

POVIDONE IODINE- povidone-iodine spray 5% liquid
Humco Holding Group, Inc.

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.

Private Label Povidone Iodine Spray 5%

Active Ingredient

Povidone-Iodine 5%
(0.5% available iodine)

Warnings

For external use only.

Do not use:

- In the eyes
- Over large areas of the body
- If you are allergic to povidone-iodine or any other ingredients in this preparation

Ask a doctor before use if you have:

- Deep or puncture wounds
- Serious burns
- Animal bites

Stop and ask a doctor if:

- The condition persists or gets worse
- You need to use this product for more than 1 week

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center right away.

Other Information

Store at 25°C (77°F); Excursions permitted between 15-30°C (59-86°F). Do not freeze.

Inactive ingredients:

citric acid, disodium phosphate, glycerin, poloxamer 407, potassium iodate, purified

water, sodium hydroxide.

Directions:

- Clean the affected area
- Spray a small amount of product on the area 1 to 3 times daily
- May be covered with a sterile bandage
- If bandaged, let dry first

Uses

First aid to help prevent infection in minor

- cuts
- scrapes
- burns

Purpose

Antiseptic

Drug Facts

Principal Display Panel

BETADINE
ANTISEPTIC

50 YEARS

5% POVIDONE-IODINE SPRAY
FIRST AID ANTISEPTIC

Spray

NO-STING PROMISE*
Kills Germs Promptly in
Minor Cuts,
Scrapes & Burns

3 fl oz (88.7 ml)

Drug Facts

Active ingredient Povidone-iodine, 5% (0.5% available iodine).....First aid antiseptic

Purpose First aid antiseptic

Uses first aid to help prevent infection in minor ■ cuts ■ scrapes ■ burns

Warnings For external use only
Do not use ■ in the eyes ■ over large areas of the body ■ if you are allergic to povidone-iodine or any other ingredients in this preparation
Ask a doctor before use if you have ■ deep or puncture wounds ■ serious burns ■ animal bites
Stop use and ask a doctor if ■ the condition persists or gets worse ■ you need to use this product for more than 1 week
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away

Directions ■ clean the affected area ■ spray a small amount of product on the area 1 to 3 times daily ■ may be covered with a sterile bandage ■ if bandaged, let dry first

Other information ■ store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F) Do Not Freeze

Inactive ingredients citric acid, disodium phosphate, glycerin, poloxamer 407, potassium iodate, purified water, sodium hydroxide

Questions? 1-888-827-0624 (8am-5pm, EST, Mon.-Fri.).

Helps protect against skin infection

Golden brown color indicates area treated

*Visit www.Betadine.com for details.

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AVRIO health

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POVIDONE IODINE

povidone-iodine spray 5% liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0395-9129
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POVIDONE-IODINE (UNII: 85H0HZU99M) (IODINE - UNII:9679TC07X4)	IODINE	50 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
POTASSIUM IODATE (UNII: I139E44NHL)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
SODIUM PHOSPHATE, DIBASIC (UNII: GR686LBA74)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0395-9129-93	89 mL in 1 CONTAINER; Type 0: Not a Combination Product	01/23/2020	

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End

Category	Citation	Date	Date
OTC monograph not final	part333A	01/23/2020	

Labeler - Humco Holding Group, Inc. (825672884)

Registrant - Pharma Nobis, LLC (118564114)

Establishment

Name	Address	ID/FEI	Business Operations
Pharma Nobis, LLC		118564114	manufacture(0395-9129) , pack(0395-9129) , label(0395-9129) , analysis(0395-9129)

Revised: 12/2022

Humco Holding Group, Inc.