

HYPEROSMOTIC LAXATIVES

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Note: The mechanism of action for hyperosmotic laxatives is the attraction of water into the stool, promoting bowel movement.

Table 1: Medicinal ingredients

Proper name(s)	Common name(s)	Source material(s)
Glycerine/glycerol (Gottschalck and McEwen 2006; USP 29; O'Neil <i>et al.</i> 2001)	Glycerine/glycerol (Gottschalck and McEwen 2006; USP 29; O'Neil <i>et al.</i> 2001)	Glycerine/glycerol* (Gottschalck and McEwen 2006; USP 29; O'Neil <i>et al.</i> 2001) CAS No. 000056-81-5 ⁺
Sorbitol/D-glucitol (NF 24; BP 2003; O'Neil <i>et al.</i> 2001)	Sorbitol/D-glucitol (NF 24; BP 2003; O'Neil <i>et al.</i> 2001)	Sorbitol/D-glucitol* (NF 24; BP 2003; O'Neil <i>et al.</i> 2001) CAS No. 000050-70-4 ⁺

*Ingredient must be pharmacopoeial grade (for a list of acceptable pharmacopoeial grades, see the Compendium of Monographs Guidance Document) or requires citation of an approved NHP Master File, authorized by a letter of access issued to the applicant by the NHP Master File's registered owner.

⁺The CAS number may be provided as additional information.

Note: Optional pharmacopoeial standard formulations are shown in Appendix 1.

Route(s) of administration: Rectal (FDA 1985)

Dosage form(s): Suppository, enema (FDA 1985)

Use(s) or Purpose(s): Statement(s) to the effect of:

- For relief of occasional constipation (irregularity of the bowel; lack of regular bowel movement) (FDA 1985)
- Laxative (FDA 1985)
- Promotes evacuation of the lower bowel (Sweetman).

Dose(s):

Subpopulation: For all products: Adults and children 2 years and older (FDA 1985)

Quantity:

Glycerine rectal suppository:

Children 2-5 years: 1.0-1.7 g per day (FDA 1985)

Adults and children 6 years and older: 2-3 g per day (FDA 1985)

Glycerine rectal enema:

Children 2-5 years: 2-5 mL of 80% v/v solution per day (FDA 1985)

Adults and children 6 years and older: 5-15 mL of 80% v/v solution (FDA 1985)

Sorbitol rectal enema:

Children 2-11 years: 30-60 mL of 25-30% w/v solution (FDA 1985)

Adults and children 12 years and older: 120 mL of 25-30% w/v solution (FDA 1985)

Directions for use: Statement(s) to the effect of:

For all products:

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

For suppositories:

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

For 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 (FDA 1985).

Duration of use: Do not use for more than 7 days (FDA 1985).

Risk information: Statement(s) to the effect of:

Cautions and warnings:

For all products:

- Consult a health care practitioner if condition persists or worsens (FDA 1990).
- Consult a health care practitioner promptly in case of bleeding (FDA 1990).

For products containing glycerine:

- Discontinue use and consult a health care practitioner if rectal discomfort or a burning sensation occurs (FDA 1985).

Contraindications:

For all products:

- Do not use in the presence of abdominal pain, nausea, fever or vomiting (FDA 1985).

For products containing glycerine:

- Do not use if you have rectal irritation (Berardi *et al.* 2002).

Non-medicinal ingredients: Must be chosen from the current List of Acceptable Non-medicinal Ingredients and must meet the limitations outlined in the list.

Specifications: Must comply with the minimum specifications outlined in the current Compendium of Monographs.

References:

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.

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. [Accessed 2006-01-26]. Available at:
http://www.fda.gov/cder/otcmonographs/Anorectal/anorectal_FR_19900803.pdf

FDA 1985. USA Department of Health and Human Services: Food and Drug Administration. 21 CFR Part 334. Laxative Drug Products for Over-the-Counter Human Use; Tentative Final Monograph; 1985. [Accessed 2005-12-23]. Available at:
http://www.fda.gov/cder/otcmonographs/Laxative/laxative_TF_19850115.pdf

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. 13th edition. Whitehouse Station (NJ): Merck and Co., Inc; 2001.

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, 17th edition. Rockville (MD): United States Pharmacopeial Convention; 1996.

Appendix 1: Optional pharmacopoeial standard formulations

Formulation	USP 29	BP 2003
Glycerol/glycerine suppositories	X	X