

PVP IODINE- povidone-iodine swab
HART Health

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.

PVP IODINE WIPES

Active Ingredient

Povidone Iodine 10% (equivalent to 1% titratable iodine)

Purpose

Topical Antiseptic

Uses

First aid topical antiseptic to help prevent infection in:

- minor cuts
- scrapes
- burns
- abrasions

Warnings

For external use only

Do not use

- in the eyes or over large portions of the body
- on serious burns
- on animal bites
- on deep or puncture wounds

Stop use and ask a doctor if

- symptoms last more than 72 hours
- redness, swelling, irritation or pain occurs

Keep out of reach of children

If swallowed get medical help or contact a Poison Control Center right away 1-800-222-1222

Directions

Adults and children 12 years of age and over:

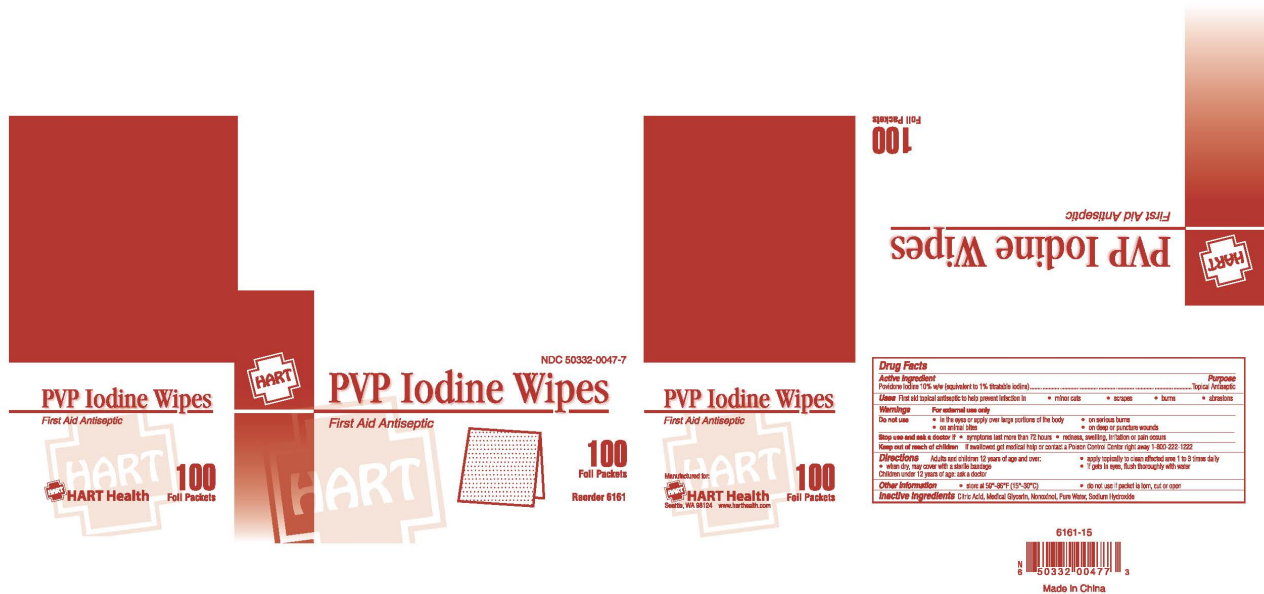
- apply topically to clean affected area 1 to 3 times daily
- when dry, may be covered with a sterile bandage
- if gets in eyes, flush thoroughly with water

Children under 12 years of age:

- ask a doctor

Inactive Ingredients

Citric Acid, Glycerin, Nonoxynol, Sodium Hydroxide, Water



| PVP IODINE | | | |
|---|----------------|--------------------|----------------|
| povidone-iodine swab | | | |
| Product Information | | | |
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:50332-0047 |
| 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 1 g |
| Inactive Ingredients | | | |
| Ingredient Name | | | Strength |
| CITRIC ACID ACETATE (UNII: DSO12WL7AU) | | | |
| GLYCERIN (UNII: PDC6A3C0OX) | | | |
| NONOXYNOL-9 (UNII: 48Q180SH9T) | | | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | | | |

WATER (UNII: 059QF0KO0R)

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:50332-0047-0 | 10 in 1 BOX | 04/01/1974 | |
| 1 | | .35 g in 1 PACKET; Type 0: Not a Combination Product | | |
| 2 | NDC:50332-0047-7 | 100 in 1 BOX | 04/20/2016 | |
| 2 | | .35 g in 1 PACKET; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part333A | 04/01/1974 | |

Labeler - HART Health (069560969)

Revised: 11/2019

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