HYDROGEN PEROXIDE ORAL RINSE- hydrogen peroxide oral rinse liquid
Den-Mat Holdings, 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.

Drug Facts

Hydrogen peroxide 1.5% (w/v)

Bacteria reducing rinse and oral debriding agent/oral wound cleanser

For temporary use to reduce bacteria in the mouth before and after dental procedures. Other uses include removal of oral debris and cleansing or healing of minor mouth irritations, such as canker sores, minor wounds and minor gum inflammation resulting from dental procedures, dentures, orthodontic appliances, accidental injury or other irritations of the mouth and gums.

Do not use this product for more than 7 days unless directed by a dentist or physician.

do not swallow

Stop use and ask a doctor if
- sore mouth symptoms do not improve within 7 days
- irritation, pain or redness persists or worsens
- swelling, rash or fever develops

If more than used for rinsing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

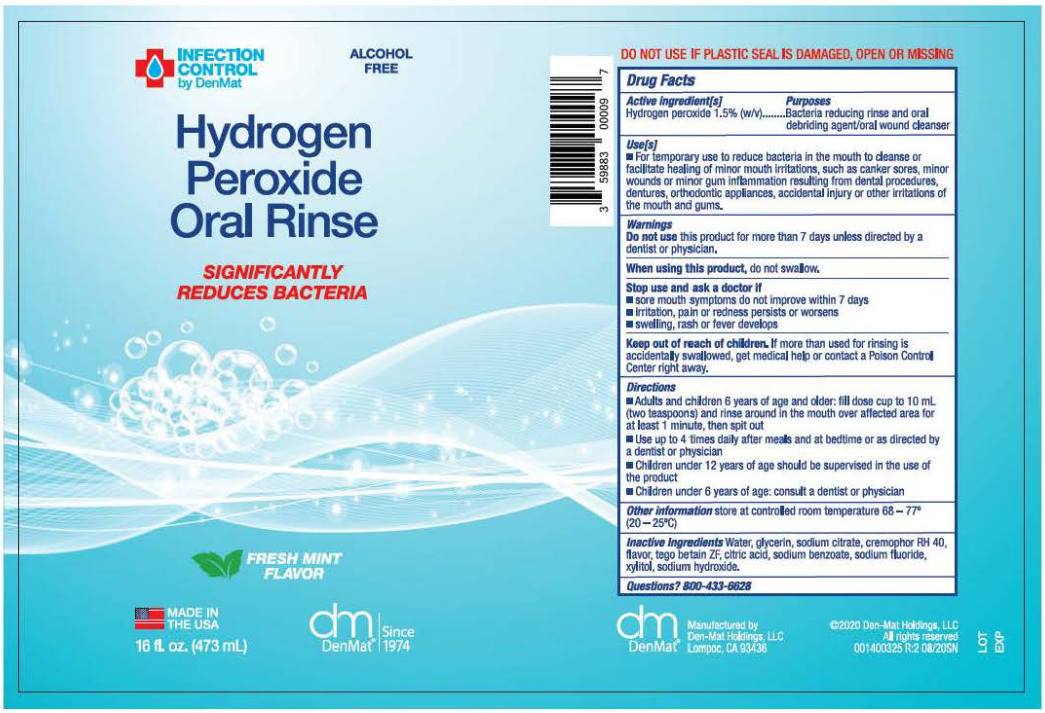
Directions
- Adults and children 6 years of age and older: fill dose cup to 10 mL (two teaspoons) and rinse around in the mouth over affected area for at least 1 minute, then spit out.
- Use up to 4 times daily after meals and at bedtime or as directed by a dentist or physician
- Children under 12 years of age should be supervised in the use of the product
- Children under 6 years of age: consult a dentist or physician

Other Information

store at controlled room temperature 68-77° (20-25°C)

Water, glycerin, sodium citrate, cremophor RH 40, flavor, tego betain ZF, citric acid, sodium benzoate, sodium fluoride, xylitol, sodium hydroxide

800-433-6628



HYDROGEN PEROXIDE ORAL RINSE

hydrogen peroxide oral rinse liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:59883-201
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
HYDROGEN PEROXIDE (UNII: BBX060AN9V) (HYDROGEN PEROXIDE - UNII:BBX060AN9V)	HYDROGEN PEROXIDE	15 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
SODIUM FLUORIDE (UNII: 8ZYQ1474W7)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
POLYOXYL 40 CASTOR OIL (UNII: 4ERD2076EF)	

CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
XYLITOL (UNII: VCQ006KQ1E)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
MINT (UNII: FV98Z8GITP)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	

Product Characteristics

Color		**Score**	
Shape		**Size**	
Flavor	MINT	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59883-201-28	3785 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	08/17/2020	
2	NDC:59883-201-64	1893 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	08/17/2020	
3	NDC:59883-201-16	473 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	08/17/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	08/17/2020	

Labeler - Den-Mat Holdings, LLC (809857704)

Establishment

Name	Address	ID/FEI	Business Operations
Den-Mat Holdings, LLC		809857704	manufacture(59883-201) , pack(59883-201) , label(59883-201)

Revised: 8/2020 Den-Mat Holdings, LLC