

4-N-1 WASH- otc skin protectant drug product cream
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: 4-N-1 WASH CREAM

Active Ingredients:

Dimethicone 1%

Purpose:

Skin Protectant

Uses:

- A gentle alternative to soap and water.
- Cleans, restores, nourishes, and protects even most delicate skin.
- Ideal for frequent cleansing and incontinence care.

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.
- **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:

- **For skin care:** Apply quarter-sized amount to warm, damp cloth. Wash skin, turning the cloth as the skin is cleansed to remove residue.
- **For incontinence care:** Remove excess fecal matter. Follow skin care directions above

Other Information:

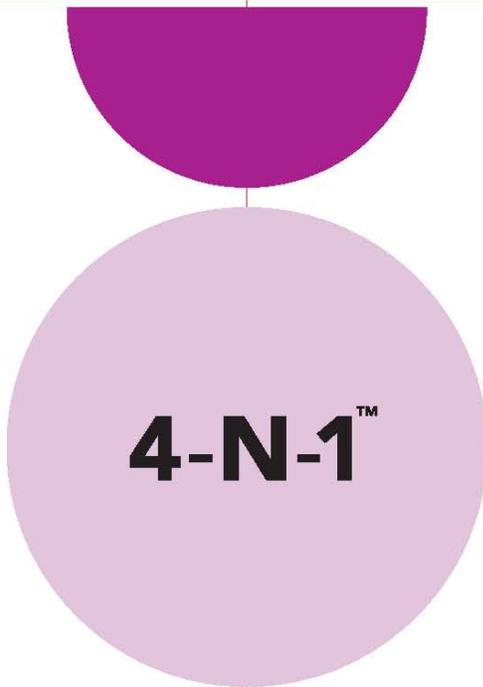
Store at room temperature (59°-86°F)

Ingredients:

Butylparaben, Cetareth-20, Cetearyl Alcohol, Cetearyl Isononanoate, Cetyl Palmitate, Ehtylparaben, Fragrance, Glyceryl Stearate, Isobutylparaben, Methyl paraben, PEG-100 Stearate, PEG-20 Glyceryl Stearate, Phenoxyethanol, Propylparaben, Water

4-N-1 Wash Cream Package Label Principal Display Panel

NDC 61924-208-16



SKIN PROTECTANT

NO RINSE WASH CREAM
with DIMETHICONE

Ideal for frequent cleansing
and incontinence care

- 1 cleanse 2 protect
- 3 moisturize 4 nourish

DermaRite®

REORDER #00208

Net Wt. 113 g (4 oz.)

Drug Facts

Active ingredient	Purpose
Dimethicone 1%	Skin protectant

Uses
Temporarily protects and helps relieve chafed or cracked skin.

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 symptoms last more than 7 days or clear up and occur again within a few days.
Do not use on deep puncture wounds, animal bites, or serious burns.
Keep out of reach of children. In case of accidental ingestion contact a physician or Poison Control Center right away.

Directions
For skin care: Apply quarter-sized amount to a warm, damp cloth. Wash skin, turning the cloth as the skin is cleansed to remove residue. For incontinence care: Remove excess fecal matter. Follow skin care directions above.

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 Isononanoate, Cetyl Palmitate, Glyceryl Stearate, PEG-100 Stearate, PEG-20 Glyceryl Stearate, Ceteareth-20, Cetearyl Alcohol, Butylparaben, Ethylparaben, Isobutylparaben, Methylparaben, Phenoxyethanol, Propylparaben, Fragrance

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

Patient Name

Room #



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

MADE
IN THE
USA
101432

4-N-1 WASH

otc skin protectant drug product cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61924-208
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	0.01 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
CETEARYL ISONONANOATE (UNII: P5O01U99NI)	
CETYL PALMITATE (UNII: 5ZA2S6B08X)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
PEG-20 GLYCERYL STEARATE (UNII: MJV0165YY8)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
BUTYLPARABEN (UNII: 3QPI1U3FV8)	
ETHYLPARABEN (UNII: 14255EXE39)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
ISOBUTYLPARABEN (UNII: 0QJ25X58G)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61924-208-16	452 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/02/2010	
2	NDC:61924-208-04	113 g in 1 TUBE; Type 0: Not a Combination Product	01/02/2010	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	01/02/2010	

Labeler - DermaRite Industries, LLC (883925562)**Registrant** - DermaRite Industries, LLC (883925562)

Establishment			
Name	Address	ID/FEI	Business Operations
DermaRite Industries, LLC		883925562	manufacture(61924-208)

Revised: 1/2020

DermaRite Industries, LLC