

POVIDONE-IODINE- povidone-iodine solution
James Alexander Corporation

POVIDONE IODINE TOPICAL SOLUTION USP

Drug Facts

Active Ingredients (each swab)

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

Purpose

Topical Antiseptic

Uses

To treat minor skin cuts and abrasions.

Warnings

For external use only.

Ask a doctor before use if you have • deep or puncture wounds • serious burns

Stop use and ask a doctor if • redness, irritation, swelling or pain persists or increases

• infection occurs.

Keep out of reach of children. If swallowed, get medical help immediately 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. **Discard after single use.**

Other Information

Store at room temperature away from light. Keep from freezing or excessive heat.

Inactive Ingredients

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

Questions?

Call 1-908-362-9266 Monday through Friday, 9:00am - 5:00pm e.s.t.

DISPENSING SOLUTIONS®

JAMES ALEXANDER CORPORATION

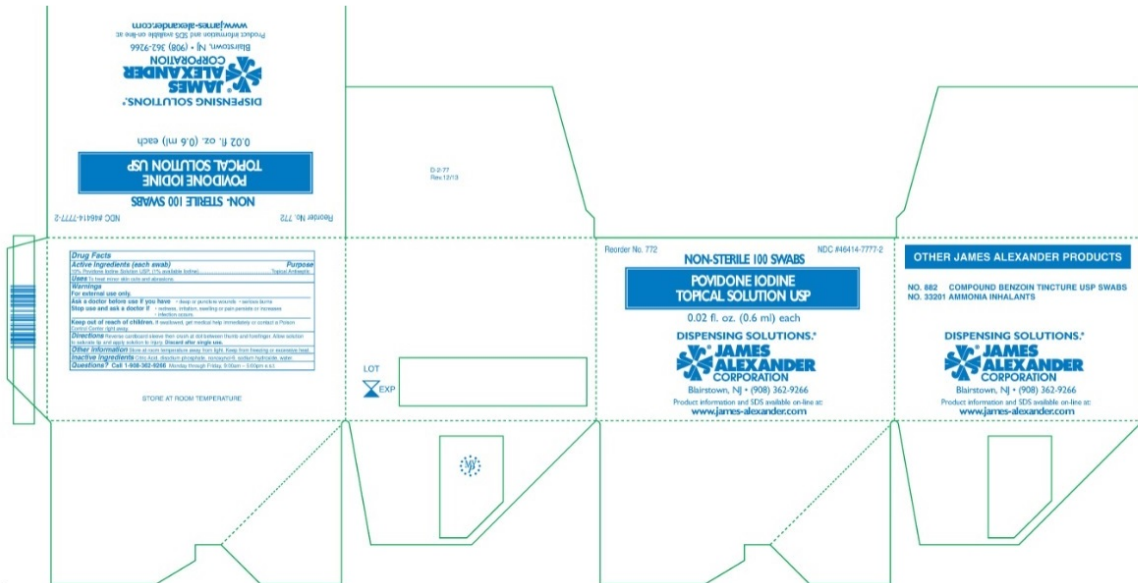
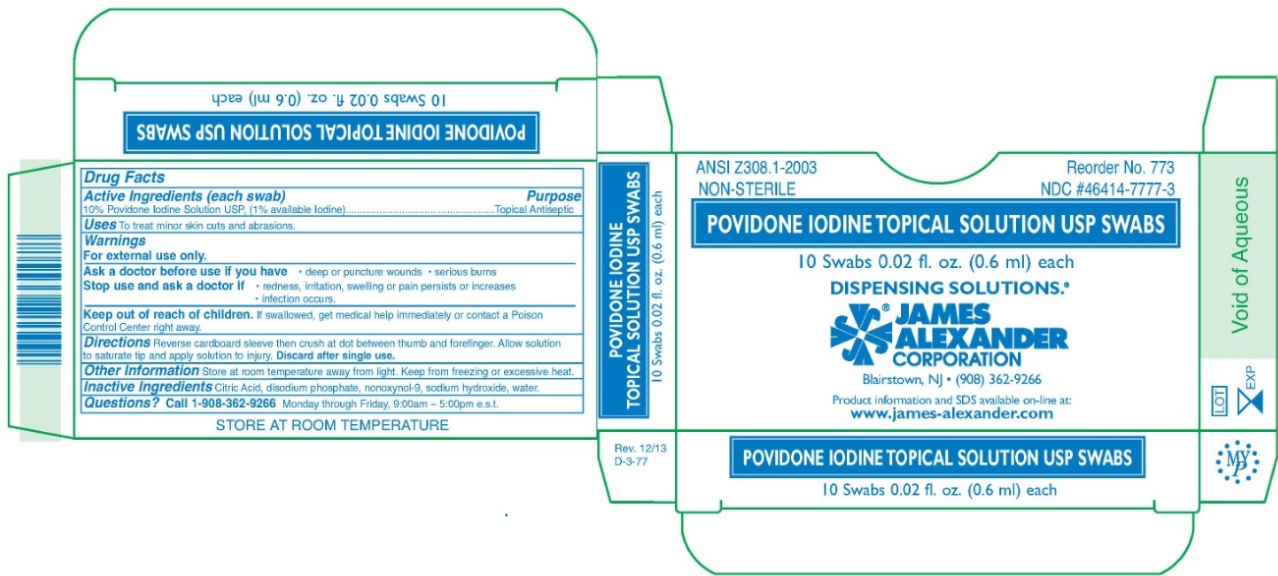
Blairstown, NJ • (908) 362-9266

Product information and MSDS available on-line at:

www.james-alexander.com

Void of Aqueous

Packaging



Drug Facts

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|--|--------------------------------------|
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POVIDONE-IODINE

povidone-iodine solution

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:46414-7777 |
| 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) | |
| SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F) | |
| NONOXYNOL-9 (UNII: 48Q180SH9T) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |
| WATER (UNII: 059QF0KO0R) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|----------|------------------|---|-----------------------------|---------------------------|
| 1 | NDC:46414-7777-3 | 10 in 1 CONTAINER | 02/14/1976 | |
| 1 | | 0.6 mL in 1 VIAL, SINGLE-USE; Type 0: Not a Combination Product | | |
| 2 | NDC:46414-7777-2 | 100 in 1 CONTAINER | 02/14/1976 | |
| 2 | | 0.6 mL in 1 VIAL, SINGLE-USE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------------|---|-----------------------------|---------------------------|
| OTC Monograph Drug | M003 | 02/14/1976 | |

Labeler - James Alexander Corporation (040756421)

Registrant - James Alexander Corporation (040756421)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------|----------------|---------------|----------------------------|
|-------------|----------------|---------------|----------------------------|

| | | | |
|-----------------------------|--|-----------|-------------------------|
| James Alexander Corporation | | 040756421 | manufacture(46414-7777) |
|-----------------------------|--|-----------|-------------------------|

Revised: 11/2023

James Alexander Corporation