

NATURAL HEALTH PRODUCT

HYPEROSMOTIC LAXATIVES

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 ingredient.

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 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(s)
1,2,3-Propanetriol	<ul style="list-style-type: none"> • Glycerin • Glycerine • Glycerol 	Glycerol
<ul style="list-style-type: none"> • D-Glucitol • D-Sorbitol 	<ul style="list-style-type: none"> • D-Glucitol • D-Sorbitol • Sorbitol 	Sorbitol

¹The 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 Ingredient(s)	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.



Direction(s) 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.

Product Facts	
Medicinal ingredient in each suppository	
Glycerol	XX g
Uses <ul style="list-style-type: none"> • For relief of occasional constipation and/or irregularity • Laxative • Promotes evacuation of the lower bowel 	
Warnings	
If applicable: Allergens: food allergen, gluten (gluten source), sulphites Contains aspartame	
Do not use if • you have abdominal pain, nausea, fever or vomiting • you have rectal irritation.	
Stop use and ask a health care practitioner if you experience rectal discomfort or a burning sensation.	
Ask a health care practitioner • if symptoms persist or worsen • promptly in case of bleeding.	
Directions Adults, adolescents and children 6 and older: • Use 1 suppository per day • Do not use this product within 2 hours of another medicine as the desired effect of the other medicine may be reduced • Remove suppository from wrapper (for suppositories packaged in a wrapper) • Gently insert into the rectum • Allow 15 minutes to 1 hour to produce bowel movement • Do not use beyond 7 days.	
Other information (Add storage information)	
Non-medicinal ingredients List all NMIs	
Questions? (Call) 1-XXX-XXX-XXXX	

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. 13th edition. Washington (DC): American Pharmaceutical Association; 2002.

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RSC 2024: Royal Society of Chemistry: The Merck Index Online [Accessed 2024 January 19]. Available from: <https://merckindex.org/> Royal

Sweetman SC, editor. Martindale: The Complete Drug Reference. 33rd edition. Grayslake (IL): Pharmaceutical Press; 2002.

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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

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

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