POVIDONE IODINE- povinanz 10% antiseptic solution solution
1201258 Ontario Inc. O/A Nanz Pharma

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.

Povinanz 10% Antiseptic Solution

Active Ingredient:

Povidone-Iodine USP 10% (0.1% of available iodine)

Purpose:

Topical Antiseptic

Warnings:

For external use only. Do not use in the eyes or apply over large areas of the body. In case of deep or puncture wounds, animal bites, or serious burns, consult a doctor. Stop use and ask a doctor if the condition persists or gets worse. Stop use and ask doctor if redness, irritation, swelling, or pain persists, and infection occurs. Do not use longer than 1 week unless directed by a doctor. Do not use if allergic to iodine, in the eyes. Avoid pooling beneath the patient. Avoid excessive heat. Store at room temperature.

Keep out of reach of children:

In case of accidental ingestion, seek professional assistance or consult a poison control center immediately.

Directions:

Clean the affected area. Apply a small amount of this product on the area 1 to 3 times daily. May be covered with a sterile bandage.

Use:

Antiseptic skin preparation

Other Information:

- not made with natural rubber latex
- for hospital and professional use only.

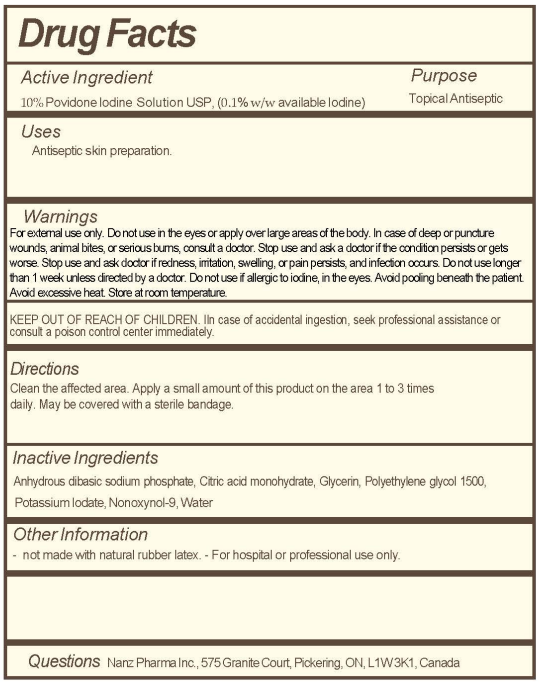
Inactive Ingredients:

Anhydrous dibasic sodium phosphate, citric acid monohydrate, glycerin, polyethylene glycol 1500, nonoxynol-9, potassium iodate, water

Questions:

Nanz Pharma Inc., 575 Granite Court, Pickering, ON, L1W 3K1, Canada

Povinanz 10% Antiseptic Solution Tentative Label for all package sizes



Drug Facts

Active Ingredient
10% Povidone Iodine Solution USP, (0.1% w/w available Iodine)

Purpose
Topical Antiseptic

Uses
Antiseptic skin preparation.

Warnings
For external use only. Do not use in the eyes or apply over large areas of the body. In case of deep or puncture wounds, animal bites, or serious burns, consult a doctor. Stop use and ask a doctor if the condition persists or gets worse. Stop use and ask doctor if redness, irritation, swelling, or pain persists, and infection occurs. Do not use longer than 1 week unless directed by a doctor. Do not use if allergic to iodine, in the eyes. Avoid pooling beneath the patient. Avoid excessive heat. Store at room temperature.

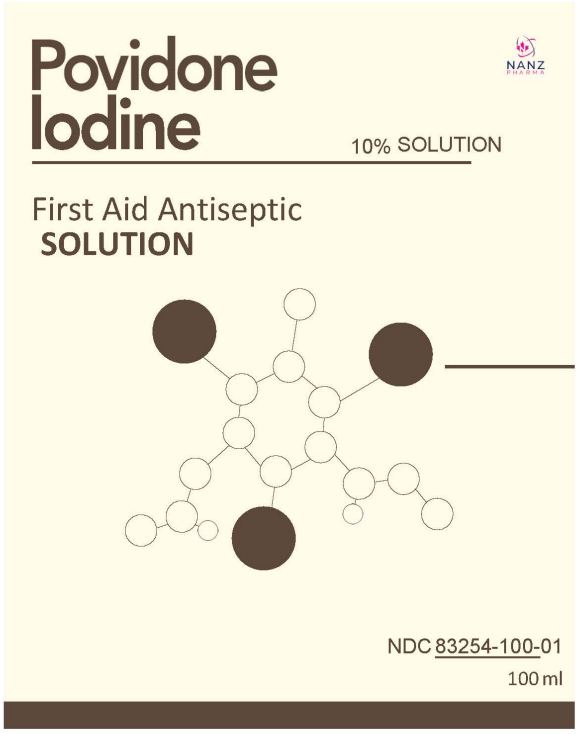
KEEP OUT OF REACH OF CHILDREN. IIn case of accidental ingestion, seek professional assistance or consult a poison control center immediately.

Directions
Clean the affected area. Apply a small amount of this product on the area 1 to 3 times daily. May be covered with a sterile bandage.

Inactive Ingredients
Anhydrous dibasic sodium phosphate, Citric acid monohydrate, Glycerin, Polyethylene glycol 1500, Potassium Iodate, Nonoxynol-9, Water

Other Information
- not made with natural rubber latex. - For hospital or professional use only.

Questions Nanz Pharma Inc., 575 Granite Court, Pickering, ON, L1W 3K1, Canada



POVIDONE IODINE

povinanz 10% antiseptic solution solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:83254-100
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
POVIDONE-IODINE (UNII: 85H0HZU99M) (IODINE - UNII:9679TC07X4)	IODINE	10 g in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
NONOXYNOL-9 (UNII: 48Q180SH9T)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)	
WATER (UNII: 059QF0KO0R)	

POTASSIUM IODATE (UNII: I139E44NHL)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
POLYETHYLENE GLYCOL 1500 (UNII: 1212Z7S33A)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83254-100-02	200 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/08/2023	
2	NDC:83254-100-05	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/08/2023	
3	NDC:83254-100-25	225 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/08/2023	
4	NDC:83254-100-01	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/08/2023	
5	NDC:83254-100-15	150 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/08/2023	
6	NDC:83254-100-50	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/08/2023	
7	NDC:83254-100-60	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/08/2023	
8	NDC:83254-100-90	90 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/08/2023	
9	NDC:83254-100-20	120 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/08/2023	
10	NDC:83254-100-18	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/08/2023	
11	NDC:83254-100-22	22.5 mL in 1 POUCH; Type 0: Not a Combination Product	06/08/2023	
12	NDC:83254-100-33	30 mL in 1 POUCH; Type 0: Not a Combination Product	06/08/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	06/08/2023	

Labeler - 1201258 Ontario Inc. O/A Nanz Pharma (256906595)

Registrant - 1201258 Ontario Inc. Nanz Pharma (256906595)

Establishment

Name	Address	ID/FEI	Business Operations
1201258 Ontario Inc. O/A Nanz Pharma		256906595	manufacture(83254-100) , pack(83254-100) , label(83254-100)