

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.

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)

WITH APPLICATOR



GENTIAN VIOLET TOPICAL SOLUTION

gentian violet liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65055-401
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GENTIAN VIOLET (UNII: J4Z741D6O5) (GENTIAN VIOLET CATION - UNII:3GVJ31T6YY)	GENTIAN VIOLET	1 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65055-401-01	25 mL in 1 BOTTLE, PLASTIC		
2	NDC:65055-401-02	40 mL in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	09/27/2013	

Labeler - Laboratorios Jaloma, S.A. de C.V. (81122357)

Establishment

Name	Address	ID/FEI	Business Operations
Laboratorios Jaloma, S.A. de C.V.		81122357	manufacture(65055-401)

Revised: 9/2013

Laboratorios Jaloma, S.A. de C.V.