

ISODINE COPITOS - povidone-iodine solution
Swabplus Inc.

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.

Isodine Copitos

Drug Facts

Active ingredient

Povidone iodine 10%, equal to 1% available Iodine

Purpose

Antiseptic

Uses First aid to help prevent infection due to minor cuts, scrapes and burns.

Keep out of reach of children

if swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Hold the swab vertically, with the color ring tip upwards, Hold in the center of the tube with one hand at the color ring with the other.
- Gently snap the tip with the color ring, Formula inside the tube flows down and fills the opposite tip.
- Apply the product to the affected area.
- Discard swab after use.

Warnings

For external use only. Keep out of eyes and ear canal. Non-Sterile. Discontinue use if irritation.

Do not use. If you are sensitive to Iodine. Longer than one week unless directed by a doctor.

Stop use and ask a doctor. If you have deep or puncture wounds, or serious burns. redness, irritation, swelling or pain continue or increase, infection occurs.

Administration

For adults and children 2 and older: for minor wounds, burns and infections, apply directly to affected area. May be covered with a bandage.

Children under 2 years of age: Do not use, consult a doctor.

Other information: Store at room temperature, Avoid direct sunlight, excessive heat and moisture.

Inactive ingredients

Glycerin, water

Manufacturer Statement

Patented and manufactured by Swabplus Inc. Rancho Cucamonga, CA 91730 USA Made in USA
 Imported and Distributed by Boehringer Ingelheim

Package and Labeling

Image of iodine carton label



ISODINE COPITOS

povidone-iodine solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65734-511
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Povidone-Iodine (UNII: 85H0HZU99M) (Iodine - UNII:9679TC07X4)	Iodine	10 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Glycerin (UNII: PDC6A3C0OX)	
Sodium Hydroxide (UNII: 55X04QC32I)	
WATER (UNII: 059QF0K00R)	

Product Characteristics

Color	brown (dark)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65734-511-72	72 in 1 PACKAGE		
1	NDC:65734-511-00	0.15 mL in 1 APPLICATOR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	06/01/2008	

Labeler - Swabplus Inc. (876441549)

Registrant - Swabplus Inc. (876441549)

Establishment

Name	Address	ID/FEI	Business Operations
Swabplus Inc.		876441549	manufacture(65734-511) , relabel(65734-511) , repack(65734-511)