POVIDONE IODINE- povidone iodine 7.5 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.

Nanz Povidone Iodine 7.5 Solution

Purpose:

Topical Antifungal

Active Ingredients:

7.5% Povidone Iodine Solution USP, (0.75% available Iodine)

Uses:

For the treatment of athlete's foot, jock itch, and ringworm

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 of 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 use 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.

Inactive Ingredients:

Anydrous dibasic sodium phosphate, Citric acid monohydrate, Glycerin, Polyethylene glycol 1500, Nonoxynol-3, Potassium iodate, Water

Questions?

Nanz Pharma

575 Granite Ct.

Pickering, ON

L1W 3K1

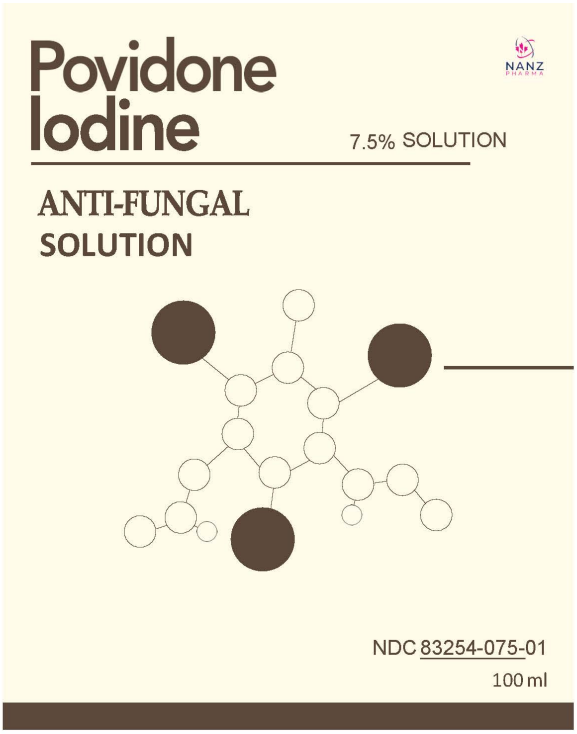
Directions:

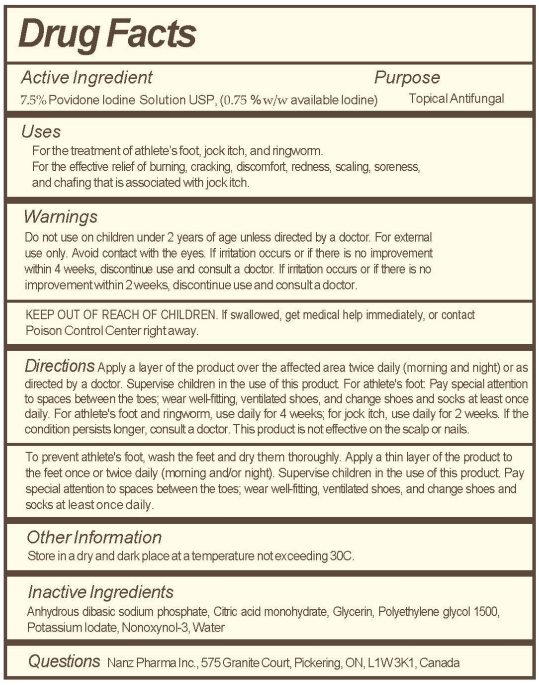
Apply a thin layer of the product over the affected area twice daily (morning and night) or as directed by a doctor. Supervise children in the use of this product. For athlete's foot: Pay special attention to spaces between the toes; wear well-fitting, ventilated shoes, and change shoes and socks at 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.

Storage:

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





Drug Facts

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Other Information
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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

POVIDONE IODINE

povidone iodine 7.5 solution solution

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:83254-705
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POVIDONE-IODINE (UNII: 85H0HZU99M) (IODINE - UNII:9679TC07X4)	IODINE	7.5 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
POTASSIUM IODATE (UNII: I139E44NHL)	
WATER (UNII: 059QF0KO0R)	
NONOXYNOL-9 (UNII: 48Q180SH9T)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

POLYETHYLENE GLYCOL 1500 (UNII: 1212Z7S33A)	
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83254-705-02	200 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/04/2023	
2	NDC:83254-705-05	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/04/2023	
3	NDC:83254-705-25	225 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/04/2023	
4	NDC:83254-705-01	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/04/2023	
5	NDC:83254-705-15	150 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/04/2023	
6	NDC:83254-705-10	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/04/2023	
7	NDC:83254-705-50	50 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/04/2023	
8	NDC:83254-705-90	90 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/04/2023	
9	NDC:83254-705-18	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/04/2023	
10	NDC:83254-705-60	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/04/2023	
11	NDC:83254-705-20	120 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/04/2023	
12	NDC:83254-705-11	30 mL in 1 POUCH; Type 0: Not a Combination Product	05/04/2023	
13	NDC:83254-705-22	60 mL in 1 POUCH; Type 0: Not a Combination Product	05/04/2023	
14	NDC:83254-705-33	90 mL in 1 POUCH; Type 0: Not a Combination Product	05/04/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M005	05/04/2023	

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	manufacture(83254-705) , pack(83254-705) , label(83254-705)