**POVIDONE 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 Prep**

| **Active Ingredient** | **Purpose** |
|---|---|
| Povidone Iodine 10% v/v | Antiseptic |

**Purpose**

Purpose of povidone iodine prep

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.

**Inactive Ingredient**

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

**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**

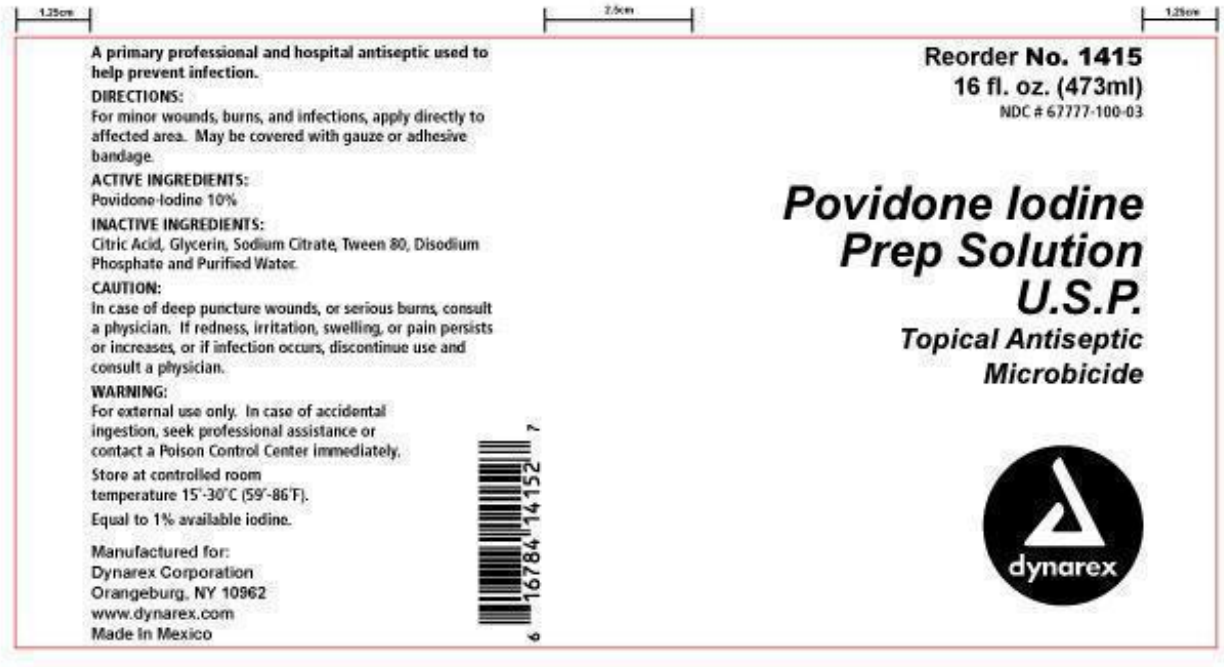
- clean area
- apply to operative site prior to surgery using the applicator

For use as an

- first aid antiseptic
- pre-operative skin preperation

**Principal Display Panel**

povidone_iodine_prep




## POVIDONE IODINE

povidine iodine solution

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:67777-100 |
| **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** |
| **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:67777-100-06 | 48 in 1 CASE | | |
| **1** | | 59 mL in 1 BOTTLE | | |
| **2** | NDC:67777-100-01 | 48 in 1 CASE | | |
| **2** | | 118 mL in 1 BOTTLE | | |
| **3** | NDC:67777-100-02 | 24 in 1 CASE | | |
| **3** | | 237 mL in 1 BOTTLE | | |
| **4** | NDC:67777-100-03 | 24 in 1 CASE | | |
| **4** | | 474 mL in 1 BOTTLE | | |
| **5** | NDC:67777-100-04 | 12 in 1 CASE | | |
| **5** | | 946 mL in 1 BOTTLE | | |
| **6** | NDC:67777-100-05 | 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(67777-100) |

Revised: 1/2015 Dynarex Corporation