

# Laxatives, Hyperosmotic

Source: [https://webprod.hc-sc.gc.ca/nhp/nd-bdipsn/atReq?atid=laxa\\_hyperosmo](https://webprod.hc-sc.gc.ca/nhp/nd-bdipsn/atReq?atid=laxa_hyperosmo) (eng)

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Hyperosmotic Laxatives Help on accessing alternative formats, such as Portable Document Format ( PDF ), Microsoft Word and PowerPoint ( PPT ) files, can be obtained in the alternate format help section. (PDF Version - 52 K) This monograph is intended to serve as a guide to industry for the preparation of Product Licence Applications (PLAs) and labels for natural health product market authorization. It is not intended to be a comprehensive review of the medicinal ingredients. Notes Text in parentheses is additional optional information which can be included on the PLA and product label at the applicant's discretion. The solidus (/) indicates that the terms and/or the statements are synonymous. Either term or statement may be selected by the applicant. Date February 23, 2024 Proper name(s), Common name(s), Source information Table 1. Proper name(s), Common name(s), Source information Proper name(s) Common name(s) Source information 1 Source ingredient 1,2,3-Propanetriol Glycerin Glycerine Glycerol Glycerol D-Glucitol D-Sorbitol D-Glucitol D-Sorbitol Sorbitol Sorbitol 1 The ingredients must be pharmacopoeial grade. References: Proper names: RSC 2024; USP-NF 2023; Gottschalck and McEwen 2006; BP 2003; Common names: RSC 2024; USP-NF 2023; Gottschalck and McEwen 2006, BP 2003; Source ingredients: RSC 2024; USP-NF 2023; Gottschalck and McEwen 2006; BP 2003. Route of administration Rectal (US FDA 2023) Dosage form(s) Suppository, Enema (US FDA 2023) Use(s) or Purpose(s) For relief of occasional constipation and/or irregularity (US FDA 2023) Laxative (US FDA 2023) Promotes evacuation of the lower bowel (Sweetman 2002). Note: The above uses can be combined on the product label (e.g., Laxative for the relief of occasional constipation and/or irregularity and promotes evacuation of the lower bowel). Dose(s) Subpopulation(s): As specified below Quantity(ies): 1 suppository or enema per day. Table 2. Dose information of Glycerine and Sorbitol based on dosage forms and subpopulations Medicinal - Ingredients Dosage form(s) Subpopulation(s) Dose/day Minimum Maximum Glycerine Rectal suppository Children 2-5 years 1.0 g 1.7 g Children 6-11 years 2 g 3 g Adolescents 12-17 years Adults 18 years and older Rectal enema Children 2-5 years 2 ml of 80% v/v solution 5 ml of 80% v/v solution Children 6-11 years 5 ml of 80% v/v solution 15 ml of 80% v/v solution Adolescents 12-17 years Adults 18 years and older Sorbitol Rectal enema Children 2-11 years 30 ml of 25-30% w/v solution 60 ml of 25-30% w/v solution Adolescents 12-17 years 120 ml of 25-30% w/v solution Adults 18 years and older Reference: US FDA 2023. Directions for use All products Do not use within 2 hours of another medicine as the desired effect of the other medicine may be reduced (Berardi et al. 2002). Suppositories Remove suppository from wrapper (for suppositories packaged in a wrapper) (US FDA 2021). Gently insert into the rectum Allow 15 minutes to 1 hour to produce bowel movement (US FDA 2023). Enemas Lubricate anus with petroleum jelly before inserting the enema applicator (USP DI 1997). Gently insert the tip of the enema applicator to prevent damage to the rectal wall (USP DI 1997). Allow 15 minutes to 1 hour to produce bowel movement (US FDA 2023). Duration(s) of use Do not use beyond 7 days (US FDA 2023). Risk information Caution(s) and warning(s) All products Ask a health care practitioner/health care provider/health care professional/doctor/physician if symptoms persist or worsen (US FDA 2021). Ask a health care practitioner/health care provider/health care professional/doctor/physician promptly in case of bleeding (US FDA 2021). Products containing glycerine Stop use and ask a health care practitioner/health care provider/health care professional/doctor/physician if you experience rectal discomfort or a burning sensation (US FDA 2023). Contraindication(s) All products Do not use if you have abdominal pain, nausea, fever or vomiting (US FDA 2023). Products containing glycerine Do not use if you have rectal irritation (Berardi et al. 2002). Known adverse reaction(s) No statement required Non-medicinal ingredients Must be chosen from the current Natural Health Products Ingredients Database (NHPID) and must meet the limitations outlined in the database. Storage conditions Must be established in accordance with the requirements described in the Natural Health Products Regulations . Specifications The finished product specifications must be established in accordance with the requirements described in the Natural and Non-prescription Health Products Directorate (NNHPD) Quality of Natural Health Products Guide. The medicinal ingredient must comply with the requirements outlined in the NHPID. Example of Product Facts Consult the Guidance Document, Labelling of Natural Health Products for more details. References cited Berardi RR, DeSimone EM, Newton GD, Oszko MA, Popovich NG, Rollins CJ, Shimp LA, Tietze KJ, editors. Handbook of Nonprescription Drugs: An Interactive Approach to Self-Care. 13 th edition. Washington (DC):

American Pharmaceutical Association; 2002. BP 2003: British Pharmacopoeia Commission. British Pharmacopoeia. London (UK): The Stationary Office; 2003. RSC 2024: Royal Society of Chemistry: The Merck Index Online [Accessed 2024 January 19]. Available from: <https://merckindex.org/> Sweetman SC, editor. Martindale: The Complete Drug Reference. 33rd edition. Grayslake (IL): Pharmaceutical Press; 2002. US FDA 2021. USA Department of Health and Human Services: Food and Drug Administration. Anorectal Drug Products for Over-the-Counter Human Use; 2021. [Accessed 2024 January 19]. Available at: [https://dps-admin.fda.gov/omuf/sites/omuf/files/monograph-documents/2022-09/OTC%20Monograph\\_M015-Anorectal%20Drug%20Products%20for%20OTC%20Human%20Use%20Posted%20Corrected%2002\\_23\\_22.pdf](https://dps-admin.fda.gov/omuf/sites/omuf/files/monograph-documents/2022-09/OTC%20Monograph_M015-Anorectal%20Drug%20Products%20for%20OTC%20Human%20Use%20Posted%20Corrected%2002_23_22.pdf) US FDA 2023. USA Department of Health and Human Services: Food and Drug Administration. Laxative Drug Products for Over-the-Counter Human Use; 2023. [Accessed 2024 January 19]. Available at: [https://dps-admin.fda.gov/omuf/sites/omuf/files/monograph-documents/2023-05/OTC%20Monograph\\_M007-Laxative%20Drug%20Products%20for%20OTC%20Human%20Use%2005.02.2023.pdf](https://dps-admin.fda.gov/omuf/sites/omuf/files/monograph-documents/2023-05/OTC%20Monograph_M007-Laxative%20Drug%20Products%20for%20OTC%20Human%20Use%2005.02.2023.pdf) USP-NF 2023: United States Pharmacopeia and the National Formulary. Rockville (MD): United States Pharmacopeial Convention, Inc.; 2023. USP DI 1997. Advice for the Patient, Volume II, 17 th edition. Rockville (MD): United States Pharmacopoeial Convention; 1996. Report a problem on this page Date modified: 2019-03-01

## MEDICINAL INGREDIENT(S)

Notes Text in parentheses is additional optional information which can be included on the PLA and product label at the applicant's discretion. The solidus (/) indicates that the terms and/or the statements are synonymous. Either term or statement may be selected by the applicant. Date February 23, 2024

## DOSAGE FORM(S)

Medicinal	-	Ingredients	Dosage	form(s)	Subpopulation(s)	Dose/day	Minimum	Maximum	Glycerine	Rectal
suppository		Children 2-5 years	1.0 g	1.7 g	Children 6-11 years	2 g	3 g	Adolescents 12-17 years	Adults 18 years and older	Rectal enema
		Children 2-5 years	2 ml	of 80% v/v solution	5 ml	of 80% v/v solution	Children 6-11 years	5 ml	of 80% v/v solution	15 ml
		of 80% v/v solution	15 ml	of 80% v/v solution	Adolescents 12-17 years	Adults 18 years and older	Sorbitol	Rectal enema	Children 2-11 years	30 ml
		of 25-30% w/v solution	60 ml	of 25-30% w/v solution	Adolescents 12-17 years	120 ml	of 25-30% w/v solution	Adults 18 years and older		

## RISK INFORMATION

Caution(s) and warning(s) All products Ask a health care practitioner/health care provider/health care professional/doctor/physician if symptoms persist or worsen (US FDA 2021). ASK a health care practitioner/health care provider/health care professional/doctor/physician promptly in case of bleeding (US FDA 2021). Products containing glycerine Stop use and ask a health care practitioner/health care provider/health care professional/doctor/physician if you experience rectal discomfort or a burning sensation (US FDA 2023). Contraindication(s) All products Do not use if you have abdominal pain, nausea, fever or vomiting (US FDA 2023). Products containing glycerine Do not use if you have rectal irritation (Berardiet al.2002). Known adverse reaction(s) No statement required

## NON-MEDICINAL INGREDIENTS

Must be chosen from the current Natural Health Products Ingredients Database (NHPID) and must meet the limitations outlined in the database.

## STORAGE CONDITION(S)

Must be established in accordance with the requirements described in the Natural Health Products Regulations.

## SPECIFICATIONS

The finished product specifications must be established in accordance with the requirements described in the Natural and Non-prescription Health Products Directorate (NNHPD) Quality of Natural Health Products Guide. The medicinal ingredient must comply with the requirements outlined in the NHPID.

Proper name(s)	Common name(s)	Source information <sup>1</sup>
Source ingredient		
1,2,3-Propanetriol	GlycerinGlycerineGlycerol	Glycerol
D-GlucitolD-Sorbitol	D-GlucitolD-SorbitolSorbitol	Sorbitol

	Dosage form(s)	Subpopulation(s)	Dose/day	
	Maximum			
	Rectal suppository	Children 2-5 years	1.0 g	1.7 g
	2 g	3 g		
	Children 2-5 years	2 ml of 80% v/v solution	5 ml of 80% v/v solution	
	5 ml of 80% v/v solution	15 ml of 80% v/v solution		
	Rectal enema	Children 2-11 years	30 ml of 25-30% w/v solution	60 ml o
	120 ml of 25-30% w/v solution			