DUAL SWAB SCRUB SWABSTICK- povidone iodine swab
Dynarex Corporation

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.

Dual Swab Povidone Iodine Prep Swabstick

Active Ingredient

Active ingredient	Purpose
Povidone iodine 10%	Antiseptic

Purpose

For antiseptic application at procedure site.

Indications and usage

For pre-operative patient skin preparation.

Warnings

For External Use Only

Avoid contact with the eyes. If contact occurs, flush with water.

Stop use

Stop use and ask a healthcare professional if,

- condition worsens or persists for more than 72 hours
- if pain, irritation, redness or swelling occurs

Ask a doctor

Ask a doctor before use if you have

- deep puncture wounds
- animal bites
- serious wounds

Do not use

Do not use:

- as a first aid antiseptic for more than 1 week
- over large areas of the body

Keep out of reach of children

Keep out of reach of children:

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

Dosage and administration

Directions

For preoperative patient skin preparation:

- Apply to procedure siteand allow to dry. Discard after single use.If not ready for immediate venipuncture, cover the area with a dry sterile gauze.

As a first aid antiseptic:

- clean affected area
- apply to wound once or twice daily
- may be covered with a sterile bandage
- if bandaged, let dry first.

Tear at notch, remove applicator, use only once.

Inactive ingredients

Anhydrous citric acid, disodium hydrogen phosphate, Water

Other information

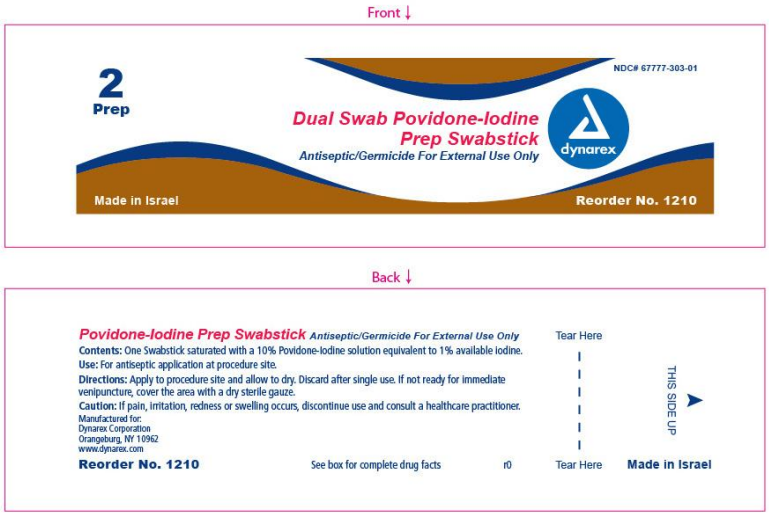
- Store at room temperature
- Avoid excessive heat

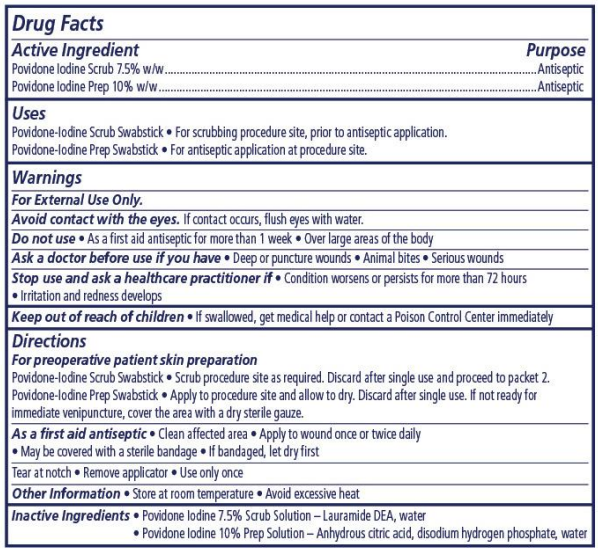
Principal Display Panel

Dynarex Dual Swab Povidone Iodine Prep Swabstick

Item #: 1210

1210 Prep.jpg





Drug Facts

Active Ingredient	Purpose
Povidone Iodine Scrub 7.5% w/w	Antiseptic
Povidone Iodine Prep 10% w/w	Antiseptic

Uses

Povidone-Iodine Scrub Swabstick • For scrubbing procedure site, prior to antiseptic application.
Povidone-Iodine Prep Swabstick • For antiseptic application at procedure site.

Warnings

For External Use Only.

Avoid contact with the eyes. If contact occurs, flush eyes with water.

Do not use • As a first aid antiseptic for more than 1 week • Over large areas of the body

Ask a doctor before use if you have • Deep or puncture wounds • Animal bites • Serious wounds

Stop use and ask a healthcare practitioner if • Condition worsens or persists for more than 72 hours • Irritation and redness develops

Keep out of reach of children • If swallowed, get medical help or contact a Poison Control Center immediately

Directions

For preoperative patient skin preparation

Povidone-Iodine Scrub Swabstick • Scrub procedure site as required. Discard after single use and proceed to packet 2.
Povidone-Iodine Prep Swabstick • Apply to procedure site and allow to dry. Discard after single use. If not ready for immediate venipuncture, cover the area with a dry sterile gauze.

As a first aid antiseptic • Clean affected area • Apply to wound once or twice daily • May be covered with a sterile bandage • If bandaged, let dry first

Tear at notch • Remove applicator • Use only once

Other Information • Store at room temperature • Avoid excessive heat

Inactive Ingredients • Povidone Iodine 7.5% Scrub Solution – Lauramide DEA, water • Povidone Iodine 10% Prep Solution – Anhydrous citric acid, disodium hydrogen phosphate, water

DUAL SWAB SCRUB SWABSTICK

povidone iodine swab

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:67777-303

Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POVIDONE-IODINE (UNII: 85H0HZU99M) (IODINE - UNII:9679TC07X4)	IODINE	10 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
SODIUM PHOSPHATE, DIBASIC ANHYDROUS (UNII: 22ADO53M6F)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67777-303-01	0.3 g in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	11/15/2015	

Labeler - Dynarex Corporation (008124539)

Registrant - Dynarex Corporation (008124539)

Establishment

Name	Address	ID/FEI	Business Operations
Sion Biotext Medical Ltd		532775194	manufacture(67777-303)

Revised: 11/2015 Dynarex Corporation