

**POVIDINE IODINE- povidine iodine solution**  
**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.*

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**Povidone Iodine Scrub**

**Active Ingredient**

Povidone Iodine 7.5% v/v

**Purpose**

Antiseptic

**Inactive Ingredients**

Inactive Ingredient: Citric Acid, Glycerin, Sodium Citrate, Tween 80, Disodium Phosphate, Water

**Purpose**

Purpose of povidone iodine scrub

First aid antiseptic to help prevent skin infection in minor cuts, scrapes and burns.

For preparation of the skin prior to surgery.

Helps reduce bacteria that can potentially cause skin infections.

**Warnings:**

- **FOR EXTERNAL USE ONLY**

**Do not use:**

- As a first aid antiseptic for more than 1 week.
- In the eyes.
- Over large areas of the body.

**Ask a doctor before use if you have:**

- Deep puncture wounds
- Animal bites
- Serious burns

**Stop Use:**

- If irritation and redness develop
- If condition persists for more than 72 hours, consult a physician.

**Keep Out Of Reach Of Children**

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

## Directions:

### As a first aid antiseptic

- clean affected area
- apply 1 to 3 times daily
- may be covered with a sterile bandage, if bandaged let dry.

### For preoperative patient skin preparation

- clean area
- apply to operative site prior to surgery using the applicator

For use as an

- first aid antiseptic
- pre-operative skin preparation

## Principal Display Panel

povidone\_iodine\_scrub

The image shows the principal display panel for Povidone Iodine Surgical Scrub Solution. The panel is rectangular with dimensions 1.25cm, 2.6cm, and 1.25cm. It contains the following text:

A microbicial cleanser for the preoperative and postoperative scrubbing or washing by hospital operating personnel and for general use in the physician's office.

**ACTIVE INGREDIENTS:**  
Povidone-Iodine 7.5% equivalent to 0.75% available iodine

**INACTIVE INGREDIENTS:**  
Deionized Water, Disodium Phosphate, Glycerin, Hydroxyethyl Cellulose, Monoethanolamine

**DIRECTIONS:**

**A. FOR PREOPERATIVE WASHING BY OPERATING PERSONNEL:**

1. Wet hands with water. Use about 5ml (one teaspoon) of the surgical scrub and spread over both hands. Without adding more water, rub the scrub thoroughly under fingernails. Add a little water and develop copious suds. Rinse thoroughly under running water.
2. Complete the wash by scrubbing with another 5ml of the surgical scrub in the same way.

**B. FOR PREOPERATIVE USE ON A PATIENT:**  
After the skin area is shaved, wet it with water. Apply the surgical scrub (1ml is sufficient to cover an area of 20-30 square inches) and rub thoroughly for about five minutes to develop a lather, and rinse off by aid of sterile gauze saturated with water. The area may then be painted with Povidone Iodine Antiseptic Solution and allowed to dry.

**C. FOR USE IN PHYSICIANS OFFICE:**  
Use for washing whenever a germicidal soap is required. For maximum degerming on the hands, proceed as under "A". To prepare patients' skin, proceed as under "B".

**Warning: FOR EXTERNAL USE ONLY.**  
In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately. Should not be used by iodine sensitive persons. Store in tight container at room temperature. Dispose in tight container as described in official compendia.

**Reorder No. 1425**  
**16 fl. oz. (473ml)**  
NDC # 67777-110-13

**Povidone Iodine Surgical Scrub Solution**  
**Antiseptic Microbicide for Skin Prepping and Cleansing**

**dynarex**

Manufactured for:  
Dynarex Corporation  
Orangeburg, NY 10962  
www.dynarex.com  
Made in Mexico

Barcode: 16784114252

## POVIDINE IODINE

povidine iodine solution

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67777-110
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
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SODIUM PHOSPHATE (UNII: SE337SVY37)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67777-110-16	48 in 1 CASE		
1		59 mL in 1 BOTTLE		
2	NDC:67777-110-11	48 in 1 CASE		
2		118 mL in 1 BOTTLE		
3	NDC:67777-110-12	24 in 1 CASE		
3		237 mL in 1 BOTTLE		
4	NDC:67777-110-13	24 in 1 CASE		
4		474 mL in 1 BOTTLE		
5	NDC:67777-110-14	12 in 1 CASE		
5		946 mL in 1 BOTTLE		
6	NDC:67777-110-15	4 in 1 CASE		
6		3784 mL in 1 BOTTLE		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	01/03/2002	

**Labeler** - Dynarex Corporation (008124539)**Registrant** - Dynarex Corporation (008124539)**Establishment**

Name	Address	ID/FEI	Business Operations
Degasa, S.A. de C.V.		812771980	manufacture(67777-110)