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.

---------

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 sore
• 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 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 dentist or doctor

**For direct application**
- do not dilute
- apply several drops directly from 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 77°F (25°C)
- store bottle in the outer carton

**Inactive ingredients**
citric acid, flavor, glycerin, propylene glycol, sodium lauroyl sarcosinate, sodium stannate, water

**Questions or comments?**
call toll-free 1-866-255-5202 (English/Spanish) weekdays, or visit glyoxide.com

**PRINCIPAL DISPLAY PANEL**
Gly-Oxide LIQUID
(Carbamide peroxide 10%) Non USP*
ANTISEPTIC ORAL CLEANSER
½ FL OZ (15 mL)
**GLY-OXIDE**
carbamide peroxide liquid

### Product Information

<table>
<thead>
<tr>
<th>Product Type</th>
<th>HUMAN OTC DRUG</th>
<th>Item Code (Source)</th>
<th>NDC:63029-500</th>
</tr>
</thead>
<tbody>
<tr>
<td>Route of Administration</td>
<td>ORAL</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Active Ingredient/Active Moiety

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>CARBAMIDE PEROXIDE (UNII: 31PZ2VAU81) (HYDROGEN PEROXIDE - UNIEBX060AN9V)</td>
<td>CARBAMIDE PEROXIDE</td>
<td>100 mg in 1 mL</td>
</tr>
</tbody>
</table>
# Inactive Ingredients

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)</td>
<td></td>
</tr>
<tr>
<td>GLYCERIN (UNII: PDC6A3C00X)</td>
<td></td>
</tr>
<tr>
<td>PROPYLENE GLYCOL (UNII: 6DC9Q167V3)</td>
<td></td>
</tr>
<tr>
<td>SODIUM LAUROYL SARCOSINATE (UNII: 632GS99618)</td>
<td></td>
</tr>
<tr>
<td>SODIUM STANNATE (UNII: NJ7C1V83KG)</td>
<td></td>
</tr>
<tr>
<td>WATER (UNII: 059QF0KO0R)</td>
<td></td>
</tr>
</tbody>
</table>

# Packaging

<table>
<thead>
<tr>
<th>#</th>
<th>Item Code</th>
<th>Package Description</th>
<th>Marketing Start Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>NDC:63029-500-02</td>
<td>1 in 1 CARTON</td>
<td>06/01/2012</td>
</tr>
<tr>
<td>1</td>
<td></td>
<td>60 mL in 1 BOTTLE; Type 0: Not a Combination Product</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>NDC:63029-500-01</td>
<td>1 in 1 CARTON</td>
<td>06/01/2012</td>
</tr>
<tr>
<td>2</td>
<td></td>
<td>15 mL in 1 BOTTLE; Type 0: Not a Combination Product</td>
<td></td>
</tr>
</tbody>
</table>

# Marketing Information

<table>
<thead>
<tr>
<th>Marketing Category</th>
<th>Application Number or Monograph Citation</th>
<th>Marketing Start Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>OTC MONOGRAPH NOT FINAL</td>
<td>part356</td>
<td>06/01/2012</td>
</tr>
</tbody>
</table>

# Labeler

Medtech Products Inc. (122715688)

Revised: 2/2018