

NANZ PURE- calamine lotion 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.

Pure Calamine Lotion 19%

Active Ingredients:

Calamine 19% Zinc Oxide 19%

Purpose

Skin protectant

Uses:

For temporary relief of skin irritations and itching caused by sunburn, poison ivy, sumac and poison oak.

Caution and Warnings:

FOR EXTERNAL USE ONLY. Use only as directed.

When using this product, avoid contact with eyes. If contact occurs, rinse thoroughly with water.

Stop use and as/consult a doctor/physician/healthcare practitioner/healthcare provider/ healthcare professional if symptoms worsen or last for more than 7 days.

Do not use on broken skin.

KEEP OUT OF REACH OF CHILDREN.

In case of accidental ingestion, seek professional assistance or contact Poison Control Center immediately.

Directions:

Adults and children 2 years and older. Shake well before using. Cleanse the skin with soap and water and let dry before each use. Apply lotion to the affected area using cotton or soft cloth, as often as needed for comfort. Children under 6 months of age: consult a doctor before use.

Other information:

Store at room temperature 50-86F

Inactive Ingredients:

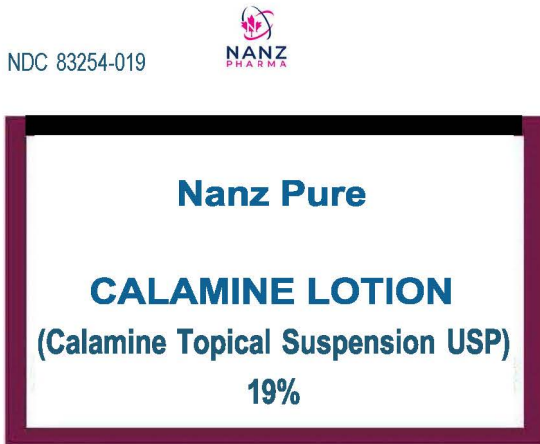
Glycerin, Bentonite, Calcium hydroxide, water

Distributed by:

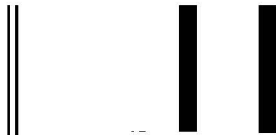
1201258 Ontario Inc. Nanz Pharma, 575 Granite Court, Pickering, ON L1W 3K1

Questions or Comments: ###-###-####

Package Label



SKIN PROTECTANT



CONTENTS FLOZ (ml)

For all bottle sizes. A tentative Label

Drug Facts	
Active ingredients	Purpose
Calamine 19%. Zinc Oxide 19%.....	Skin protectant
Uses : For temporary relief of skin irritations and itching caused by sunburn, poison ivy, sumac, and poison oak.	
Caution & Warnings	
<ul style="list-style-type: none"> ■ FOR EXTERNAL USE ONLY. Use only as directed. ■ When using this product, avoid contact with eyes. If contact occurs, rinse thoroughly with water. ■ Stop use and ask/consult a doctor/physician/healthcare practitioner/health care provider/ healthcare professional if symptoms worsen or last for more than 7 days. ■ Do not use on broken skin. ■ KEEP OUT OF REACH OF CHILDREN. In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately. 	
Directions	
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Other information Store at room temperature 50-86F	
Inactive ingredients Glycerin, Bentonite, Calcium hydroxide, Water	
Distributed by: 1201258 Ontario Inc. Nanz Pharma, 575 Granite Court, Pickering, ON L1W 3K1 Questions or Comments? ###-###-####	

NANZ PURE calamine lotion liquid
Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83254-019
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
FERRIC OXIDE RED (UNII: 1K09F3G675) (FERRIC OXIDE RED - UNII:1K09F3G675)	FERRIC OXIDE RED	19 g in 100 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	19 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
BENTONITE (UNII: A3N5ZCN45C)	
GLYCERIN (UNII: PDC6A3C0OX)	
CALCIUM HYDROXIDE (UNII: PF5DZW74VN)	
WATER (UNII: 059QF0KOOR)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83254-019-10	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/19/2023	
2	NDC:83254-019-50	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/19/2023	
3	NDC:83254-019-20	2000 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/19/2023	
4	NDC:83254-019-02	20 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/19/2023	
5	NDC:83254-019-05	50 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/12/2023	
6	NDC:83254-019-06	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/12/2023	
7	NDC:83254-019-55	5000 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/19/2023	
8	NDC:83254-019-01	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/12/2023	
9	NDC:83254-019-25	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/12/2023	
10	NDC:83254-019-22	225 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/12/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M016	02/15/2023	

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(83254-019) , pack(83254-019) , label(83254-019)

Revised: 5/2023

1201258 Ontario Inc.O/A Nanz Pharma