

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

DRUG LISTING: DERMASARRA

Active Ingredient

Camphor 0.5%

Purpose

External Analgesic

Uses:

Temporary relief of itching associated 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 daily,

Children under 2 years of age: Consult a doctor

Other Information:

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:

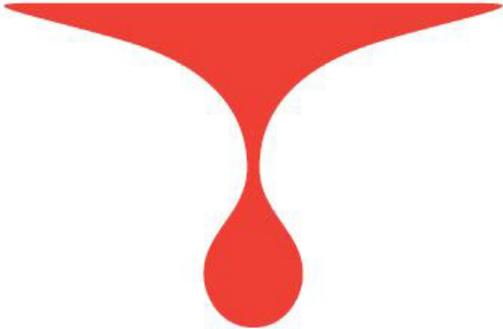
water, Cetearyl Alcohol, PEG-40 Castor Oil, Sodium Cetearyl Sulfate, Stearic Acid, Glycol Stearate, Mineral Oil, Dimethicone, PEG-4 Dilaurate, Propylene Glycol, Imidazolidinyl Urea, Methylparaben, Propylparaben, Triethanolamine, Titanium Dioxide, menthol, Carbomer, Petrolatum, Disodium EDTA

Questions?

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

DermaSarra Package Label Principal Display Panel

NDC 61924-189-08



DermaSarra™

EXTERNAL ANALGESIC

STEROID FREE

Effectively relieves
itching and irritation from:

- Insect Bites
- Minor Skin Irritations
- Minor Cuts

DermaRite®

REORDER #00188
222 mL (7.5 fl. oz.)

Patient Name

Drug Facts

Active ingredient	Purpose
Camphor 0.5%.....	External Analgesic

Uses
For temporary relief of itching associated with minor skin irritations due to: ■ dry skin ■ insect bites ■ detergents ■ 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 or does not improve within 7 days ■ symptoms clear up and occur again within a few days.
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 daily. ■ Children under 2 years of age: consult a doctor.

Other information ■ 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, Imidiazolidinyl Urea, Methylparaben, Propylparaben, Triethanolamine, Titanium Dioxide, Menthol, Carbomer, Petrolatum, Disodium EDTA

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

Room #



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DermaRite Industries LLC • 7777 West Side Avenue
North Bergen, NJ 07047 • www.dermarite.com

**MADE
IN THE
USA**
101838

DERMASARRA

otc topical analgesic drug products lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61924-189
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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	Application Number or Monograph	Marketing Start	Marketing End
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Category	Citation	Date	Date
OTC Monograph Drug	M017	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: 12/2024

DERMARITE INDUSTRIES, LLC