

## 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

July 5, 2021

#### 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 <sup>1</sup>
		Source ingredient(s)
1,2,3-Propanetriol	<ul style="list-style-type: none"> <li>▶ Glycerin</li> <li>▶ Glycerine</li> <li>▶ Glycerol</li> </ul>	Glycerol
<ul style="list-style-type: none"> <li>▶ D-Glucitol</li> <li>▶ D-Sorbitol</li> </ul>	<ul style="list-style-type: none"> <li>▶ D-Glucitol</li> <li>▶ D-Sorbitol</li> <li>▶ Sorbitol</li> </ul>	Sorbitol

<sup>1</sup>The ingredients must be pharmacopoeial grade.

References: Proper names: Gottschalck and McEwen 2006, NF 24 2006, USP 29 2006, BP 2003, O'Neil et al. 2001; Common names: Gottschalck and McEwen 2006, NF 24 2006, USP 29 2006, BP 2003, O'Neil et al. 2001; Source ingredients: Gottschalck and McEwen 2006, NF 24 2006, USP 29 2006, BP 2003, O'Neil et al. 2001.

#### Route of administration

Rectal (FDA 1985)

#### Dosage form(s)

Suppository; Enema (FDA 1985)

### Use(s) or Purpose(s)

- ▶ For relief of occasional constipation and/or irregularity (FDA 1985)
- ▶ Laxative (FDA 1985)
- ▶ Promotes evacuation of the lower bowel (Sweetman 2002).

### Dose(s)

#### Subpopulation(s)

As specified below.

#### Quantity(ies)

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: FDA 1985.

#### Direction(s) for use

*All products*

Do not take this product within 2 hours of another medicine as the desired effect of the other medicine may be reduced (Berardi et al. 2002).

### *Suppositories*

1. Remove suppository from wrapper (for suppositories packaged in a wrapper) (FDA 1990).
2. Gently insert into the rectum.
3. Allow 15 minutes to 1 hour to produce bowel movement (FDA 1985).

### *Enemas*

1. Lubricate anus with petroleum jelly before inserting the enema applicator (USP DI 1997).
2. Gently insert the tip of the enema applicator to prevent damage to the rectal wall (USP DI 1997).
3. Allow 15 minutes to 1 hour to produce bowel movement (FDA 1985).

### **Duration(s) of use**

Do not use this product beyond 7 days (FDA 1985).

### **Risk information**

#### **Caution(s) and warning(s)**

##### *All products*

- ▶ Consult a health care practitioner/health care provider/health care professional/doctor/physician if symptoms persist or worsen (FDA 1990).
- ▶ Consult a health care practitioner/health care provider/health care professional/doctor/physician promptly in case of bleeding (FDA 1990).

##### *Products containing glycerine*

Stop use and consult a health care practitioner/health care provider/health care professional/doctor/physician if rectal discomfort or a burning sensation occurs (FDA 1985).

#### **Contraindication(s)**

##### *All products*

Do not use this product if you have abdominal pain, nausea, fever or vomiting (FDA 1985).

##### *Products containing glycerine*

Do not use this product 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* (NHPR).

### **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.

### **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<sup>th</sup> edition. Washington (DC): American Pharmaceutical Association; 2002.

BP 2003: British Pharmacopoeia Commission. British Pharmacopoeia. London (UK): The Stationary Office; 2003.

FDA 1990. USA Department of Health and Human Services: Food and Drug Administration. 55 CFR Part 346. Anorectal Drug Products for Over-the-Counter Human Use; Final Monograph; 1990. FR Citation: 55FR31776 [Accessed 2019 July 4]. Available at: <https://www.fda.gov/drugs/status-otc-rulemakings/rulemaking-history-otc-anorectal-drug-products>

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NF 24: United States Pharmacopeia and the National Formulary (USP 29/NF 24). Rockville (MD): United States Pharmacopeial Convention, Inc.; 2006.

O'Neil MJ, Smith A, Heckelman PE, Budavari S, editors. Merck Index: An Encyclopedia of Chemicals, Drugs, and Biologicals. 13<sup>th</sup> edition. Whitehouse Station (NJ): Merck and Co., Inc; 2001.

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

USP 29: United States Pharmacopeia and the National Formulary (USP 29/NF 24). Rockville (MD): United States Pharmacopeial Convention, Inc.; 2006.

USP DI 1997. Advice for the Patient, Volume II, 17<sup>th</sup> edition. Rockville (MD): United States Pharmacopoeial Convention; 1996.