

COMFORT SHIELD BARRIER- dimethicone cloth
Sage Products LLC

Comfort Shield Barrier Cream Cloths

Active Ingredient

Dimethicone 3%

Purpose

Skin protectant

Uses

- helps seal out wetness
- helps treat and prevent perineal dermatitis
- protects from minor skin irritation associated with perineal dermatitis

Warnings

For external perineal use only.
Avoid contact with the eyes.

Stop use and consult a doctor if condition worsens or does not improve within 7 days

Keep out of reach of children.

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

Directions

- remove wet and soiled garment
- cleanse soiled area using a fresh barrier cream cloth
- discard cloth after use - DO NOT FLUSH CLOTHS
- use as often as necessary, especially if prolonged exposure to wetness is anticipated
- for individual use only
- reseal label between uses
- discard package immediately if cloths are dry

If warming is desired:

- peel open label without completely removing it
- heat entire package in microwave no longer than [see package for time].
- since microwave wattage varies, adjust heating time accordingly
- Comfort Shield® may also be used at room temperature or warmed in a Comfort Personal Cleansing Warmer.
- Caution: If there is any indication barrier cloths are excessively hot, do not use
- Remember, gloves diminish your sensitivity to heat

- Closely monitor heat level with infants, unresponsive or skin sensitive individuals

Inactive Ingredients

Water, glyceryl stearate, PEG-100 stearate, isopropyl palmitate, cetyl alcohol, glycerin, stearyl alcohol, phenoxyethanol, methylpropanediol, chlorhexidine gluconate, hydroxyethyl cellulose, ethylhexylglycerin, polyquaternium-37, propylene glycol dicaprylate/dicaprate, glucono-delta-lactone, PPG-1 trideceth-6

Barrier cloths: cellulose fiber/polyester (PET) fiber

Questions or Comments?

800-323-2220

Comfort Shield Barrier

stryker

Purchase for use at home:
homecare.stryker.com
 800 430 6455

**Basin
Elimination**



Package is for single patient use only
 No. made with natural rubber latex

Stryker Products LLC
 3905 Thane Oaks Blvd
 Cary, Illinois 60013
 800 323 2220
stryker.com
 Manufactured in U.S.A.
 U.S. Patent: stryker.com/patents

Reorder #7503



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15549

Tear here

Sage
Comfort
Shield
Barrier Cream Cloths

Treats and prevents incontinence-associated dermatitis
 • CIBS compliant • HSA eligible • Preclinical trial

3 **Keyways** data
 Cleans • Treats • Protects



stryker

NDC 5348-915-50 HCFS 144310

Drug Facts

Active ingredient	Purpose
Dimethicone 0%	Skin protection

Uses

- Treats and/or soothes
- Helps treat and prevent painful dermatitis
- Protects from minor skin irritation associated with perineal dermatitis

Warnings
 For external use only

When using the product

- Avoid getting into eyes

Stop use and consult a doctor if

- Contact with eyes
- Symptoms last more than 7 days or start up and occur each with a few days

Keep out of reach of children.
 If swallowed get medical help or contact a Poison Control Center right away.
 Do not use on ■ deep or puncture wounds ■ abrasions ■ burns

Directions

- Remove wet and soiled garment
- Cleanse soiled area using a fresh, gentle cleanser
- Do not use on ■ diaper rash ■ eczema ■ as needed, especially if prolonged exposure to wetness is anticipated
- Discard package immediately if soiled and dry

Inactive ingredients
 water, acacia, chondroitin sulfate, hydroxyethylcellulose, glycerin, polyquaternium-37, phenoxyethanol, methylpropanediol, isopropyl palmitate, cetyl alcohol, glycono-delta-lactone, PEG-100 stearate, ethylhexylglycerin, propylene glycol dicaprylate/dicaprate, glucono-delta-lactone, PPG-1 trideceth-6, water

Questions or Comments?
 Call 800-323-2220 (Monday - Friday, 8 am-6 pm CST)

If warning is cleared:

- Do not open bag
- Heat orifices package in microwave to separate 18 cloths
- Place in separate storage bags, add instructions accordingly
- Comfort Shield® may also be used at room temperature or stored in a zip-top bag
- Caution: If there is any indication barrier cloths are excessively hot, do not use
- Remember, please, diminish your sensitivity to heat
- Unresponsive to heat, especially with infants or unresponsive or skin sensitive individuals

Sage

NDC 53462-915-80 HCPCS Code #A6250

stryker

Comfort Shield®

Barrier Cream Cloths

Treats and prevents incontinence-associated dermatitis
• CHG compatible • pH balanced • Paraben free



8 Heavyweight cloths
8.5 in x 9 in

✓ Cleans ✓ Treats ✓ Protects

PeriCheck™ Guide

Check skin condition for incontinence-associated dermatitis and report to nurse:

Red Intact Broken
 Other _____

ID _____

Time _____

Checked by _____

Date _____

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U.S. Patients: stryker.com/patients

stryker

Purchase for use at home:
homecare.stryker.com
800 490 6493



Package is for single patient use only

Not made with natural rubber latex

Sage Products LLC
3939 Three Oaks Road
Cary, Illinois 60613
800 323 2220
stryker.com

Manufactured in U.S.A.
U.S. Patents:
stryker.com/patents

Reorder #7905



Drug Facts

Active ingredient Purpose
Dimethicone 20% (Skin protectant)

Uses

- Helps seal out wetness
- Keeps rashes and prevent perianal dermatitis
- Protects from minor skin irritations associated with perianal dermatitis

Warnings

For external perianal use only

When using this product

- Do not get into eyes
- Stop use and consult your doctor if:
 - condition worsens
 - symptoms last longer than 14 days or heal up and occur again within a few days

Keep out of reach of children. If swallowed, get medical help or contact Poison Control. Letter will help.

Do not use on: deep or ductal wounds, animal bites, herpes blisters

Directions

- Remove wet and soiled garments
- Shampoo rectal area using a fresh barrier cream cloth
- Apply as needed, especially if symptoms worsen or recur as anticipated
- Read label before use
- Do not use if package immediately if cloths are dry

Inactive Ingredients

Carb Merboc, chlorhexidine gluconate, ethoxydiglycine, glucono-celba-actone, glycerol stearate, glycerin, polybutyl acrylate, polypropylene, PEG 100 stearate, polyethylene glycol, polybutyl acrylate, propylene glycol, stearic acid, water, barrier cloth, cellulose, hydroxyethylcellulose (HEC), fiber

Questions or Comments?

Call 800 490 6493 Monday to Friday 8 am to 5 pm CST

If warning is desired:

- Open top label without completely removing it
- Heat entire package in microwave for longer than 45 seconds
- Use microwave wattage sensor, adjust heating time accordingly
- Comfort Shield® may also be used on non-dermatitis or wounds in a Sage Warmer
- Caution: If there is any indication of heat, stop use immediately. Do not use
- Remember: gloves decrease your sensitivity to heat
- Clearly marked heat level, especially with infants or unresponsive or otherwise vulnerable individuals

Sage

NDC 52462-915-24

stryker

Comfort Shield®

Barrier Cream Cloths

Treats and prevents incontinence-associated dermatitis
• CHG compatible • pH balanced • Parabens free



24 Heavyweight cloths
8.5 in x 6.5 in ✓ Cleans ✓ Treats ✓ Protects

Pericheck™ Guide

Check skin condition for incontinence-associated dermatitis and report to nurse:

Red Irritated Broken
 Other _____

ID _____

Time _____

Checked by _____

Date _____

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U.S. Patents: stryker.com/patents

Tear here ▼

stryker

Purchase for use at home:
homecare.stryker.com
800 490 6463

Basin Elimination



Package is for single patient use only

Not made with natural rubber latex

Sage Products LLC
3909 Three Oaks Road
Cary, Illinois 60013
800 323 2220
stryker.com

Manufactured in U.S.A.
U.S. Patents:
stryker.com/patents

Reorder #7502



235948

3 Heavyweight cloths 13.5 x 8.5 in

stryker

Sage
Comfort
Shield®

Barrier Cream Cloths

Treats and prevents incontinence-associated dermatitis
• CHG compatible • pH balanced • Parabens free

with dimethicone

Pericheck™

NDC 52462-915-24

MCPC 04/2020

stryker

Drug Facts

Active ingredient Purpose
Dimethicone Skin protectant

Uses
■ helps seal out wetness ■ helps treat and prevent perineal dermatitis ■ protects from minor skin irritation associated with perineal dermatitis

Warnings
For external perineal use only

When using this product
■ do not get into eyes

Stop use and consult a doctor 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 a Poison Control Center right away.

Do not use on ■ deep or puncture wounds ■ animal bites ■ serious burns

Directions
■ remove wet and soiled garment ■ cleanse soiled area using a fresh barrier cream cloth ■ discard cloth after use - do not wash cloths ■ apply as needed, especially if prolonged exposure to wetness is anticipated ■ discard package immediately if cloths are dry

Inactive Ingredients
Cetyl alcohol, chlorhexidine gluconate, cetylstearylglucoside, glucose-delta-lactone, glyceryl stearate, glycerin, hydroxyethyl cellulose, hydroxypropyl cellulose, methylparaben, PEG-100 stearate, phenoxymethyl, polyquaternium-15, propylene glycol diacrylate/acrylate, stearyl alcohol, triacetin-6, Water
barrier cloth: cellulose fiber/polyester (PET) fiber

Questions or Comments?
Call 100 323 2220 (Monday to Friday 8 am-8 pm CST)

If warming is desired:
■ tear open package ■ heat entire package in microwave for longer than 12 seconds ■ since microwave wattage varies, adjust heating time accordingly ■ Comfort Shield® may also be used at room temperature or warmed in a bag
Warning: ■ Caution: If there is any indication that the cloths are excessively hot, do not use ■ Remember: gloves diminish your sensitivity to heat
■ Closely monitor heat level, especially with infants or unresponsive or skin-sensitive individuals

GLYCERIN (UNII: PDC6A3C0OX)
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
METHYLPROPANEDIOL (UNII: N8F53B3R4R)
CHLORHEXIDINE GLUCONATE (UNII: MOR84MUD8E)
HYDROXYETHYL CELLULOSE (4000 MPAS AT 1%) (UNII: ZYD53NBL45)
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)
POLYQUATERNIUM-37 (25000 MPAS) (UNII: 31L31U8285)
PROPYLENE GLYCOL DICAPRYLATE/DICAPRATE (UNII: O4446S9CRA)
GLUCONOLACTONE (UNII: WQ29KQ9POT)
PPG-1 TRIDECETH-6 (UNII: 1K7417JX6Q)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53462-915-50	3 in 1 PACKAGE	01/01/1990	
1		26 g in 1 APPLICATOR; Type 0: Not a Combination Product		
2	NDC:53462-915-51	3 in 1 PACKAGE	01/01/1990	
2		19 g in 1 APPLICATOR; Type 0: Not a Combination Product		
3	NDC:53462-915-62	24 in 1 PACKAGE	01/01/1990	09/21/2016
3		24 g in 1 APPLICATOR; Type 0: Not a Combination Product		
4	NDC:53462-915-80	8 in 1 PACKAGE	01/01/1990	
4		27 g in 1 APPLICATOR; Type 0: Not a Combination Product		
5	NDC:53462-915-81	8 in 1 PACKAGE	01/01/1990	10/07/2025
5		19 g in 1 APPLICATOR; Type 0: Not a Combination Product		
6	NDC:53462-915-24	24 in 1 PACKAGE	12/11/2023	
6		24 g in 1 APPLICATOR; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M016	01/01/1990	

Labeler - Sage Products LLC (054326178)