NANZ POVIDONE IODINE 10% SOLUTION- povidone iodine 10% 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 10% Solution

Purpose:

Topical Antifungal

Active Ingredients

10% Povidone Iodine Solution USP, (1% 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

Use as directed.

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

Note: Change non-active ingredient from nonoxynol-3 to nonoxynol-9

Drug Facts

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

Purpose
Topical Antifungal

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 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 use and consult a doctor.

KEEP OUT OF REACH OF CHILDREN. If swallowed, get medical help immediately, or contact Poison Control Center right away.

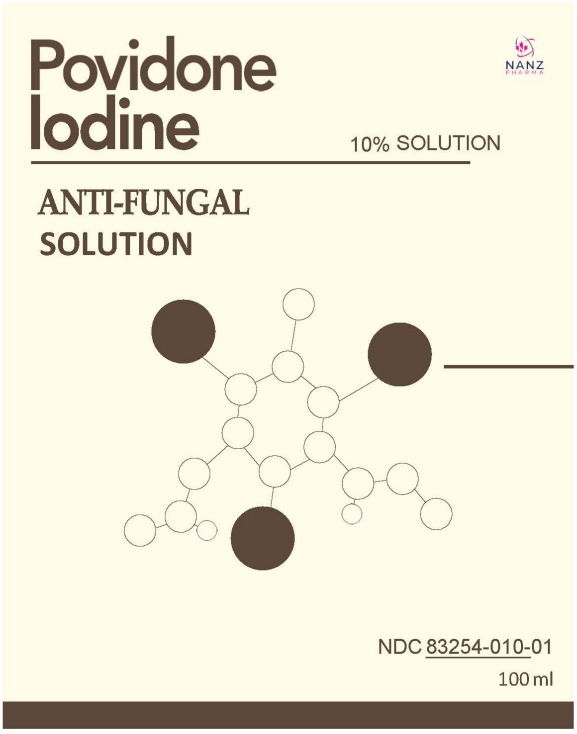
Directions Apply a layer of the product over the affected area twice daily (morning and night) or as directed by a doctor. Supervise children in the use of this product. For athlete's foot: Pay special attention to spaces between the toes; wear well-fitting, ventilated shoes, and change shoes and socks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

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, L1W 3K1, Canada



NANZ POVIDONE IODINE 10% SOLUTION

povidone iodine 10% solution liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:83254-010
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**
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
POTASSIUM IODATE (UNII: I139E44NHL)	
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)	
GLYCERIN (UNII: PDC6A3C0OX)	

POLYETHYLENE GLYCOL 1500 (UNII: 1212Z7S33A)	
NONOXYNOL-9 (UNII: 48Q180SH9T)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83254-010-02	200 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/12/2023	
2	NDC:83254-010-05	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/19/2023	
3	NDC:83254-010-25	225 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/19/2023	
4	NDC:83254-010-01	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/12/2023	
5	NDC:83254-010-15	150 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/19/2023	
6	NDC:83254-010-10	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/19/2023	
7	NDC:83254-010-50	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/12/2023	
8	NDC:83254-010-90	90 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/12/2023	
9	NDC:83254-010-18	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/19/2023	
10	NDC:83254-010-60	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/08/2023	
11	NDC:83254-010-20	120 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/08/2023	
12	NDC:83254-010-11	30 mL in 1 POUCH; Type 0: Not a Combination Product	02/08/2023	
13	NDC:83254-010-22	60 mL in 1 POUCH; Type 0: Not a Combination Product	02/08/2023	
14	NDC:83254-010-33	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	manufacture(83254-010) , label(83254-010) , pack(83254-010)