

**DUAL SWAB POVIDONE-IODINE PREP- povidone iodine
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.

1205 Dynarex Dual Prep and Scrub Swabstick NDC 67777-302-01

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

Purpose

Uses

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

Povidone Iodine Prep Swabstick - For antiseptic application at procedure site.

Indications and Usage

- For pre-operative patient skin preparation.

Warnings

☐For External Use Only

Avoid contact with 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:

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

Keep Out Of Reach Of Children

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

Dosage and Administration

Directions

For pre-operative patient skin preparation:

- 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.

Inactive Ingredients

- Povidone Iodine 7.5% Scrub Solution - Lauramide DEA, water
- Povidone Iodine 10% Prep Solution - Anhydrous citric acid, disodium hydrogen phosphate, water

Other information

- Store at room temperature
- Avoid excessive heat

Principal Display panel

Dynarex Dual Swab Prep and Scrub Kit

Item 1207

1207_pouches.jpg

Front ↓

Step 1
Scrub

Made in Israel

NDC# 67777-302-01

Dual Swab Povidone-Iodine Scrub Swabstick

Antiseptic/Germicide For External Use Only

1 Swabstick

Reorder No. 1207

Back ↓

Drug Facts	
Active Ingredient	Purpose
Povidone-Iodine Scrub 7.5% w/w Antiseptic	Povidone-Iodine Scrub 7.5% w/w Antiseptic
Povidone-Iodine Prep 10% 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 a 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. Proceed to next step.	
Povidone-Iodine Prep Swabstick	
• Apply to procedure site and allow to dry. Discard after single use. If not ready for immediate use, 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	
Other Information • Use only once • Tear at notch • Remove applicator • Store at room temperature • Avoid excessive heat	
Inactive Ingredients	
• Povidone-Iodine 7.5% Scrub Solution – Laureamide DEA, water	
• Povidone-Iodine 10% Prep Solution – Anhydrous citric acid, disodium hydrogen phosphate, water	

Reorder No. 1207

THIS SIDE UP

Manufactured for:
Dynarex Corporation
Oranburg, NY 10962
www.dynarex.com

TEAR HERE

Made in Israel

Front ↓

Step 2
Prep

Made in Israel

NDC# 67777-303-01

Dual Swab Povidone-Iodine Prep Swabstick

Antiseptic/Germicide For External Use Only

1 Swabstick

Reorder No. 1207

Back ↓

Drug Facts	
Active Ingredient	Purpose
Povidone-Iodine Scrub 7.5% w/w Antiseptic	Povidone-Iodine Scrub 7.5% w/w Antiseptic
Povidone-Iodine Prep 10% 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 a 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. Proceed to next step.	
Povidone-Iodine Prep Swabstick	
• Apply to procedure site and allow to dry. Discard after single use. If not ready for immediate use, 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	
Other Information • Use only once • Tear at notch • Remove applicator • Store at room temperature • Avoid excessive heat	
Inactive Ingredients	
• Povidone-Iodine 7.5% Scrub Solution – Laureamide DEA, water	
• Povidone-Iodine 10% Prep Solution – Anhydrous citric acid, disodium hydrogen phosphate, water	

Reorder No. 1207

THIS SIDE UP

Manufactured for:
Dynarex Corporation
Oranburg, NY 10962
www.dynarex.com

TEAR HERE

Made in Israel

povidone iodine kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67777-414
---------------------	----------------	---------------------------	---------------

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67777-414-01	1 in 1 PACKAGE; Type 1: Convenience Kit of Co-Package	04/05/2017	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	25 POUCH	32.5 mL
Part 2	25 POUCH	32.5 mL

Part 1 of 2

DUAL SWAB POVIDONE-IODINE PREP

povidone iodine swab

Product Information

Item Code (Source)	NDC:67777-302
---------------------------	---------------

Route of Administration	TOPICAL
--------------------------------	---------

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POVIDONE-IODINE (UNII: 85H0HZU99M) (IODINE - UNII:9679TC07X4)	IODINE	7.5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
LAURIC DIETHANOLAMIDE (UNII: I29I2VHG38)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67777-302-01	1.3 mL in 1 POUCH; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C		

Part 2 of 2

DUAL SWAB POVIDONE-IODINE PREP

povidone iodine swab

Product Information

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 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
SODIUM PHOSPHATE, DIBASIC DO DECAHYDRATE (UNII: E1W4N241FO)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67777-303-01	1.3 mL in 1 POUCH; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C		

Marketing Information

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

