EL VALLE DECOLORIZED IODINE- alcohol tincture
Pharmadel 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.

El Valle Decolorized Iodine (Alcohol 48%)

Drug Facts

Drug facts

Active Ingredient & Purpose

Gentian Violet 1%

Active ingredient	***Purpose***
Alcohol 48%	First aid antiseptic

Uses

First aid to help prevent infection in
- minor cuts
- scrapes
- burns

Warnings

FOR EXTERNAL USE ONLY.

Do not use
- longer than 1 week, unless directed by a doctor
- in the eyes
- over large areas of the body

Ask a doctor before use if you have
- a deep or puncture wounds
- serious burns
- animal bites

Stop use and consult a doctor if
- conditions persist or gets worse

Keep out of reach of children.

If swallowed, get medical help, or contact a Poison Control Center immediately.

Directions

- clean the affected area
- apply a small amount directly to the affected area 1 to 3 times a day
- may cover area with sterile bandage

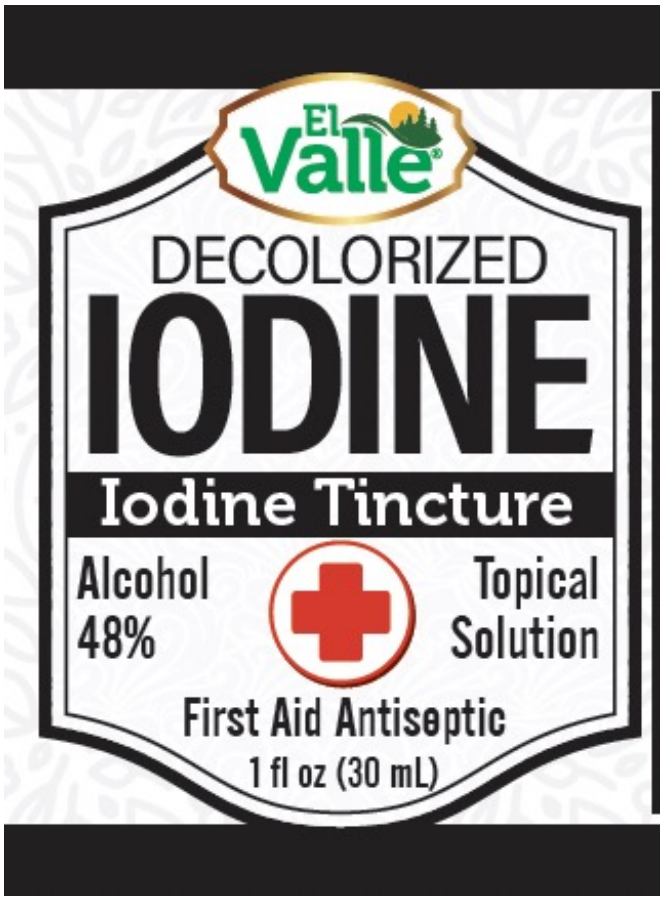
Other information

- do not use if clear seal over cap is missing or broken

Inactive ingredients

ammonia, iodine, sodium iodide, water

Prinicpal Display Panel



EL VALLE DECOLORIZED IODINE

alcohol tincture

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:55758-374
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.48 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
AMMONIA (UNII: 5138Q19F1X)	
WATER (UNII: 059QF0KO0R)	
SODIUM IODIDE (UNII: F5WR8N145C)	
IODINE (UNII: 9679TC07X4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55758-374-01	15 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/31/2023	05/31/2023
2	NDC:55758-374-02	30 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/31/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/31/2023	

Labeler - Pharmadel LLC (030129680)

Revised: 6/2023 Pharmadel LLC