

SORBITOL- sorbitol solution
Geritrex LLC

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.

Sorbitol Solution

Active Ingredients

Active Ingredients Purpose
Sorbitol 70% Laxative

Uses

For occasional relief of constipation.

Directions

For adults or children 12 years or over. Use 2-4 TBSP (30-60ml) daily or as directed by a Physician.

Use 2-4 TBSP (30-60ml) daily or as directed by a Physician.

Warnings

This product does not contain a child resistant cap. Keep out of reach of children. In case of accidental overdose, contact a doctor or a poison control center.

Cautions

Stop use if you are having rectal bleeding or failure to have a bowel movement after use. If adverse effects call 1-800-736-3437

Unless directed by your doctor

Do not take any laxative if you are having abdominal pain, nausea, or vomiting.

Laxative products should not be used longer than a week.

Ask a pharmacist or doctor if

- You have noticed a sudden change in bowel habits that persist over two weeks after using this product.
- You are pregnant or breast feeding before use.

Water

Store at room temperature (59°F-86°F). Below 59°F cloudiness may occur. Application of heat may restore clarity and fluidity without affecting the quality of Sorbitol.

DO NOT FREEZE.

Keep out of reach of children. In case of accidental overdose, contact a doctor or a poison control center.

NDC 54162-700-16



Sorbitol SOLUTION

U.S.P. (70%w/w)

For occasional relief of constipation

THIS PACKAGE FOR HOUSEHOLDS WITHOUT YOUNG CHILDREN

16 FL. OZ (474ml)

Drug Facts	Purpose
Active ingredient Sorbitol 70%.....	Laxative
Uses For occasional relief of constipation.	
Warnings Stop use if you are having rectal bleeding or failure to have a bowel movement after use. If adverse effects call 1-800-736-3437	
Unless directed by your doctor	
<ul style="list-style-type: none"> ■ Do not take any laxative if you are having abdominal pain, nausea, or vomiting. ■ Laxative products should not be used longer than a week. 	
Ask a pharmacist or doctor if	
<ul style="list-style-type: none"> ■ You have noticed a sudden change in bowel habits that persist over two weeks after using this product. ■ You are pregnant or breast feeding before use. 	
This product does not contain a child resistant cap. Keep out of reach of children. In case of accidental overdose, contact a doctor or a poison or contact a poison control center.	
Directions	
For adults or children 12 years or over. Use 2-4 TBSP (30-60ml) daily or as directed by a Physician.	
Other information	
<ul style="list-style-type: none"> ■ Store at room temperature (59°-86°F). Below 59°F cloudiness may occur. Application of heat may restore clarity and fluidity without affecting the quality of Sorbitol. ■ DO NOT FREEZE. No animal testing Latex free. 	



 **Geritrex**
 Distributed by
 Geritrex, LLC
 144 East Kingsbridge Road
 Mount Vernon NY 10550
 1-800-736-3437
 www.geritrex.com

S16C-10



Drug Facts
Active Ingredients Purpose Sorbitol 70% Laxative
Uses For occasional relief of constipation.
Warnings This medicine does not contain a child resistant cap. Keep out of reach of children. In case of accidental overdose, contact a doctor or a poison control center.
Conditions Stop use if you are having rectal bleeding or failure to have a bowel movement after use. If adverse effects call 1-800-736-3447.
Usages directed by your doctor Do not take any laxative if you are having abdominal pain, nausea, or vomiting. Laxative products should not be used longer than a week. Ask a pharmacist or doctor if • you have noticed a sudden change in bowel habits that persist over two weeks after using this product. • You are pregnant or breast feeding before use.
Directions For adults or children 12 years or over Use 2-4 TBSF (30-60ml) daily or as directed by a Physician.
Other Information Store at room temperature (59°F-86°F). Below 59°F, cloudiness may occur. Application of heat may restore clarity and fluidity without affecting the quality of Sorbitol. DONOT FREEZE. No animal testing. Latex free.

SORBITOL

sorbitol solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54162-700
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SORBITOL (UNII: 506T60A25R) (SORBITOL - UNII:506T60A25R)	SORBITOL	258.2 g in 474 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54162-700-16	474 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/31/2015	
2	NDC:54162-700-30	30 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product	07/31/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	07/17/2012	

Labeler - Geritrex LLC (112796248)

Registrant - Geritrex LLC (112796248)

Establishment

Name	Address	ID/FEI	Business Operations
Geritrex LLC		112796248	manufacture(54162-700)

Revised: 1/2018

Geritrex LLC