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Docusate

Updated: January 9, 2018.

OVERVIEW

Introduction

Docusate is an orally available, over-the-counter laxative and stool softener used to treat or prevent constipation. Docusate has not been linked to serum enzyme elevations during therapy or to clinically apparent liver injury with jaundice.

Background

Docusate (dok' ue sate) is a stool softener and surfactant previously known as dioctyl sodium [or calcium] sulfosuccinate (DSS). Docusate is commonly used to treat or prevent constipation and to promote bowel regularity in hospitalized, bed-bound or immobilized persons. Docusate salts are thought to act as detergents, reducing surface tension of liquids and fatty substances in the intestine, thereby softening stool consistency. The efficacy of docusate in treatment and prevention of constipation has not been well documented. However, extensive experience with its use has documented its safety and tolerability. Docusate has been in use in the U.S. since the 1950s and current indications are for treatment and prevention of constipation. Docusate is available without prescription in capsules of 50, 100, 240 and 250 mg generically and under various brand names such as Colace, Doxidan, Regulex, Silace and Surfak. A liquid formulation for oral use is also available. The typical oral dose is 50 to 300 mg daily until bowel movements are normal. Common side effects include diarrhea, abdominal cramping, nausea, bitter taste and dizziness.

Hepatotoxicity

Docusate has not been linked to elevations in serum enzyme levels during treatment, although there have been few published studies of its effects of liver tests. There have been no cases of clinically apparent liver injury attributable to docusate published in the literature and, thus, significant liver injury from docusate must be exceedingly rare, if it occurs at all.

Likelihood score: E (unlikely cause of clinically apparent liver injury).

Mechanism of Injury

Docusate is metabolized by the liver and undergoes extensive first-pass metabolism to both active and inactive metabolites. Despite its hepatic metabolism and high level of plasma protein binding, it has not been implicated in causing drug-drug interactions. The lack of reported cases of liver injury due to docusate may be due to the low doses of typical therapy.

Drug Class: Gastrointestinal Agents, Cathartics and Laxatives

PRODUCT INFORMATION

REPRESENTATIVE TRADE NAMES

Docusate – Generic, Colace®

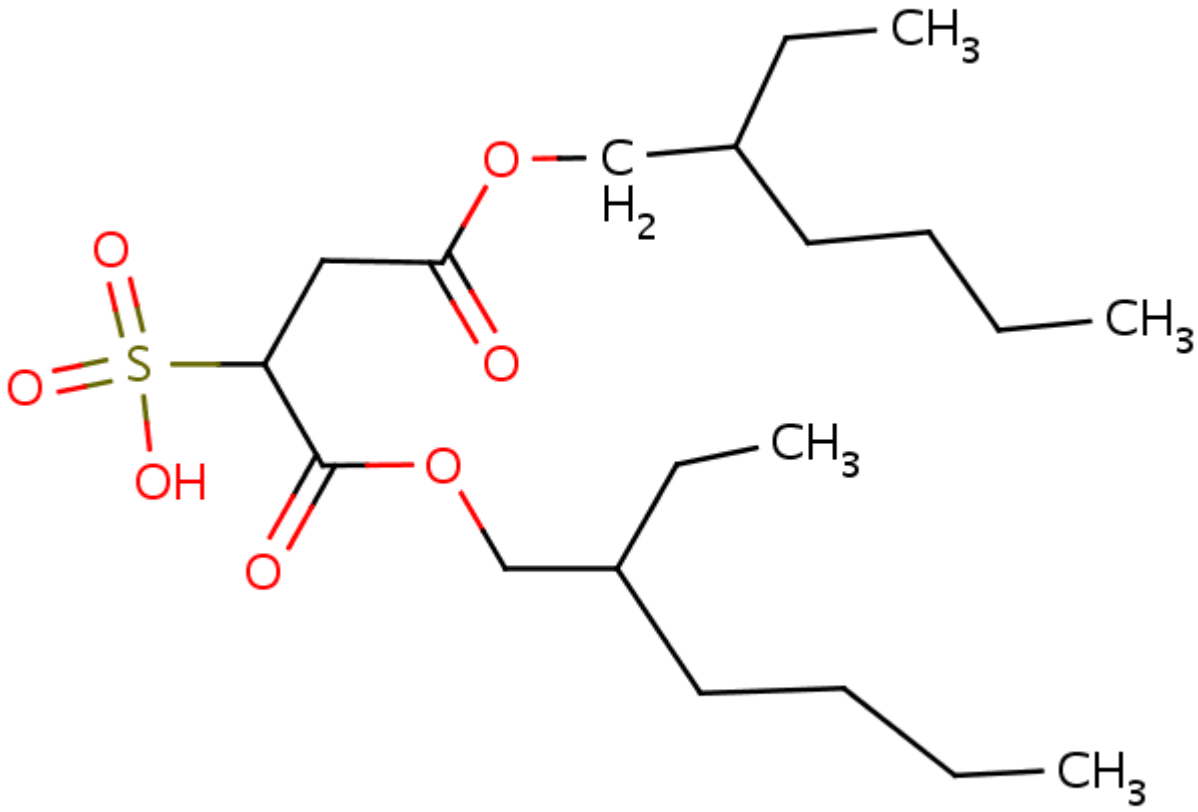
DRUG CLASS

Gastrointestinal Agents

COMPLETE LABELING

Product labeling at DailyMed, National Library of Medicine, NIH

CHEMICAL FORMULA AND STRUCTURE

DRUG	CAS REGISTRY NO.	MOLECULAR FORMULA	STRUCTURE
Docusate	10041-19-7	C20-H38-O7-S	

ANNOTATED BIBLIOGRAPHY

References updated: 09 January 2018

Zimmerman HJ. Antiemetic and prokinetic compounds. Miscellaneous drugs and diagnostic chemicals. In, Zimmerman, HJ. Hepatotoxicity: the adverse effects of drugs and other chemicals on the liver. 2nd ed. Philadelphia: Lippincott, 1999: pp. 721.

(Expert review of hepatotoxicity published in 1999 does not discuss docusate).

Sharkey KA, Wallace JL. Treatment of disorders of bowel motility and water flux: anti-emetics; agents used in biliary and pancreatic disease. In, Brunton LL, Chabner BA, Knollman BC, eds. Goodman & Gilman's the pharmacological basis of therapeutics. 12th ed. New York: McGraw-Hill, 2011, pp. 1323-50.

(Textbook of pharmacology and therapeutics).

Ramkumar D, Rao SS. Efficacy and safety of traditional medical therapies or chronic constipation: systematic review. Am J Gastroenterol 2005; 100: 936-71. PubMed PMID: 15784043.

(Systematic review of the literature for controlled trials of traditional therapies for constipation reported "a paucity of trials for many commonly used agents", including bisacodyl and docusate).

Hurdon V, Viola R, Schroder C. How useful is docusate in patients at risk for constipation? A systematic review of the evidence in the chronically ill. J Pain Symptom Manage 2000; 19: 130-6. PubMed PMID: 10699540.

(Systematic review of efficacy of docusate for constipation in chronically ill patients identified four studies of docusate vs placebo for 20 to 26 days in doses of 60-480 mg daily, all showing slight effect on stool frequency, but only one documenting normal laboratory test results on treatment).

Chalasani N, Fontana RJ, Bonkovsky HL, Watkins PB, Davern T, Serrano J, Yang H, Rochon J; Drug Induced Liver Injury Network (DILIN). Causes, clinical features, and outcomes from a prospective study of drug-induced liver injury in the United States. Gastroenterology 2008; 135: 1924-34. PubMed PMID: 18955056.

(Among 300 cases of drug induced liver disease in the US collected between 2004 and 2008, no cases were attributed to laxatives).

Mueller-Lissner SA, Wald A. Constipation in adults. Clin Evid (Online) 2010; 2010. pii: 0413. PubMed PMID: 21418672.

(Review of evidence of efficacy of conventional therapies of constipation).

Ruston T, Hunter K, Cummings G, Lazarescu A. Efficacy and side-effect profiles of lactulose, docusate sodium, and sennosides compared to PEG in opioid-induced constipation: a systematic review. Can Oncol Nurs J 2013; 23: 236-46. PubMed PMID: 24428006.

(Systematic review of literature on controlled trials of docusate in opioid induced constipation found no articles that met the authors' criteria for medical evidence of efficacy; no discussion of safety).

Tarumi Y, Wilson MP, Szafran O, Spooner GR. Randomized, double-blind, placebo-controlled trial of oral docusate in the management of constipation in hospice patients. J Pain Symptom Manage 2013; 45: 2-13. PubMed PMID: 22889861.

(In 74 hospice patients treated with docusate or placebo for 10 days, there were no differences in stool frequency or consistency between the two groups; adverse events were not mentioned).

Müller-Lissner S. Pharmacokinetic and pharmacodynamic considerations for the current chronic constipation treatments. Expert Opin Drug Metab Toxicol 2013; 9: 391-401. PubMed PMID: 23425050.

(Review of the pharmacology, efficacy and safety of medications for constipation mentions that docusate is commonly used, but "there is apparently no evidence at all that it is better than placebo"; no mention of side effects).

Björnsson ES, Bergmann OM, Björnsson HK, Kvaran RB, Olafsson S. Incidence, presentation and outcomes in patients with drug-induced liver injury in the general population of Iceland. Gastroenterology 2013; 144: 1419-25. PubMed PMID: 23419359.

(In a population based study of drug induced liver injury from Iceland, 96 cases were identified over a 2 year period, but none were attributed to laxatives).

Chalasani N, Bonkovsky HL, Fontana R, Lee W, Stolz A, Talwalkar J, Reddy KR, et al.; United States Drug Induced Liver Injury Network. Features and outcomes of 899 patients with drug-induced liver injury: The DILIN Prospective Study. Gastroenterology 2015; 148: 1340-52.e7. PubMed PMID: 25754159.

(Among 899 cases of drug induced liver injury enrolled in a US prospective study between 2004 and 2013, none were attributed to docusate or other over-the-counter laxatives).