

## **Drugs and Therapeutics Backgrounder**

### Stool Softeners: WHY are they still used?

# **BOTTOM LINE:** Docusate is no more effective than placebo for the prevention and treatment of constipation.

#### Background:

Docusate salts (sodium and calcium) are widely available, over-the-counter medications classified as stool softeners. Their surfactant action, in theory, keeps stool pliable and prevents straining during defecation. The utility of stool softeners have been questioned for a number of years<sup>1</sup>, and objective evidence for their effectiveness in treating and preventing constipation shows no benefit.<sup>2,3</sup> Despite this, stool softeners are frequently dispensed in Alberta Health Services (AHS) - there were over 2.1 million 100mg doses dispensed in 2013. Although not expensive medications (approximately \$108,000 in acquisition costs), this does represent significant use of pharmacy and nursing resources, and adds to the medication burden borne by our patients for a therapy that has no efficacy.

#### Efficacy:

A recent review of the evidence and a Canadian consensus statement conclude that that docusate is no more effective than placebo in the prevention or management of constipation in geriatric patients, irritable bowel syndrome patients, and otherwise healthy patients.<sup>3,4</sup> Using docusate for constipation in palliative or terminally ill patients does not improve stool frequency, consistency or the patient's perceptions of bowel movements.<sup>6,7</sup> In a study with palliative care patients, adding docusate to sennosides did not improve the frequency or consistency of bowel movements, and it was observed that the patients receiving docusate had an increased need for rescue laxatives.<sup>8</sup> In patients with opioid induced bowel dysfunction, stool softeners are not effective when administered alone.<sup>10</sup> There is no data for the use of docusate in children.<sup>5</sup>

#### Safety of stopping docusate:

Docusate is not absorbed systemically and does not interact with receptors in the gastrointestinal tract, withdrawal or rebound effects are not a concern.<sup>11</sup> Docusate may be stopped without tapering or additional monitoring.

#### Sustainability:

As comparative trials between docusate and other laxatives do not indicate any benefit<sup>2,12</sup>, *patients already using docusate could have it withdrawn <u>without the need to replace it with another laxative</u>. For patients requiring treatment or prevention of constipation, there are several other effective formulary options available to choose from, such as magnesium hydroxide, polyethylene glycol 3350, psyllium, and lactulose.<sup>9</sup> Selection of laxative agent(s) depends on several factors and must be individualized to the patient.* 

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