NANZ POVIDONE IODINE 5% SOLUTION- povidone iodine 5% solution liquid
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.

Nanz Povidone Iodine 5% Solution

Active Ingredients

10% Povidone Iodine Solution USP, (1% available Iodine)

Purpose:

Topical Antifungal

Uses

For the treatment of athlete's foot, jock itch, and ring worm.

For the effective relief of burning, cracking, discomfort, redness, scaling, soreness, and chafing that is associated with jock itch.

Warnings

Do not use on children under 2 years of age unless directed by a doctor. For external use only. Avoid contact with the eyes. If irritation occurs or if there is no improvement within 4 weeks, discontinue use and consult a doctor. If irritation occurs or if there is no improvement within 2 weeks, discontinue and consult a doctor.

KEEP OUT OF REACH OF CHILDREN

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

Storage:

Store in dry and dark place at temperature not exceeding 30C. Do not freeze

Label for all sizes

Inactive Ingredients

Anhydrous dibasic sodium phosphate, citric acid monohydrate, glycerin, polyethylene glycol 1500, nonoxynol-3, potassium iodate, water

Manufactured and Marketed by:

1201258 Ontario Inc. Nanz Pharma

575 Granite Ct.

Pickering,ON

L1W 3K1

Directions:

Apply a thin layer of the product over the affected area twice daily (morning and night) or as directed by a doctor. Supervise children in the use of this product. For athlete's foot: Pay special attention to spaces between the toes; wear well-fitting, ventilated shoes, and socks at least once daily. For athlete's foot and ringworm, use daily for 4 weeks; for jock itch, use daily for 2 weeks. If the condition persists longer, consult a doctor. This product is not effective on the scalp or nails.

To prevent athlete's foot, wash the feet and dry thoroughly. Apply a thin layer of the product to the feet once or twice daily (morning and/or night). Supervise children in the use of this product. Pay special attention to spaces between the toes; wear well-fitting, ventilated shoes, and change shoes and socks at least once daily.

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.

Distributed by:

1201258 Ontario Inc. Nanz Pharma

575 Granite Court

Pickerin, Ontario

L1W 3K1

Canada

Packagae Label

Drug Facts

Active Ingredient
5% Povidone Iodine Solution USP, (0.5 % w/w available Iodine)

Purpose
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Uses
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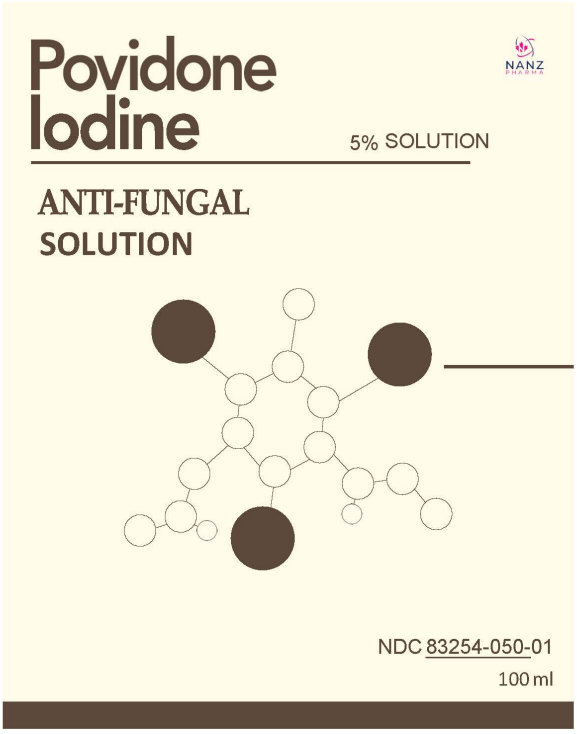
Other Information
Store in a dry and dark place at a temperature not exceeding 30C.

Inactive Ingredients
Anhydrous dibasic sodium phosphate, Citric acid monohydrate, Glycerin, Polyethylene glycol 1500, Potassium Iodate, Nonoxynol-3, Water

Questions Nanz Pharma Inc., 575 Granite Court, Pickering, ON, L1W3K1, Canada



NANZ POVIDONE IODINE 5% SOLUTION

povidone iodine 5% solution liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:83254-050
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
POVIDONE-IODINE (UNII: 85H0HZU99M) (IODINE - UNII:9679TC07X4)	IODINE	5 g in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
NONOXYNOL-9 (UNII: 48Q180SH9T)	
POLYETHYLENE GLYCOL 1500 (UNII: 1212Z7S33A)	
GLYCERIN (UNII: PDC6A3C0OX)	

SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)	
WATER (UNII: 059QF0KO0R)	
POTASSIUM IODATE (UNII: I139E44NHL)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83254-050-02	200 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/08/2023	
2	NDC:83254-050-05	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/08/2023	
3	NDC:83254-050-25	225 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/08/2023	
4	NDC:83254-050-01	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/08/2023	
5	NDC:83254-050-15	150 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/08/2023	
6	NDC:83254-050-10	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/08/2023	
7	NDC:83254-050-50	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/08/2023	
8	NDC:83254-050-60	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/08/2023	
9	NDC:83254-050-90	90 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/08/2023	
10	NDC:83254-050-20	120 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/08/2023	
11	NDC:83254-050-18	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/08/2023	
12	NDC:83254-050-11	30 mL in 1 POUCH; Type 0: Not a Combination Product	02/08/2023	
13	NDC:83254-050-22	60 mL in 1 POUCH; Type 0: Not a Combination Product	02/08/2023	
14	NDC:83254-050-33	90 mL in 1 POUCH; Type 0: Not a Combination Product	02/08/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M005	02/08/2023	

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

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

Establishment

Name	Address	ID/FEI	Business Operations
1201258 Ontario Inc. O/A Nanz Pharma		256906595	label(83254-050) , manufacture(83254-050) , pack(83254-050)