

**BETADINE DRY POWDER- povidone-iodine aerosol, spray**  
**Atlantis Consumer Healthcare, 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.*

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**BETADINE® Dry Powder Spray**

**5% Povidone-iodine**

***Drug Facts***

***Active ingredient***

Povidone-iodine, 5% (0.5% available iodine).

***Purpose***

First aid antiseptic

***Uses***

First aid to help prevent infection in minor

- cuts
- scrapes
- burns

***Warnings For external use only***

**Extremely Flammable** Do not use near heat, flame or while smoking. Do not puncture or incinerate. Contents under pressure. Do not store at temperatures above 120°F. Intentional misuse by deliberately concentrating and inhaling the contents can be harmful or fatal

***Do not use***

- in or near eyes
- over large areas of the body
- if you are allergic to povidone-iodine or any other ingredients in this preparation

***When using this product***

- do not get into eyes. If contact occurs, rinse eyes thoroughly with water. If irritation persists, consult a doctor.

***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
- SHAKE WELL BEFORE USE
- Hold can approximately 6 inches from wound and apply a thin layer over affected area 1 to 3 daily
- May be covered with a sterile bandage

***Other information***

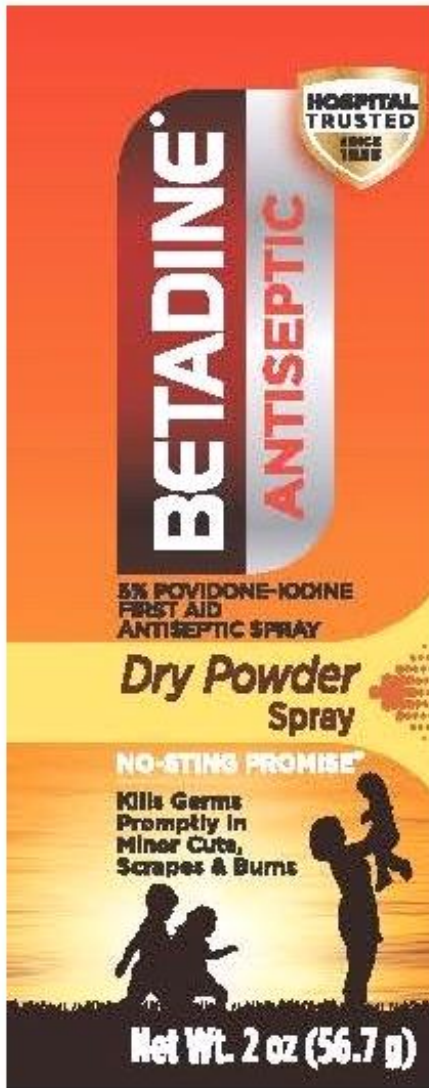
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)

***Inactive ingredients***

Isobutane, isopropyl myristate, pentrane, propane

Dist. by: **Avrio Health L.P. Stamford, CT 06901-3431**  
305653-0A

Betadine Dry Powder Spray  
NDC: 67618-165-01



## BETADINE DRY POWDER

povidone-iodine aerosol, spray

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:67618-165
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>POVIDONE-IODINE</b> (UNII: 85H0HZU99M) (IODINE - UNII:9679TC07X4)	IODINE	.05 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>ISOBUTANE</b> (UNII: BXR49TP611)	
<b>ISOPROPYL MYRISTATE</b> (UNII: 0RE8K4LNJS)	

<b>PROPANE</b> (UNII: T75W9911L6)	
<b>METHOXYFLURANE</b> (UNII: 30905R807B)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67618-165-01	56.7 mL in 1 CAN; Type 0: Not a Combination Product	06/15/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/15/2020	

**Labeler** - Atlantis Consumer Healthcare, Inc. (118983925)

**Registrant** - Atlantis Consumer Healthcare, Inc. (118983925)

### Establishment

Name	Address	ID/FEI	Business Operations
TRI-PAC, INC.		020844956	MANUFACTURE(67618-165) , PACK(67618-165)

Revised: 6/2023

Atlantis Consumer Healthcare, Inc.