

BETADINE- povidone-iodine spray
Purdue Products LP

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.

Betadine Spray

Povidone-iodine, 5%

Drug Facts

Active ingredient

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

Purpose

Antiseptic

Uses

Patient pre-operative skin preparation

- for preparation of the skin prior to surgery
- helps reduce bacteria that potentially can cause skin infection

Warnings

For external use only

Do not use

- in the eyes
- If you are allergic to povidone-iodine or any other ingredients in this preparation

When using this product

- prolonged exposure to wet solution may cause irritation or, rarely, severe skin reactions
- in pre-operative prepping, avoid “pooling” beneath the patient

Stop use and ask a doctor if

- irritation, sensitization, or allergic reaction occurs and lasts for 72 hours. These may be signs of a serious condition.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- hold container about 4-6 inches from skin
- spray desired area n allow to dry
- may be bandaged
- replace cap after use

Other information

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

Inactive ingredients

citric acid, dibasic sodium phosphate, glycerin, nonoxynol-9, purified water

Dist. by: **Purdue Products L.P., Stamford, CT 06901-3431**
301821-0B

Betadine Spray
NDC 67618-148-03

NDC 67618-148-03		NSN 6505-01-189-3975	
For Professional and Hospital Use Only			
BETADINE[®]			
Spray			
Povidone-iodine, 5%			
Topical Antiseptic Bactericide			
3 fl oz (88.7 mL)			
Dist. by: Purdue Products L.P., Stamford, CT 06901-3431 301821-0B			
Drug Facts			
Active ingredient		Purpose	
Povidone-iodine, 5% (0.5% available iodine)		Antiseptic	
Uses Patient pre-operative skin preparation			
<ul style="list-style-type: none"> ■ for preparation of the skin prior to surgery ■ helps reduce bacteria that potentially can cause skin infection 			
			 3 67618-148-037

BETADINE			
povidone-iodine spray			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67618-148
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			

Ingredient Name	Basis of Strength	Strength
POVIDONE-IODINE (UNII: 85H0HZU99M) (POVIDONE-IODINE - UNII:85H0HZU99M)	POVIDONE-IODINE	.05 mL in 1 mL

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID (UNII: 2968PHW8QP)	
SODIUM PHOSPHATE, DIBASIC (UNII: GR686LBA74)	
GLYCERIN (UNII: PDC6A3C0OX)	
NONOXYNOL-9 (UNII: 48Q180SH9T)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67618-148-03	89 mL in 1 BOTTLE		

Marketing Information

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

Labeler - Purdue Products LP (141916531)

Establishment

Name	Address	ID/FEI	Business Operations
Thatcher Company		041307356	MANUFACTURE

Revised: 1/2011

Purdue Products LP