

SORBITOL- sorbitol solution
Geri-Care Pharmaceuticals, Corp

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.

gc sorbitol

Active ingredient (In each 15 mL tablespoonful)

Sorbitol 13.5 g

Purpose

Laxative

Uses

- relieves occasional constipation and irregularity
- generally produces bowel movement in 1/4 to 1 hour when used rectally
- as a pharmaceutical aide (sweetner)
- for other uses, as your doctor

Warnings

Do not use

- when abdominal pain, nausea, or vomiting are present
- for more than one 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.

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. In case of overdose, get medical help or contact a

Poison Control Center right away.

Directions

- **do not exceed recommended dose**

Age	Dose
adults and children 12 years and over	For rectal use only. Enema dosage is 120 mL of a 25 to 30% w/v solution (1 part of this product with 2.3 parts water) in a single daily dose as needed, or as directed by your doctor.
children under 12 years	Ask a doctor

Other information

- store at room temperature 15-30C (59-86F)
- below 59F cloudiness and thickening may occur; warming will restore clarity and fluidity without affecting product quality
- do not freeze
- store in original container

Inactive ingredient

water

Questions or comments?

1-800-540-3765

package Label



NDC 57896-435-16

SORBITOL SOLUTION USP 70% W/W LAXATIVE

TAMPER EVIDENT: Do not use this product if inner foil seal over the mouth of bottle is missing or broken.



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210-21001-5



16 FL OZ (1 PT) (473 mL)

REV 0518

Drug Facts

Active Ingredient	Purpose
(In each 15 mL tablespoonful) Sorbitol 13.5 g.....	Laxative

Uses

- relieves occasional constipation and irregularity
- generally produces bowel movement in ¼ to 1 hour when used rectally
- as a pharmaceutical aide (sweetener)
- for other uses, ask your doctor

Warnings

Do not use

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- for more than one week unless directed by a doctor

Ask a doctor before use if you

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- 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.

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Inactive Ingredient: water

Dist. by: Geri-Care Pharmaceuticals
1650 63rd Street
Brooklyn, NY 11204
REV 0518 910-21001-4

Questions or comments?
1-800-540-3765

SORBITOL

sorbitol solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57896-435
Route of Administration	RECTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SORBITOL (UNII: 506T60A25R) (SORBITOL - UNII:506T60A25R)	SORBITOL	13.5 g in 15 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57896-435-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2012	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	01/01/2000	

Labeler - Geri-Care Pharmaceuticals, Corp (611196254)

Registrant - GCP Laboratories (965480861)

Establishment

Name	Address	ID/FEI	Business Operations
GCP LABORATORIES		965480861	manufacture(57896-435) , pack(57896-435)

Revised: 12/2018

Geri-Care Pharmaceuticals, Corp