DERMASARRA- otc topical analgesic drug products lotion
DERMARITE INDUSTRIES, LLC

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.

DRUG LISTING: DERMASARRA

Active Ingredient

Camphor 0.5%

Purpose

External Analgesic

Uses:

Temporary relief of itching associiated with minor skin irritations due to:

- dry skin
- insect bites
- detergent
- sunburn

Warnings:

- **For external use only**.
- **Avoid contact with eyes.** In case of contact, flush thoroughly with water.
- **Stop use and ask a doctor if**, condition worsens, symptoms last for more than 7 days, symptoms clear up and occur again within a few days
- **Do not use on** deep puncture wounds, animal bites, or serious burns.

Warnings

- Keep out of reach of children. In case of accidental ingestion contact a physician or Poison Control Center right away

Directions:

Adults and children 2 years of age and older: Apply to affected area not more than 3 to 4 times dialy,

Children under 2 years of age: Consult a doctor

Other Infomation:

Store at room temperature (59°-86°F)

You may report a serious adverse event to DermaRite Industries, PO Box 7209, North Bergen, NJ 07047

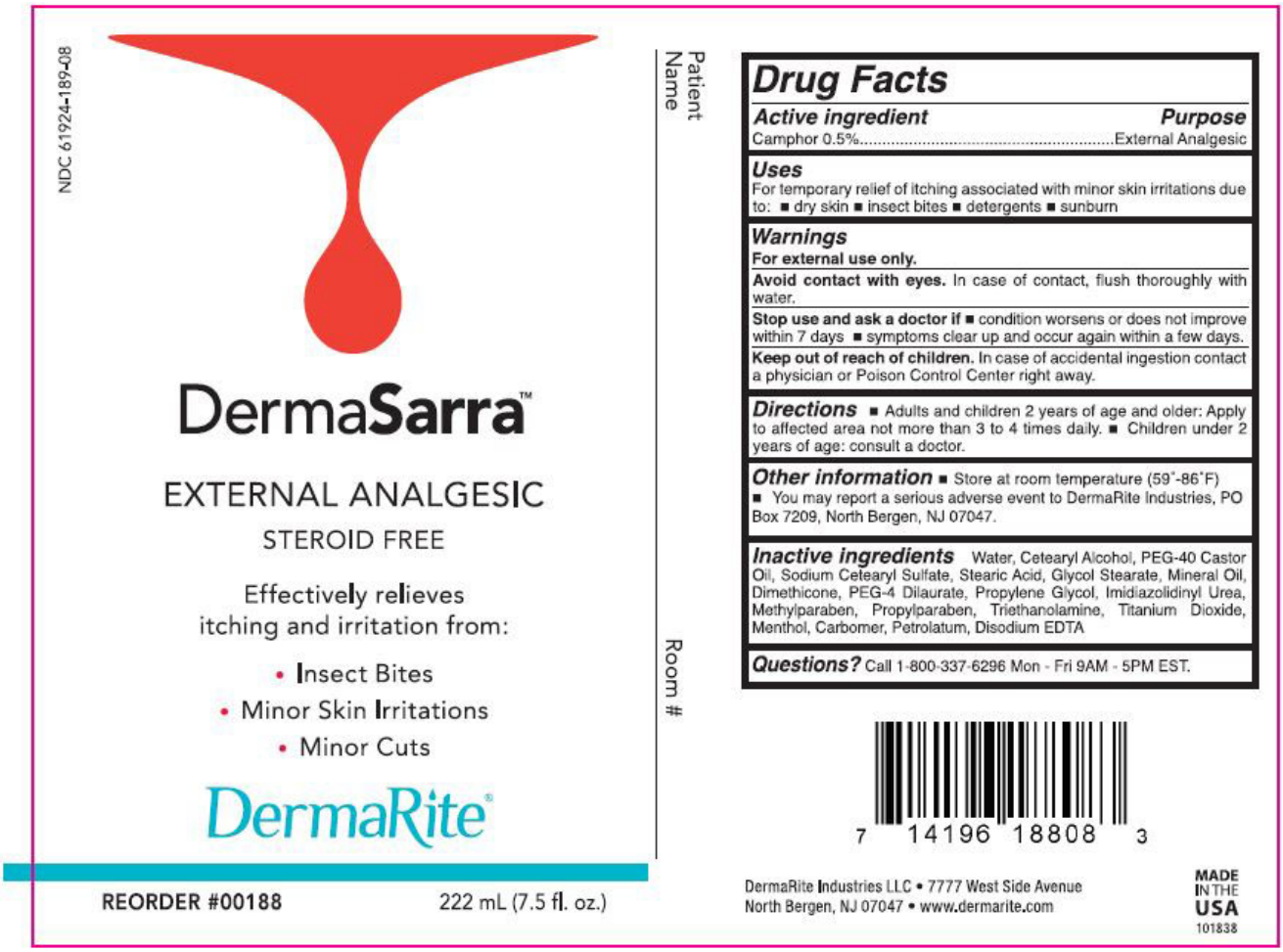
Inactive Ingredients:

water, Cetearyl Alcohol, PEG-40 Castor Oil, Sodium Cetearyl Sulfate, Stearic Acid, Glycol Stearate, Mineral Oil, Dimethicone, PEG-4 Dilaurate, Propylene Glycol, Imidazolidinyl Urea, Methylparaben, Propylparaben, Triethanolamine, Titanium Dioxide, menthol, Carbomer, Petrolatum, Disodium EDTA

Questions?

Call 1-800-337-6296 Mon-Fri 9AM-5PM EST.

DermaSarra Package Label Principal Display Panel



DERMASARRA

otc topical analgesic drug products lotion

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:61924-189
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAMPHOR (NATURAL) (UNII: N20HL7Q941) (CAMPHOR (NATURAL) - UNII:N20HL7Q941)	CAMPHOR (NATURAL)	0.005 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
CARBOMER HOMOPOLYMER TYPE C (UNII: 4Q93RCW27E)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
IMIDUREA (UNII: M629807ATL)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCOL STEARATE (UNII: 0324G66D0E)	
PEG-40 CASTOR OIL (UNII: 4ERD2076EF)	
PEG-4 DILAURATE (UNII: KCR71CW036)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
MINERAL OIL (UNII: T5L8T28FGP)	
PETROLATUM (UNII: 4T6H12BN9U)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SODIUM CETOSTEARYL SULFATE (UNII: 7ZBS06BH4B)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	
MENTHOL (UNII: L7T10EIP3A)	

Product Characteristics

Color	white	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61924-189-08	222 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	02/24/2010	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	02/24/2010	

Labeler - DERMARITE INDUSTRIES, LLC (883925562)

Registrant - DERMARITE INDUSTRIES, LLC (883925562)

Establishment

Name	Address	ID/FEI	Business Operations
DERMARITE INDUSTRIES, LLC		883925562	manufacture(61924-189)

Revised: 1/2022 DERMARITE INDUSTRIES, LLC