GENTIAN VIOLET TOPICAL SOLUTION- gentian violet liquid
Laboratorios Jaloma, S.A. de C.V.

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

Active Ingredient
Gentian Violet 1%

Purpose
Antiseptic

Uses
Topical antiseptic as first aid to help prevent infection in minor cuts, scrapes and burns.

Warnings
For external use only
Do not use in the eyes or apply over large areas of the body.

Consult a doctor in case of deep or puncture wounds, animal bites or serious burns.
Stop use and consult a doctor if the condition persists or gets worse.
Do not use longer than 1 week unless directed by a doctor.

Keep out of the reach of children.
In case of accidental ingestion get medical help or contact a Poison Control Center right away.

Directions
Clean the affected area and apply a small amount of this product on the area 1 to 3 times daily. May be covered with a sterile bandage.

Inactive Ingredients
glycerin, water
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Jaloma
VIOLETA DE GENCIANA
SOLUCION TOPICA
1%
ANTISEPTICO
GENTIAN VIOLET
TOPICAL SOLUTION
1%
ANTISEPTIC
NET 0.84 FL. OZ. (25 ml)
GENTIAN VIOLET TOPICAL SOLUTION
gentian violet liquid

Product Information

<table>
<thead>
<tr>
<th>Product Type</th>
<th>Item Code (Source)</th>
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<tbody>
<tr>
<td>HUMAN OTC DRUG</td>
<td>NDC:65055-401</td>
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Route of Administration: TOPICAL

Active Ingredient/Active Moiety

<table>
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<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
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<tbody>
<tr>
<td>GENTIAN VIOLET (UNII: J4Z741D6OS) (GENTIAN VIOLET CATION - UNII:3GVJ31T6YY)</td>
<td>GENTIAN VIOLET</td>
<td>1 g in 100 mL</td>
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</tbody>
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Inactive Ingredients

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Strength</th>
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<tbody>
<tr>
<td>WATER (UNII: 059QF0KOOR)</td>
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<tr>
<td>GLYCERIN (UNII: PDC6A3C0OX)</td>
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Packaging

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<tr>
<th>#</th>
<th>Item Code</th>
<th>Package Description</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
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<tbody>
<tr>
<td>1</td>
<td>NDC:65055-401-01</td>
<td>25 mL in 1 BOTTLE, PLASTIC</td>
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<td>2</td>
<td>NDC:65055-401-02</td>
<td>40 mL in 1 BOTTLE, PLASTIC</td>
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Marketing Information

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<th>Marketing Category</th>
<th>Application Number or Monograph Citation</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
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<tr>
<td>OTC monograph not final</td>
<td>part333A</td>
<td>09/27/2013</td>
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Labeler - Laboratorios Jaloma, S.A. de C.V. (811122357)

Establishment

<table>
<thead>
<tr>
<th>Name</th>
<th>Address</th>
<th>ID/FEI</th>
<th>Business Operations</th>
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<tr>
<td>Laboratorios Jaloma, S.A. de C.V.</td>
<td></td>
<td>811122357</td>
<td>manufacture(65055-401)</td>
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Revised: 9/2013