PREVENTION ONCOLOGY MOUTH RINSE- glycerin liquid Prevention Health Sciences, 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.

Prevention Oncology Mouth Rinse

Drug Facts

Active Ingredients

Glycerin 4.5%

Purpose

Oral Demulcent

Uses

for temporary relief of minor discomfort and protection of irritated areas in sore mouth and sore throat.

Warnings

Do not use this product for more than 7 days unless directed by a dentist or physician When using this product, do not swallow.

Stop use and ask a doctor if

• sore throat is severe • lasts for more than 2 days • is accompanied or followed by fever, headache, rash, nausea or vomiting • sore mouth symptoms do not improve in 7 days

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

adults and children 2 years of age and older: gargle, swish around in the mouth over the affected area for at least one minute and then spit out. Use as needed or as directed by dentist or doctor.

children under 12 years of age should be supervised in the use of product.

children under 2: consult with a dentist or doctor.

Other information

keep product away from heat or direct sunlight

DO NOT USE IF SAFETY SEAL IS BROKEN

Inactive ingredients

citric acid, de-ionized water, disodium EDTA, hydrogen peroxide, menthol, peppermint oil, poloxamer 407, sodium citrate, xylitol, zinc chloride

Questions Call 800-473-1205

Formulated and Ditributed by:

Prevention Health Sciences, Inc.

Raleigh, IL 62977

800-473-1205

PHS Brands

www.preventionhs.com

ALCOHOL FREE

PREVENTION MOUTH RINSE

Formulated for Oncology Patients

√ Soothes & Protects Oral Mucosa

√ Provides Temporary Oral Pain Relief

√ Hydrating Formula

Soothing Mint

NET. 16 FL OZ (1 PT) 473 ML

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PREVENTION ONCOLOGY MOUTH RINSE

glycerin liquid

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:69951-001

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name

Basis of Strength

GLYCERIN (UNII: PDC6A3C00X) (GLYCERIN - UNII: PDC6A3C00X)

GLYCERIN (UNII: PDC6A3C00X) GLYCERIN 4.5 mg in 100 mL

Inactive Ingredients Ingredient Name Strength CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) WATER (UNII: 059QF0KOOR) EDETATE DISODIUM (UNII: 7FLD91C86K) HYDROGEN PEROXIDE (UNII: BBX060AN9V) MENTHOL (UNII: L7T10EIP3A)

PEPPERMINT OIL (UNII: AV092KU4JH)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
ZINC CHLORIDE (UNII: 86Q357L16B)	
XYLITOL (UNII: VCQ006KQ1E)	

Product Characteristics				
Color		Score		
Shape		Size		
Flavor	MINT	Imprint Code		
Contains				

ı	P	ackaging					
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
	1	NDC:69951- 001-16	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/10/2023			
	2	NDC:69951- 001-03	95 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/10/2023			

Marketing In	arketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC monograph not final	part356	01/10/2023				

Labeler - Prevention Health Sciences, Inc. (968930540)

Revised: 1/2023 Prevention Health Sciences, Inc.