

**BETADINE- povidone-iodine spray**  
**Avrio Health L.P.**

*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® Spray**  
**5% Povidone-iodine**

***Drug Facts***

***Active ingredients***

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**

**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 the product on the area 1 to 3 times a daily
- may be covered with 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

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

Betadine 3 oz Spray  
NDC: 67618-160-03

**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)

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

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

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**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

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**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

305537-0C  
LOT/EXP UNVARNISHED

\*Visit [www.Betadine.com](http://www.Betadine.com) for details.

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Dist. by: Avrio Health L.P. Stamford, CT 06901-3431

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**BETADINE**  
povidone-iodine spray

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:67618-160
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>POVIDONE-IODINE</b> (UNII: 85H0HZU99M) (IODINE - UNII:9679TC07X4)	IODINE	5 mg in 1 mL

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>SODIUM PHOSPHATE, DIBASIC, MONOHYDRATE</b> (UNII: BWZ7K44R51)	
<b>GLYCERIN</b> (UNII: PDC6A3C00X)	
<b>POLOXAMER 407</b> (UNII: TUF2IVW3M2)	
<b>POTASSIUM IODATE</b> (UNII: I139E44NHL)	
<b>WATER</b> (UNII: 059QF0K00R)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:67618-160-03	89 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/15/1992	

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph not final	part333A	04/15/1992	

**Labeler** - Avrio Health L.P. (141916531)

**Registrant** - Purdue Pharma LP (932323652)

## Establishment

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Pharma Nobis, LLC		118564114	MANUFACTURE(67618-160)

Revised: 6/2022

Avrio Health L.P.