ANTISEPTIC ORAL CLEANSER- hydrogern peroxide mouthwash
DOLGENCORP, 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.

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Drug Facts 462

Active ingredient (in each 10 mL)
Hydrogen Peroxide 150mg

Purpose
Oral debriding agent/Oral wound cleanser

Use
oral debriding agent/oral wound cleanser for temporary use to cleanse canker sores and minor wounds or minor gum inflammation resulting from minor dental procedures, dentures, orthodontic appliances, accidental injury, or other irritations of the mouth and gums such as mouth burns, cheek bites and toothbrush abrasions

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 mouth symptoms do not improve in 7 days
• irritation, pain or redness persists or worsens
• swelling, rash or fever develops

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

Directions
• rinse half a capful (two teaspoons or 10 mL mark on cap) around in 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 2 years of age: consult a dentist or physician

Other information
• store at controlled room temperature 20-25°C (68-77°F)
Inactive ingredients
water, sorbitol, propylene glycol, poloxamer 338, polysorbate 20, flavor, sodium saccharin, blue 1

Rexall
Antiseptic Oral Cleanser Hydrogen Peroxide
Do not use if printed neckband on bottle is broken or missing

Visit us at: Rexall.com or call us 1-866-4-REXALL
PACKAGED FOR DOLGENCORP, LLC
100 MISSION RIDGE
GOODLETTSVILLE, TN 37027
DSP-TN-15000
DSP-MO-34
SDS-TN-15012
462.001/462AA

principal display panel
Rexall
Antiseptic Oral Cleanser Hydrogen Peroxide
•Promotes healing of oral irritations
•Oral debriding agent
•Great tasting original flavor
8 FL OZ (236 mL)
Product Type: HUMAN OTC DRUG  
Item Code (Source): NDC:55910-171

Route of Administration: ORAL

Active Ingredient/Active Moiety

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
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<tbody>
<tr>
<td>HYDROGEN PEROXIDE (UNII: BBX060AN9V) (HYDROGEN PEROXIDE - UNII:BBX060AN9V)</td>
<td>HYDROGEN PEROXIDE</td>
<td>150 mg in 100 L</td>
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Inactive Ingredients

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<tr>
<th>Ingredient Name</th>
<th>Strength</th>
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<tbody>
<tr>
<td>ALCOHOL (UNII: 3K9958V90M)</td>
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<tr>
<td>FD&amp;C BLUE NO. 1 (UNII: H3R47K3TBD)</td>
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<tr>
<td>MENTHOL (UNII: L7T10EIP3A)</td>
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<tr>
<td>METHYL SALICYLATE (UNII: LAV5U5022Y)</td>
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<tr>
<td>POLYXAMER 338 (UNII: F75JV2T505)</td>
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<tr>
<td>POLYSORBATE 20 (UNII: 7T1F30V5YH)</td>
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<tr>
<td>WATER (UNII: 059QF0KO0R)</td>
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</tr>
<tr>
<td>SACCHARIN SODIUM (UNII: SB8ZUX40TY)</td>
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<tr>
<td>SORBITOL (UNII: 506T60A25R)</td>
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Packaging

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<tr>
<th>#</th>
<th>Item Code</th>
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<th>Marketing End Date</th>
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<td>NDC:55910-171-34</td>
<td>.236 L in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product</td>
<td>04/19/2009</td>
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Marketing Information

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<td>OTC monograph not final</td>
<td>part356</td>
<td>04/19/2009</td>
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Labeler - DOLGENCORP, LLC (068331990)

Registrant - Vi-Jon (790752542)

Establishment

Name | Address | ID/FEI | Business Operations |
---|--------|-------|---------------------|
Vi-Jon | 790752542 | manufacture(55910-171) |