

**GENTIAN VIOLET 2% - gentian violet 2% solution**

**The Podiatree Company**

**Reference Label Set Id: a972c857-1e3e-4a89-9fb2-da5a64d55bf7**

*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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**Active Ingredient**

Gentian Violet 2%

**Purpose**

Antiseptic

**Purpose**

First aid antiseptic to help protect against skin infection in minor cuts, scrapes or burns

**Warnings**

For external use only

**Do not use**

in eyes; with bandages; on large areas of the body; longer than one week unless directed by a doctor; stop use and consult a doctor if condition persists; in case of deep puncture wounds, animal bites or serious burns, consult a doctor; if known to be sensitive to any ingredients in the product; do not apply to ulcerative lesions as this may result in tattooing of the skin.

**Stop use and ask a doctor or pharmacist**

if skin irritation or sensitivity develops or increases or if the condition persists or gets worse.

**KEEP OUT OF REACH OF CHILDREN.**

In case of accidental ingestion, seek medical help or contact a Poison Control Center immediately.

**Directions**

Clean the affected area. Apply a small amount using a cotton-tipped applicator one to three times daily. Do not bandage.

**Other Information**

Store at controlled room temperature. Will stain skin and clothing.

**Inactive Ingredients**

SD alcohol (10%), water

## Questions or Suggestions?

1.855.763.8733 or visit us at [www.thepodiatreecompany.com](http://www.thepodiatreecompany.com)

### PRINCIPAL DISPLAY PANEL

 <p>NDC 54633-014-02 Use Caution: Will Stain Skin &amp; Clothing</p> <p><b>Gentian Violet</b> Topical Solution 2%</p> <p>2 fl oz (59.14mL)</p>	<p><b>First Aid Antiseptic</b></p>	<p><b>Drug Facts</b></p> <table border="1"> <tr> <td><b>Active Ingredient</b></td> <td><b>Purpose</b></td> </tr> <tr> <td>Gentian Violet 2%</td> <td>First Aid Antiseptic</td> </tr> <tr> <td colspan="2"><b>Uses</b></td> </tr> <tr> <td colspan="2">First aid antiseptic to help protect against skin infection in minor cuts, scrapes or burns</td> </tr> <tr> <td colspan="2"><b>Warnings</b></td> </tr> <tr> <td colspan="2"><i>For external use only</i></td> </tr> <tr> <td colspan="2"> <p><b>Do not use</b> • in eyes • with bandages • on large areas of the body • longer than one week unless directed by a doctor • stop use and consult a doctor if condition persists • in case of deep puncture wounds, animal bites or serious burns, consult a doctor • if known to be sensitive to any ingredients in the product • do not apply to ulcerative lesions as this may result in tattooing of the skin</p> <p><b>Stop use and ask a doctor or pharmacist</b> if skin irritation or sensitivity develops or increases or if the condition persists or gets worse.</p> <p><b>KEEP OUT OF REACH OF CHILDREN.</b> In case of accidental ingestion, seek medical help or contact a Poison Control Center immediately.</p> <p><b>Directions</b> • clean the affected area • apply a small amount using a cotton-tipped applicator one to three times daily • do not bandage</p> <p><b>Other Information</b> • store at controlled room temperature • will stain skin and clothing</p> <p><b>Inactive Ingredients</b> SD alcohol (10%), water</p> <p><b>Questions or Suggestions?</b> 1.855.763.8733 or visit us at <a href="http://www.thepodiatreecompany.com">www.thepodiatreecompany.com</a></p> </td> </tr> <tr> <td colspan="2"> <p>Manufactured for: The Podiatree Company Holbrook, NY 11741 639014020514</p> </td> </tr> </table>	<b>Active Ingredient</b>	<b>Purpose</b>	Gentian Violet 2%	First Aid Antiseptic	<b>Uses</b>		First aid antiseptic to help protect against skin infection in minor cuts, scrapes or burns		<b>Warnings</b>		<i>For external use only</i>		<p><b>Do not use</b> • in eyes • with bandages • on large areas of the body • longer than one week unless directed by a doctor • stop use and consult a doctor if condition persists • in case of deep puncture wounds, animal bites or serious burns, consult a doctor • if known to be sensitive to any ingredients in the product • do not apply to ulcerative lesions as this may result in tattooing of the skin</p> <p><b>Stop use and ask a doctor or pharmacist</b> if skin irritation or sensitivity develops or increases or if the condition persists or gets worse.</p> <p><b>KEEP OUT OF REACH OF CHILDREN.</b> In case of accidental ingestion, seek medical help or contact a Poison Control Center immediately.</p> <p><b>Directions</b> • clean the affected area • apply a small amount using a cotton-tipped applicator one to three times daily • do not bandage</p> <p><b>Other Information</b> • store at controlled room temperature • will stain skin and clothing</p> <p><b>Inactive Ingredients</b> SD alcohol (10%), water</p> <p><b>Questions or Suggestions?</b> 1.855.763.8733 or visit us at <a href="http://www.thepodiatreecompany.com">www.thepodiatreecompany.com</a></p>		<p>Manufactured for: The Podiatree Company Holbrook, NY 11741 639014020514</p>	
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## GENTIAN VIOLET 2%

gentian violet 2% solution

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:54633-014
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GENTIAN VIOLET (UNII: J4Z741D6O5) (GENTIAN VIOLET CATION - UNII:3GVJ31T6YY)	GENTIAN VIOLET	2 g in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
WATER (UNII: 059QF0KO0R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54633-014-02	59.14 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/14/2014	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	10/14/2014	

**Labeler** - The Podiatree Company (078656000)

Revised: 12/2017

The Podiatree Company