

PERSONAL CLEANSING WITH DIMETHICONE- dimethicone cloth
Cardinal Health 200, Inc.

Personal Cleansing Cloth with Dimethicone

Drug Facts

Active Ingredient

Dimethicone 3.2%

Purpose

Skin Protectant

Uses

- temporarily protects and helps relieve chapped or cracked skin
- helps prevent perineal dermatitis
- protects minor skin irritation associated with perineal dermatitis

Warnings

For external use only

When using this product

- Avoid direct contact with the eyes

Stop use and contact a physician

- if condition worsens
- symptoms last more than 7 days or clear up and occur again within a few days.

Keep out of reach of children.

If swallowed, get medical help or contact Poison Control Center right away.

- Discontinue if irritation or redness develops
- Gloves diminish sensitivity to heat
- Closely monitor heat level with infants, unresponsive or skin sensitive individuals

Do not use

- On deep or puncture wounds
- Animal bites
- Serious burns

Directions

- Pull back label and remove wipes

- Thoroughly cleanse soiled area, using one wipe at a time
 - Use as often as necessary
 - Dispose of cloths in a waste receptacle
 - Do not flush
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- Wipes may be used at room temperature but if heating is desired, wipes may be warmed in a wipes warmer. Wipes should be warmed:
 - In a single warming session at temperatures not exceeding 52°C (125°F) and
 - for a maximum of 200 hours. Discard wipes that have been:
 - Exposed to warming temperatures exceeding 52°C (125°F); or
 - Stored longer than 200 hours within the warmer; or
 - Been warmed, allowed to cool, and then re-warmed

Warming Instructions:

Other Information

When not in a warmer, store between 15-30°C (59-86°F).

Inactive Ingredients

Aqua, Glycerin, PPG-15 Stearyl Ether, Glyceryl Stearate, PEG-100 Stearate, Phenoxyethanol, Aloe Barbadensis Leaf Extract, Caprylyl Glycol, Cetearyl Alcohol, Xanthan Gum

Package Labeling:

REF 2AWUD-18

PERSONAL CLEANSING WITH DIMETHICONE

dimethicone cloth

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63517-125
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	32 mg in 1 mL

Inactive Ingredients	
Ingredient Name	Strength

WATER (UNII: 059QF0KO0R)				
GLYCERIN (UNII: PDC6A3C0OX)				
PPG-15 STEARYL ETHER (UNII: 1II18XLS1L)				
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)				
PEG-100 STEARATE (UNII: YD01N1999R)				
PHENOXYETHANOL (UNII: HIE492ZZ3T)				
ALOE VERA LEAF (UNII: ZY81Z83H0X)				
CAPRYLYL GLYCOL (UNII: 00YIU5438U)				
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)				
XANTHAN GUM (UNII: TTV12P4NEE)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63517-125-21	18 in 1 PACKET	05/15/2019	
1		1 in 1 POUCH		
1		10.34 mL in 1 PATCH; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC Monograph Drug	M022		05/15/2019	

Labeler - Cardinal Health 200, Inc. (961027315)

Revised: 10/2023

Cardinal Health 200, Inc.