

4-N-1 WASH- otc skin protectant drug product cream
DermaRite Industries, LLC

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:

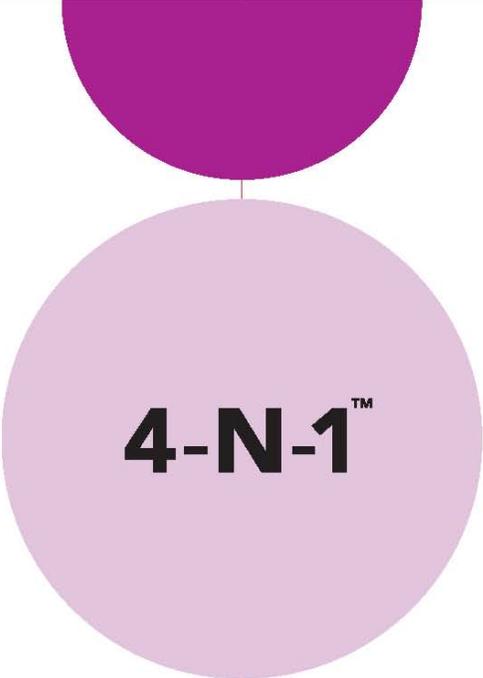
Store at room temperature (59°-86°F)

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

<p style="writing-mode: vertical-rl; transform: rotate(180deg);">NDC 61924-208-16</p>  <p>SKIN PROTECTANT NO RINSE WASH CREAM with DIMETHICONE</p> <p>Ideal for frequent cleansing and incontinence care</p> <p>1 cleanse 2 protect 3 moisturize 4 nourish</p> 	<div style="border: 2px solid black; padding: 5px;"> <p>Drug Facts</p> <table border="1"> <tr> <td>Active ingredient Dimethicone 1%</td> <td>PurposeSkin protectant</td> </tr> </table> <p>Uses ■ Temporarily protects and helps relieve chafed or cracked skin.</p> <p>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 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.</p> <p>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.</p> <p>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.</p> <p>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</p> <p>Questions? Call 1-800-337-6296 Mon - Fri 9AM - 5PM EST.</p> </div> <p style="writing-mode: vertical-rl; transform: rotate(180deg);">Patient Name</p> <p style="writing-mode: vertical-rl; transform: rotate(180deg);">Room #</p>  <p style="text-align: center;">7 14196 20804 0</p>	Active ingredient Dimethicone 1%	PurposeSkin protectant
Active ingredient Dimethicone 1%	PurposeSkin protectant		
<p>REORDER #00208 Net Wt. 113 g (4 oz.)</p>	<p>DermaRite Industries LLC • 7777 West Side Avenue North Bergen, NJ 07047 • www.dermarite.com</p> <p style="text-align: right;">MADE IN THE USA 101432</p>		

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: 059QF0KO0R)	
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: 0QQJ25X58G)	

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 Drug	M016	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: 12/2024

DermaRite Industries, LLC