

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

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.

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

Warming Instructions:

- 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

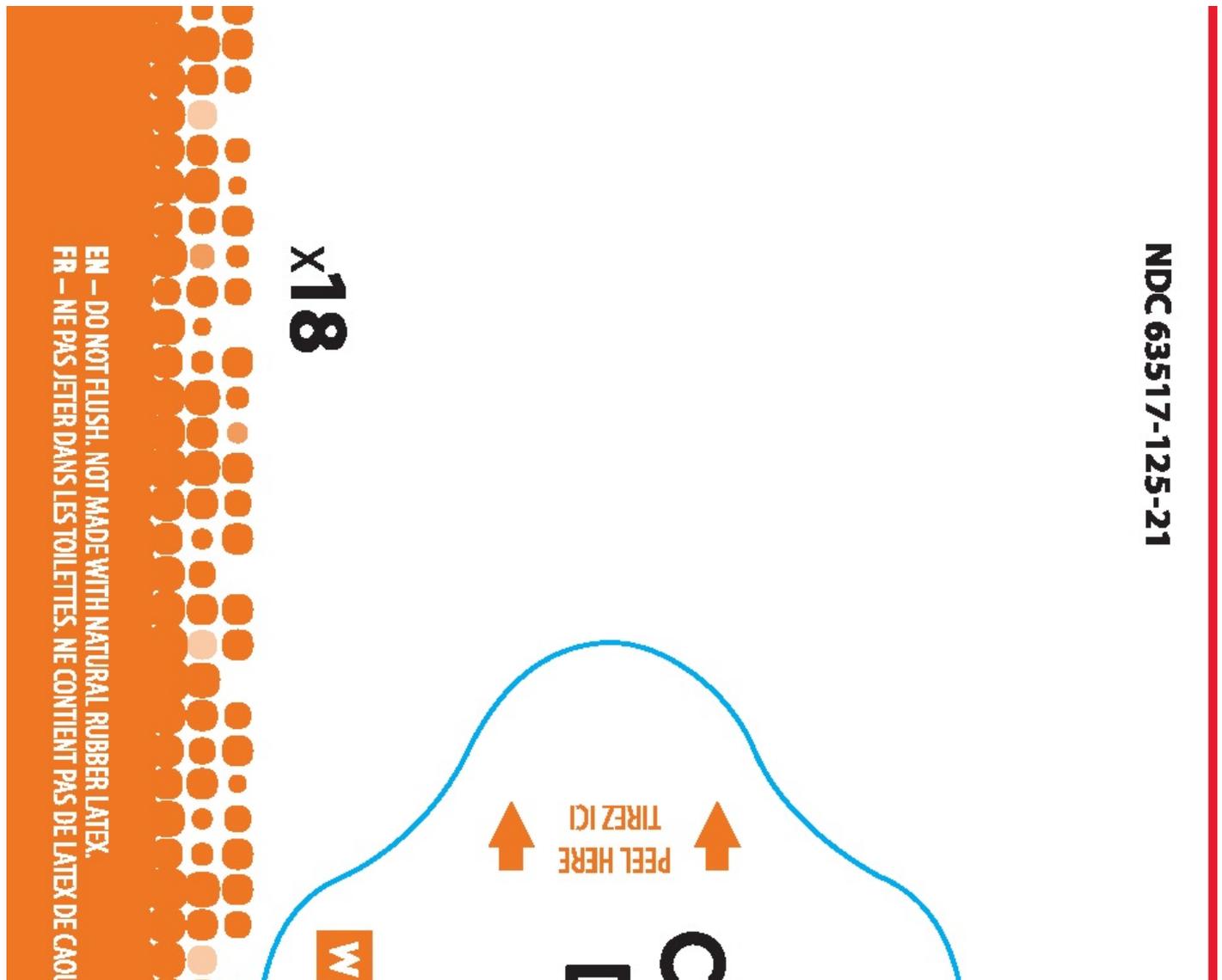
Other Information

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 Barbadosensis Leaf Extract, Caprylyl Glycol, Cetearyl Alcohol, Xanthan Gum

Package Labeling:



REF 2AWUD-18



PERSONAL CLEANSING CLOTHS DÉBARBOUILLETTE POUR L'HYGIÈNE CORPORELLE

WITH DIMETHICONE / AVEC DIMÉTIKONE

PRODUIT CHOUX NATUREL.



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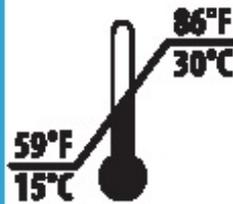
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EN – DO NOT FLUSH. NOT MADE WITH NATURAL RUBBER LATEX.
FR – NE PAS JETER DANS LES TOILETTES. NE CONTIENT PAS DE LATEX DE CAOUTCHOUC NATUREL.



cardinalhealth.com/symbolsglossary

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WAUKEGAN, IL 60085 USA

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Caractéristiques du produit

Fonction de l'ingrédient actif

Diméthicone 3,2 %.....Barrière cutanée

Usage ■ Soulage et prévient les gerçures et les fissures de la peau

- Aide à prévenir la dermatite périnéale
- Prévient les Irritation mineures de la peau associées à la dermatite périnéale

Mise en garde

Pour usage externe seulement

Lors de l'usage de ce produit

- Éviter tout contact avec les yeux

Cesser l'utilisation et contacter un médecin

- Si la condition s'aggrave
- Les symptômes durent plus de 7 jours ou s'estompent et réapparaissent après quelques jours.

Garder hors de la portée des enfants.

Si ingéré, consulter immédiatement un médecin ou le Centre anti-poison.

- En cas d'irritation ou de rougeurs, cesser l'utilisation
- Les gants diminuent la sensibilité à la chaleur
- Bien vérifier la température avant d'utiliser sur les nourrissons, les personnes inconscientes ou sur les peaux sensibles

Ne pas utiliser ■ Sur une plaie profonde ou punctiforme ■ La morsure d'un animal
■ Une brûlure sévère

Mode d'emploi

- Ouvrir la pochette et retirer les lingettes
- Bien nettoyer les endroits souillés, utiliser une lingette à la fois ■ Répéter au besoin
- Jeter les lingettes souillées dans une poubelle
- Ne pas jeter dans les toilettes

Pour réchauffer : Les lingettes peuvent être utilisées à la température ambiante, mais les lingettes peuvent être réchauffées dans un chauffe-lingette, si désiré.

Mode de chauffage : ■ Réchauffer une seule fois à une température inférieure à 52 °C (125 °F) et
■ Pendant 200 heures maximum.

Jeter les lingettes : ■ Exposées à une température supérieure à 52 °C (125 °F) ou
■ Laissées plus de 200 heures dans le chauffe-lingette, ou
■ Si déjà chauffées, laisser refroidir, avant de les chauffer de nouveau.

Autre information

Lorsque les lingettes ne sont pas dans le chauffe-lingette, entreposez-les à une température de 15-30 °C (59-86 °F).

Ingrédients inactifs

eau, glycérine, PPG-15 stearyl ether, stéarate de glyceryl, stéarate du PEG-100, phénoxyéthanol, Gel d'aloë vera, caprytyl glycol, alcool cétéarylique, gomme de xanthan

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 not final	part356	05/15/2019	

Labeler - Cardinal Health 200, Inc (961027315)

Revised: 1/2020

Cardinal Health 200, Inc