#### GLY-OXIDE- carbamide peroxide liquid Medtech Products 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.

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#### Gly-Oxide

#### **Drug Facts**

#### Active ingredient

Carbamide peroxide 10% non USP\*

\*pH differs from USP specifications

#### Purposes

Oral debriding agent

Oral wound cleanser

#### Uses

- temporary use in cleansing:
  - canker sores
  - minor wounds or gum inflammation resulting from minor dental procedures, dentures, orthodontic appliances, accidental injury, or other irritations of the mouth and gums
- aids in the removal of phlegm, mucus, or other secretions associated with occasional sore mouth

#### Warnings

#### Do not use

this product for more than 7 days unless directed by a dentist or doctor.

# When using this product

- do not swallow
- avoid contact with eyes

# Stop use and ask a doctor if:

- swelling, rash or fever develops
- irritation, pain, or redness persists or worsens

• sore mouth symptoms do not improve in 7 days

#### Keep out of the reach of children.

If more than used for rinsing is swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

#### Directions

• replace tip on bottle when not in use

#### Adults and children 2 years and older:

 use up to 4 times daily after meals and at bedtime or as directed by a dentist or doctor

#### For direct application

- do not dilute
- apply several drops directly from the bottle onto affected area
- spit out after 2 to 3 minutes

## As a mouthwash (oral rinse)

- place 10 to 20 drops onto tongue
- mix with saliva
- swish around in the mouth over the affected area for at least 1 minute and spit out

Children under 12 years: should be supervised in the use of this product

Children under 2 years: consult a dentist or doctor

#### Other information

- do not store above 25°C (77°F )
- store bottle in the outer carton

#### Inactive ingredients

citric acid, flavor, glycerin, propylene glycol, sodium lauroyl sarcosinate, water

## Questions?

1-866-255-5202 weekdays

## PRINCIPAL DISPLAY PANEL

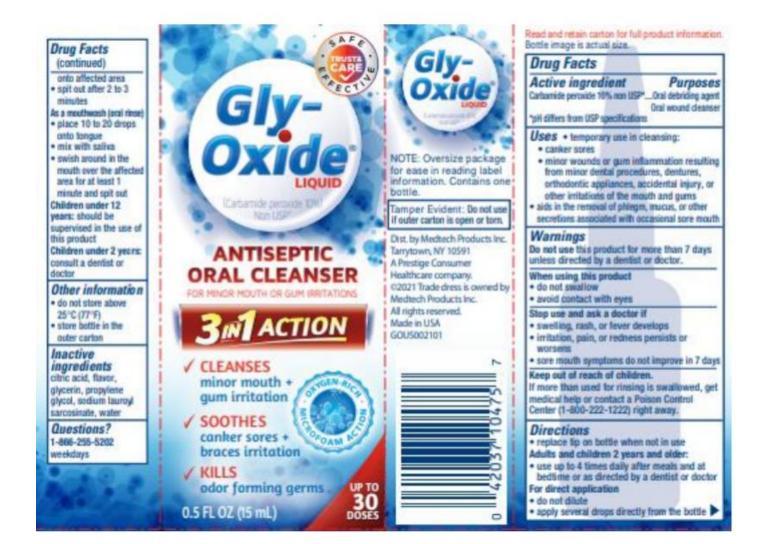
Gly-Oxide LIQUID (Carbamide peroxide 10%) Non USP\*

#### ANTISEPTIC ORAL CLEANSER 2FL OZ (60 mL)



#### **PRINCIPAL DISPLAY PANEL**

Gly-Oxide LIQUID (Carbamide peroxide 10%) Non USP\* ANTISEPTIC ORAL CLEANSER 0.5 FL OZ (15 mL)



## **GLY-OXIDE**

carbamide peroxide liquid

Product Information						
Product Type	HUMAN OTC DRUG	Item Code (Source)		NDC:63	NDC:63029-500	
Route of Administration	ORAL					
Active Ingredient/Active	Mojety					
Active mgreulent/Active	Molecy					
Ingredient Name Basis of Strength				-	Strength	
CARBAMIDE PEROXIDE (UNII: 31P UNII:BBX060AN9V)	Z 2VAU81) (HYDROGEN PER	OXIDE -	CARBAMIDE PEROXIDE		100 mg in 1 mL	
Inactive Ingredients						
	Ingredient Name			9	Strength	
CITRIC ACID MONOHYDRATE (UN	NII: 2968PHW8QP)					
GLYCERIN (UNII: PDC6A3C0OX)						
PROPYLENE GLYCOL (UNII: 6DC9	Q167V3)					

	DDIUM LAUROYL							
w	ATER (UNII: 059Q							
Packaging								
#	Item Code	Package Description	Marketing Start Date	Marketing End Date				
1	NDC:63029-500- 01	1 in 1 CARTON	06/01/2012					
1		15 mL in 1 BOTTLE; Type 0: Not a Combination Product						
2	NDC:63029-500- 02	1 in 1 CARTON	06/01/2012					
2		60 mL in 1 BOTTLE; Type 0: Not a Combination Product						
Marketing Information								
	Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date				
01 fin	FC monograph not ial	part356	06/01/2012					

# Labeler - Medtech Products Inc. (122715688)

Revised: 7/2023

Medtech Products Inc.