

POVIDONE IODINE- povidone iodine swab
Custom Kits Company Inc

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, [click here](#).

Povidone Iodine Swabs

Drug Facts

Active Ingredient

10% Povidone Iodine Solution USP (1% available iodine)

Purpose

Topical Antiseptic

Directions

Reverse cardboard sleeve then crush at dot between thumb and forefinger. Allow solution to saturate tip and apply solution to injury.

Warnings

- For External Use Only

Ask a Doctor before use if you have

Deep or puncture wounds

Serious Burns

Stop Use

redness, irritation, swelling or pain persists or increases

infection occurs

Keep Out Of Reach Of Children

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

Directions

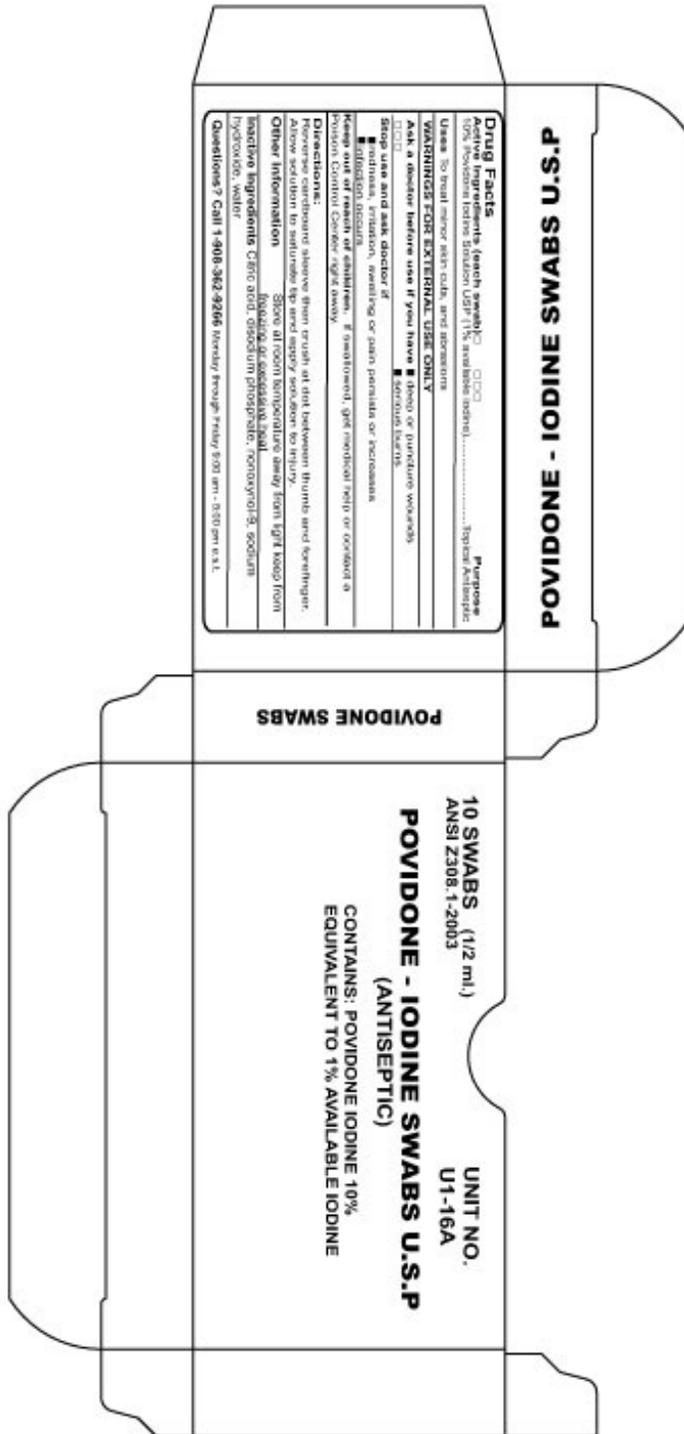
Reverse cardboard sleeve then crush at dot between thumb and forefinger. Allow solution to saturate tip and apply solution to injury.

Other Information

Store at room temperature away from light keep from freezing or excessive heat

Inactive Ingredient

Citric acid, disodium phosphate, nonoxynol-9, sodium hydroxide, water



POVIDONE IODINE

povidone iodine swab

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68 183-116
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
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68183-116-01	10 mL in 1 BOX, UNIT-DOSE; Type 0: Not a Combination Product	10/14/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		10/14/2015	

Labeler - Custom Kits Company Inc (928643712)**Establishment**

Name	Address	ID/FEI	Business Operations
James Alexander Corporation		040756421	manufacture(68183-116)

Establishment

Name	Address	ID/FEI	Business Operations
Custom Kits Company Inc		928643712	repack(68183-116) , relabel(68183-116)

Revised: 1/2020

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