

SORBITOL- sorbitol solution**H&H Laboratories, Inc.**

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

DRUG FACTS

Active Ingredient in each tablespoon=15 ml Sorbitol 15gm

Purpose-Laxative

Uses-Relieves occasional constipation and irregularity. Generally produces bowel movement in 1/4 to 1 hour when used rectally. As a pharmaceutical aid (sweetener). For other uses, ask your doctor.

Directions: For adults and children 12 years or older: Dose-2 tablespoons. maximum single dose-4 tablespoons. Not to exceed 6 tablespoons daily

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Warnings: Do not use: When abdominal pain, nausea, or vomiting are present for more than a week unless directed by a doctor.

Ask a doctor before use if you are taking mineral oil, have noticed a sudden change in bowel habits that lasts over 2 weeks.

Stop use and ask a doctor if: You have rectal bleeding or no bowel movement after using this product. These could be signs of a serious condition.

Inactive Ingredients: Purified Water

MM1

SORBITOL

sorbitol solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52471-111
Route of Administration	RECTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SORBITOL (UNII: 506T60A25R) (SORBITOL - UNII:506T60A25R)	SORBITOL	1 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52471-111-16	473 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	06/10/2013	

Labeler - H&H Laboratories, Inc. (151357175)

Registrant - H&H Laboratories, Inc. (151357175)

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H&H Laboratories, Inc.