

**ALOE VERA CALAMINE- nanz aloe vera calamine lotion lotion
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 Aloe Vera Calamine Lotion

Active Ingredients

Calamine Lotion 8%

Purpose:

Skin protectant

Uses:

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

Caution & Warnings:

For external use only. Keep out of reach of children. If swallowed, call a poison control centre or get medical help right away. Stop use and ask/consult a doctor/physician/health care practitioner/health care provider/health care professional if symptoms worsen or last for more than 7 days. When using this product, avoid contact with eyes. If contact occurs, rinse thoroughly with water. 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

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

Children under 6 months of age: Consult a doctor before use.

Inactive Ingredients:

Aloe Barbadensis Leaf Juice, Light liquid paraffin, Glycerin, Cetostearyl alcohol,

Cetomacrogol 1000, White petroleum jelly, Propylene glycol, Fragrance, Methylparaben, Propylparaben, Purified water.

Storage

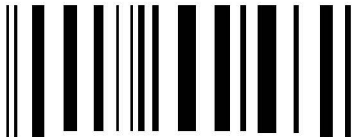
Store at room temperature 13-30C (50-86F)

Label

NDC 83254-008



SKIN PROTECTANT



CONTENTS FLOZ (ml)

Drug Facts	
Active ingredients	Purpose
Calamine 8%, Zinc Oxide 8%	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	
<ul style="list-style-type: none"> Adults and children 2 years of age 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 age: Consult a doctor before use. 	
Other information Store at room temperature 50-86F	
Inactive ingredients Aloe Barbadosis Leaf Juice, Light liquid paraffin, Glycerin, Cetostearyl alcohol, Cetomacrogol 1000, White petroleum jelly, Propylene glycol, Fragrance, Methylparaben, Propylparaben, Purified water	
Distributed by: 1201258 Ontario Inc. Nanz Pharma, 575 Granite Court, Pickering, ON L1W 3K1 Questions or Comments? ###-###-####	

ALOE VERA CALAMINE

nanz aloe vera calamine lotion lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83254-008
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	8 g in 100 mL	
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)		ZINC OXIDE	8 g in 100 mL	
Inactive Ingredients				
Ingredient Name		Strength		
LIGHT MINERAL OIL (UNII: N6K5787QVP)		10 g in 100 mL		
FRAGRANCE 13576 (UNII: 5EM498GW35)				
PROPYLPARABEN (UNII: Z8IX2SC1OH)				
WHITE PETROLATUM (UNII: B6E5W8RQJ4)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
METHYLPARABEN (UNII: A2I8C7HI9T)				
GLYCERIN (UNII: PDC6A3C0OX)				
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)				
CETETH-20 (UNII: I835H2IHHX)				
ALOE VERA LEAF (UNII: ZY81Z83H0X)		10 g in 100 mL		
WATER (UNII: 059QF0KO0R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83254-008-15	150 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/05/2023	
2	NDC:83254-008-02	20 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/05/2023	
3	NDC:83254-008-22	225 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/05/2023	
4	NDC:83254-008-20	2000 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/05/2023	
5	NDC:83254-008-01	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/05/2023	
6	NDC:83254-008-25	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/05/2023	
7	NDC:83254-008-10	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/05/2023	
8	NDC:83254-008-05	50 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/05/2023	
9	NDC:83254-008-50	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/05/2023	
10	NDC:83254-008-06	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/05/2023	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	M016	05/05/2023		

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(83254-008) , label(83254-008) , pack(83254-008)

Revised: 5/2023

1201258 Ontario Inc O/A Nanz Pharma