 hours of lactose ingestion. LI results from lactose malabsorption, which occurs in 28% of European populations and in up to 68% of the global population. People have varying degrees of lactose malabsorption and not everyone with lactose malabsorption will experience LI.

Lactose malabsorption is due to low lactase enzyme activity in the small intestine. Unabsorbed lactose passes into the colon where it causes an osmotic shift of fluids and is fermented by intestinal bacteria, resulting in symptoms of LI, as illustrated below.



Severity of symptoms depends on the amount of lactose ingested and the extent of malabsorption. In general, individuals experiencing symptoms after consuming only a small amount of lactose are thought to have a lower tolerance threshold due to a greater degree of lactose malabsorption. Ingesting lactose with foods having a higher osmolality (typically those with a high sugar or salt content, such as juices, sports drinks, or broths) and fat content slows gastric emptying and reduces the severity of LI symptoms.

Decreased lactase enzyme production by cells in the small intestine may result from:

- Reduced genetic expression of lactase
- Temporary gastrointestinal (GI) injury (e.g., infection, surgery, antibiotics, anti-inflammatory medications)
- Injury to bowel mucosa from fluorouracil or pelvic radiation therapy (RT)
    - Usually reversible upon discontinuation; persists in about 5% of patients receiving RT
- Immune checkpoint inhibitors (ICIs) may theoretically affect the gut microbiome
    - Currently, there is no clinical evidence whether ICIs increase LI

2. Does excipient lactose cause LI symptoms?

Lactose is commonly used as a tablet and capsule filler because it is assumed to be pharmacologically inactive. As of October 2019, 33% of all oral medications marketed in Canada and 47 oral oncology medications on the BC Cancer formulary contained lactose. A literature review found only 9 case reports involving 16 patients over a 49-year period (1970 to 2019) attributing LI symptoms to excipient lactose. These case reports varied in the strength of their causality and none of the reports were specific to oncology medications. Given the widespread use of lactose-containing medications and the high prevalence of lactose malabsorption, reports of LI due to excipient lactose have been extremely rare.

3. How much lactose can people with LI tolerate?

Although there are rare reports of LI developing after as little as 100 mg of excipient lactose, studies report most people with LI can tolerate:

- Up to 12 g of dietary lactose in a single daily dose (about 1 cup of milk)
- Up to 18 g of dietary lactose in a single daily dose when taken with food
- Up to 12 g of dietary lactose twice daily, widely spaced, when taken with food

There is currently no clinical evidence suggesting patients with LI and cancer, or LI secondary to cancer treatments, tolerate a lower amount of lactose. It is reported that most oral medications contain less than 2 g of excipient lactose per daily dose, with a median of 350 mg per daily dose found in non-oncology GI medications.

4. How much lactose is found in oral oncology medications?

Because published data was unavailable in 2019, we evaluated a sample of 72 commonly used oncology tablets and capsules. We assumed lactose accounted for all excipient weight to estimate the maximum possible lactose content in each product. The median excipient weight was 145 mg per dosage form, with values ranging from 30 mg to 650 mg. These amounts are far below the 12 to 18 g of lactose reported to be tolerated daily by patients with LI.

5. What additional factors should be considered?

Some patients who have experienced LI symptoms after consuming larger amounts of dietary lactose may anticipate symptoms after ingesting a very small quantity of excipient lactose. This is referred to as a **nocebo effect,** an adverse response to an inert substance driven by expectations rather than pharmacologic effects. Nocebo responses may be subjective, such as nausea, headache, or itching, or objective, such as tachycardia, vomiting, or skin rash. Nocebo effects are well

documented in drug allergy practice and may contribute to perceived intolerance of excipient lactose. Patient education and reassurance have been shown to counter these nocebo effects and prevent adverse events in patients receiving chemotherapy for GI cancers.

6. How can I help patients with LI when they start a new oncology medication containing excipient lactose?

Minimize the nocebo effect:

- Avoid routinely highlighting lactose content in medications
- BC Cancer is removing lactose information from Patient Handouts and Monographs

If patients enquire, reassure and educate:

- Most patients with LI can tolerate substantially more lactose than is present in the majority of medications we dispense
  - **≥ 5 to 10 times** the amount of lactose present in oncology regimens requiring several large tablets or capsules per dose (e.g., capecitabine)
- GI symptoms are more likely to result from adverse effects of the medication or from medical conditions than from LI
- Explain the nocebo effect

Lactase enzyme replacement (e.g., Lactaid®):

- Reduces LI symptoms for many patients, as shown in some studies
- Cannot hydrolyze all lactose, therefore, effectiveness varies between individuals
- Reasonably safe option for an empiric trial

Do not recommend probiotics:

- Though probiotics have been tried to increase lactase production, a systematic review showed they generally did not improve LI symptoms
- May pose an infection risk to immunocompromised oncology patients

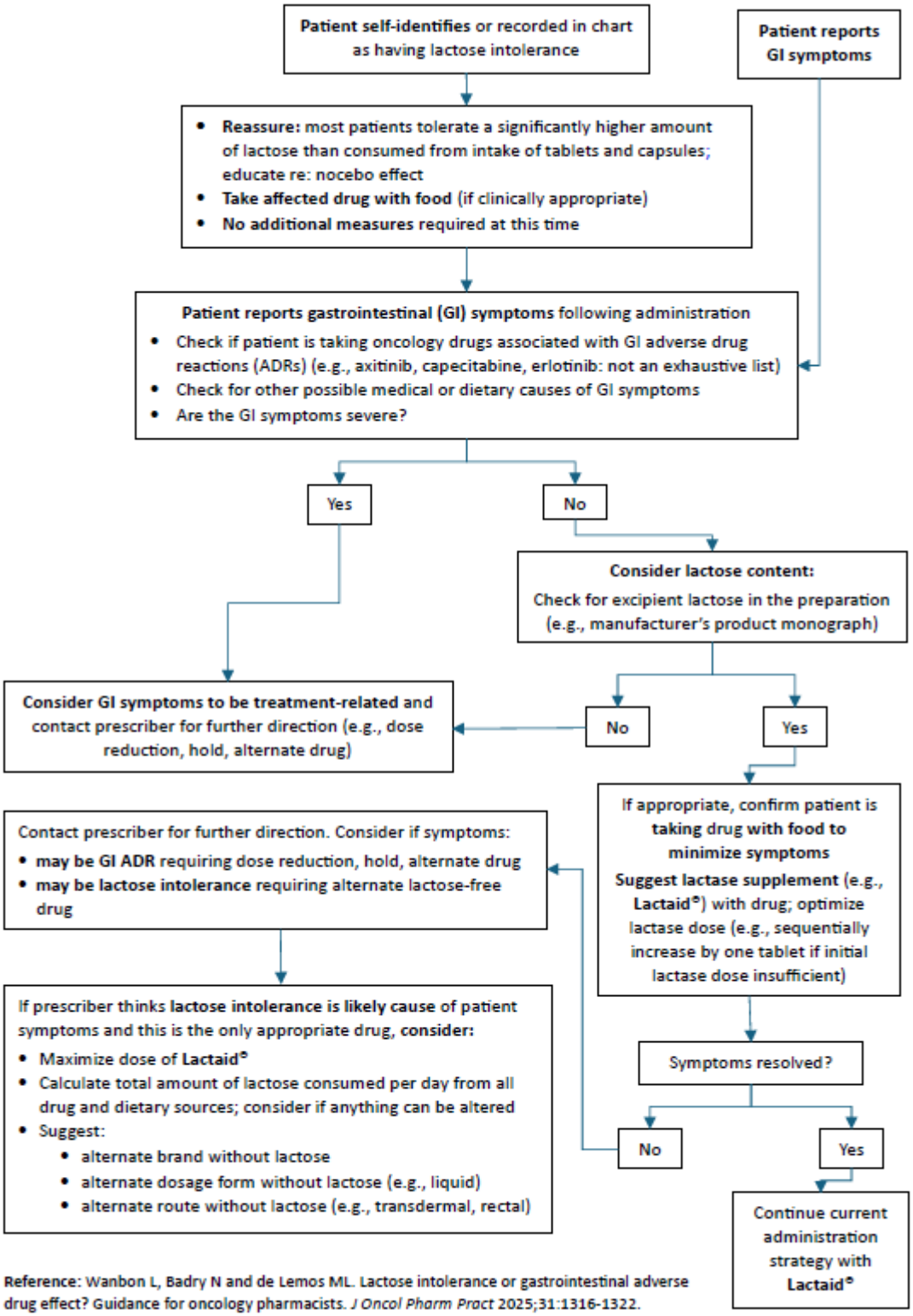
7. How do I know if my patient is experiencing LI or GI adverse effects?

If you need to determine whether the GI symptoms a patient is experiencing are caused by excipient lactose or are the result of an oncology medication adverse effect, use the **Approach to Dispensing Oral Medications for Patients with Lactose Intolerance** flowchart, available below and in the Cancer Drug Manual appendix, to guide assessment and management.

References:

1. Wanbon L, Badry N, de Lemos ML. Lactose intolerance or gastrointestinal adverse drug effect? guidance for oncology pharmacists. Journal of Oncology Pharmacy Practice ; December, 2025;31(8):1316–1322
2. Microsoft. Copilot for Microsoft 365 v2023. Accessed September 24, 2026. Available at: https://copilot.microsoft.com/ (Image credit)

Approach to Dispensing Oral Medications for Patients with Lactose Intolerance



Reference: Wanbon L, Badry N and de Lemos ML. Lactose intolerance or gastrointestinal adverse drug effect? Guidance for oncology pharmacists. *J Oncol Pharm Pract* 2025;31:1316-1322.

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