CALAMINE- nanz relieve 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 Relieve Calamine Lotion

Active Ingredients

Calamine 7.6% and Zinc Oxide 7.6%

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 chidren 2 years of age and older: shake well before using. Cleanse the skin with soap and water and let it dry befroe 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

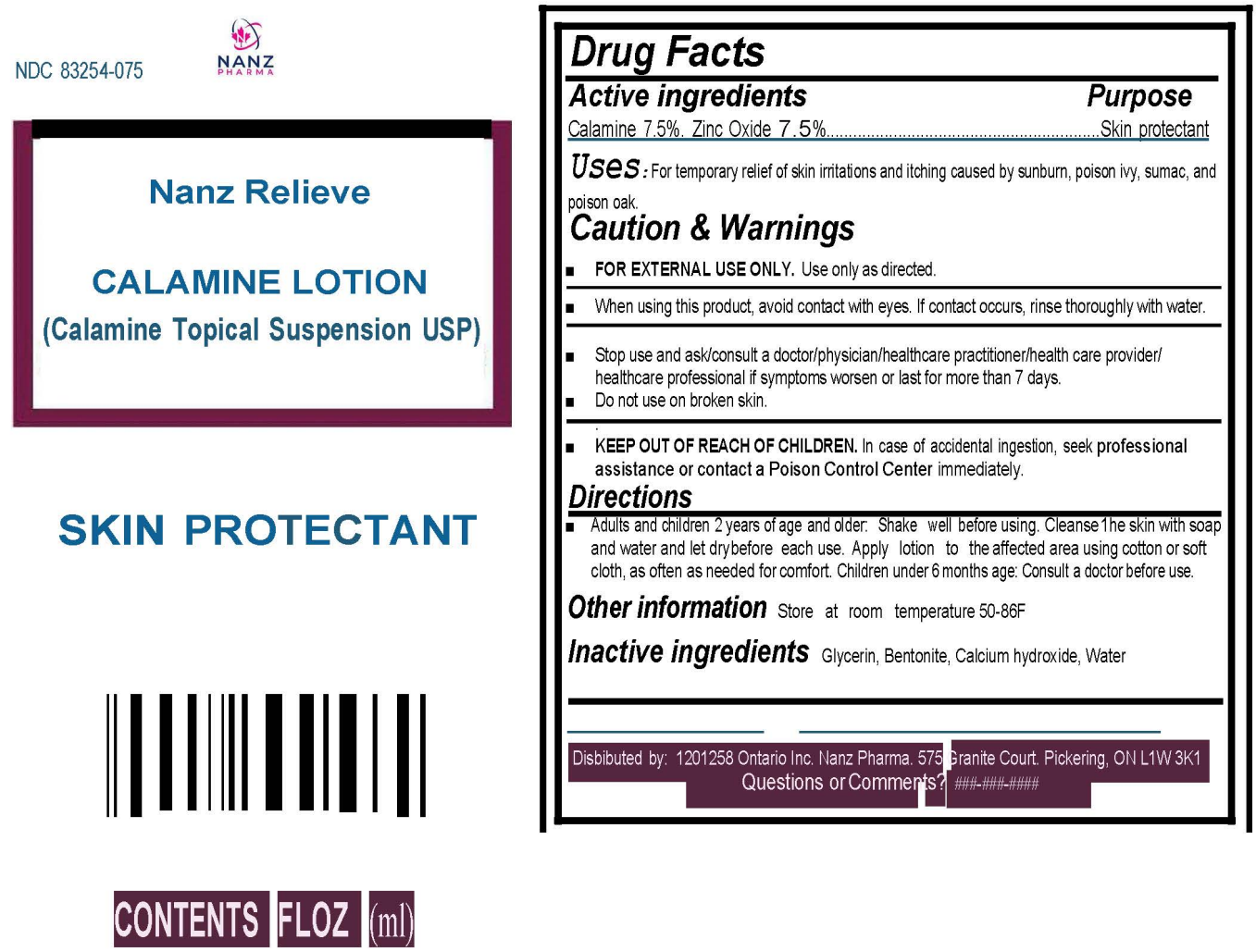
Glycerin, Bentonite, Calcium Hydroxide, Water

Other information:

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

NDC: 83254-075

Labels for all sizes



CALAMINE

nanz relieve calamine lotion lotion

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:83254-076
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
FERRIC OXIDE RED (UNII: 1K09F3G675) (FERRIC OXIDE RED - UNII:1K09F3G675)		7.6

FERRIC OXIDE RED (UNII: 1K09F3G675) (FERRIC OXIDE RED - UNII:1K09F3G675)	FERRIC OXIDE RED	7.6 g in 100 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	7.6 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
CALCIUM HYDROXIDE (UNII: PF5DZW74VN)	
BENTONITE (UNII: A3N5ZCN45C)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83254-076-02	200 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/05/2023	
2	NDC:83254-076-05	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/05/2023	
3	NDC:83254-076-25	225 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/05/2023	
4	NDC:83254-076-01	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/05/2023	
5	NDC:83254-076-15	150 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/05/2023	
6	NDC:83254-076-10	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/05/2023	
7	NDC:83254-076-50	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/05/2023	
8	NDC:83254-076-00	50 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/05/2023	
9	NDC:83254-076-06	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(83254-076) , pack(83254-076) , label(83254-076)