

POVIDONE-IODINE PREP PAD- povidone-iodine swab
Caribbean Medical Brokers d.b.a. Specialty Medical Supplies

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.

Povidone Iodine Prep Pad

Active ingredient

Povidone Iodine USP 10% v/v

Purpose

Antiseptic

Uses

- Health Care Antiseptic for preparation of the skin prior to surgery
- First Aid Antiseptic to help prevent infection in minor cuts, scrapes and burns

Warnings

For external use only

Do not

- use in the eyes
- use on individuals who are allergic or sensitive to iodine
- apply over large areas of the body
- use as a first aid antiseptic for longer than 1 week unless directed by a doctor.

Discontinue use if irritation and redness develop.

Consult a doctor in case of

- deep or puncture wounds
- animal bites
- serious burns

Stop use and consult a doctor

If condition persists or gets worse.

Keep out of reach of children.

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

Directions:

For preparation of the skin prior to surgery

- clean the affected area
- apply a small amount of this product to the area

For use as a first aid antiseptic

- clean the affected area
- apply a small amount of the product on the area 1-3 times daily
- may be covered with a sterile bandage
- If bandaged, let dry first.

Other Information:

Store at room temperature: 59^o -86^o F (15^o - 30^o C)

Inactive Ingredients

citric acid, glycerin, Makon 8, purified water, sodium hydroxide

Package Label

Specialty Medical Supplies

Povidone Iodine Prep Pads Medium

For Individual, Professional and Hospital Use

Saturated with 10% Povidone Iodine for external use only

100 Individual Pads

Latex free

Two ply folded pad

10% Povidone Iodine for optimum bacterial action

Use for preparation of the skin prior to an injection;

to decrease germs in minor cuts and scrapes.

Four layer wrapper provides air-tight seal...

prevents leakage and drying out.

Manufactured by


Specialty Medical Supplies

Coral Springs, FL 33065

954-752-5603

www.specialtymedicalsupplies.com

Made in China

<p>Drug Facts</p> <p>Active ingredient: Povidone Iodine USP, 10% w/v</p> <p>Purpose: Antiseptic</p> <p>Use:</p> <ul style="list-style-type: none"> Health-care antiseptic for preparation of the skin prior to surgery First aid antiseptic to help prevent the risk of skin infection in minor cuts, scrapes, and burns <p>Warnings: For external use only</p> <p>Do not:</p> <ul style="list-style-type: none"> use in the eyes use on individuals who are allergic or sensitive to iodine apply over large areas of the body use as a first aid antiseptic longer than 1 week unless directed by a doctor. <p>Discontinue use if irritation and redness develop.</p> <p>Consult a doctor in case of:</p> <ul style="list-style-type: none"> deep or puncture wounds animal bites serious burns <p>Stop use and consult a doctor if the condition persists or gets worse.</p>	<p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p> <p>Directions:</p> <p>For preparation of the skin prior to surgery:</p> <ul style="list-style-type: none"> clean the affected area apply a small amount of this product on the area daily <p>For use as a first aid antiseptic:</p> <ul style="list-style-type: none"> clean the affected area apply a small amount of this product on the area 1-3 times daily may be covered with a sterile bandage if bandaged, let dry first. <p>Other information: Store at room temperature: 59°-86° F (15°-30° C)</p> <p>Inactive ingredients: citric acid, glycerin, Makon 8, purified water, sodium hydroxide</p>	<p>100 Individual Pads NDC: 68113-107-01</p> <p>Specialty Medical Supplies</p> <p>Povidone Iodine Prep Pads Medium</p> <ul style="list-style-type: none"> Two-ply, folded pad 10% Povidone Iodine for optimum anti-bacterial action. Use for preparation of skin prior to an injection; to decrease germs in minor cuts and scrapes. Four-layer wrapper provides air-tight seal... prevents leakage and drying out. <p>For Individual, Professional, and Hospital Use Saturated with 10% Povidone Iodine for external use only</p> <p>Latex Free</p> 
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Specialty Medical Supplies

Povidone Iodine Prep Pads Medium

For Individual, Professional and Hospital Use

Saturated with 10% Povidone Iodine for external use only

200 Individual Pads

Latex free

Two ply folded pad

10% Povidone Iodine for optimum bacterial action

Use for preparation of the skin prior to an injection;

to decrease germs in minor cuts and scrapes.

Four layer wrapper provides air-tight seal...

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POVIDONE-IODINE PREP PAD

povidone-iodine swab

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68 113-107
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POVIDONE-IODINE (UNII: 85H0HZU99M) (IODINE - UNII:9679TC07X4)	IODINE	0.10 g

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
WATER (UNII: 059QF0K00R)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68 113-107-01	100 in 1 PACKAGE		
2	NDC:68 113-107-02	200 in 1 PACKAGE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	02/11/2013	

Labeler - Carribbean Medical Brokers d.b.a. Specialty Medical Supplies (018354907)

Registrant - Specialty Medical Supplies Beijing (527931082)

Establishment

Name	Address	ID/FEI	Business Operations
Specialty Medical Supplies Beijing		527931072	manufacture(68 113-107)