STUDIO35 EXTRA STRENGTH MEDICATED BODY- dimethicone and menthol lotion Walgreen Company

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.

Walgreens Gold Max Extra Strength Medicated Body

Active ingredient

Dimethicone, 5.0% Menthol, 0.5%

Purpose

Skin Protectant

Anti-Itch

Uses

- temporarily relieves itching associated with
 - sunburn
 - minor skin irritation
 - minor burns
 - rashes due to poison ivy, oak or sumac
 - insect bites
- temporarily protects and helps relieve chapped or cracked skin

Warnings

For external use only.

Do Not Use On

- deep or puncture wounds
- animal bites
- serious burns

When using this product

avoid contact with eyes

Stop use and ask a doctor if

condition worsens

- symptoms persist for more than 7 days or clear up and occur again within a few days
- redness, irritation, swelling or pain persists or increases

Keep Out of Reach of Children.

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

Directions

For adults and children 2 years and older: Apply liberally 3 to 4 times daily to affected area. Children under 2 years: consult with a doctor.

Inactive ingredients

water, cetyl alcohol, glycerin, stearamidopropyl PG-dimonium chloride phosphate, stearyl alcohol, cetearyl alcohol, cetearyl alcohol, cetearyl distearyldimonium chloride, petrolatum, steareth-21, propylene glycol, diazolidinyl urea, methylparaben, propylparaben, steareth-2, aloe barbadensis leaf juice, tocopheryl acetate (vitamin E), butylene glycol, pentylene glycol, hydroxyphenyl propamidobenzoic acid, xylitylglucoside, anhydroxylitol, xylitol, disodium EDTA, fragrance, triethanolamine.

Questions or comments?

1-800-925-4733

Package/Label Principal Display Panel

COMPARE TO GOLD BOND® EXTRA STRENGTH MEDICATED BODY LOTION*

studio35TM

EXTRA STRENGTH
MEDICATED
BODY LOTION

WITH ALOE AND VITAMIN E

ENRICHED WITH SYMCALMIN® TO SOOTHE

MOISTURIZES & COOLS SEVERELY DRY, IRRITATED SKIN

ANTI-ITCH/SKIN PROTECTANT

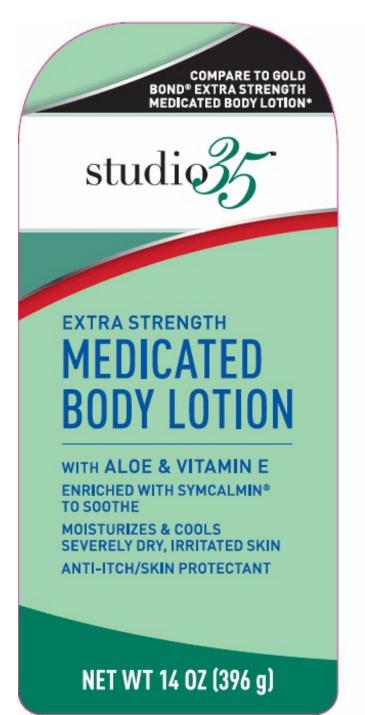
NET WT 14 OZ (396 g)

EXTRA STRENGTH

MEDICATED BODY LOTION

*This product is not manufactured or distributed by Chattem, Inc., owner of the registered trademark Gold Bond[®].

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EXTRA STRENGTH MEDICATED BODY LOTION

Drug Facts

Active ingredients

Purpose

Dimethicone, 5,0%_____ Menthal, 0.5%_____ .Skin Protectant

- temporarily relieves itching associated with sunburn minor skin imitation . minor burns . rashes due to poison ivy, oak or sumac
- insect bites temporarily protects and helps relieve chapped or cracked skin

Warnings

For external use only.

Do not use on • deep or puncture wounds • animal bites • serious burns When using this product • avoid contact with eyes

Stop use and ask a doctor if . condition worsens . symptoms persist for more than 7 days or clear up and occur again within a few days redness, irritation, swelling or pain persists or increases

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

For adults and children 2 years and older: Apply liberally 3 to 4 times daily to affected area. Children under 2 years: consult with a doctor,

Inactive ingredients water, cetyl alcohol, glycerin, stearamiclopropyl PG-dimonium chloride phosphate, stearyl alcohol, cetearyl alcohol, ceteareth-20, distearyldimonium chloride, petrolatum, steareth-21, propylene glycol, diazolidinyl urea, methylparaben, propylparaben, steareth-2, aloe barbadensis leaf juice, tocopheryl acetate (vitamin E), butylene glycol, pentylene glycol, hydroxyphenyl propamidobenzoic acid, xylitylglucoside, anhydroxylitol, xylitol, disodium EDTA, fragrance, triethanolamine.

Questions or comments? 1-800-925-4733

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Carton Label

STUDIO35 EXTRA STRENGTH MEDICATED BODY

dimethicone and menthol lotion

Product Information

HUMAN OTC DRUG Product Type Item Code (Source)

TOPICAL Route of Administration

NDC:0363-8410

| Active Ingredient/Active Moiety | | | |
|---|-------------------|-----------------|--|
| Ingredient Name | Basis of Strength | Strength | |
| DIMETHICO NE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O) | DIMETHICONE | 5 g in 100 mL | |
| MENTHOL (UNII: L7T10 EIP3A) (MENTHOL - UNII:L7T10 EIP3A) | MENTHOL | 0.5 g in 100 mL | |

| Inactive Ingredients | |
|--|----------|
| Ingredient Name | Strength |
| WATER (UNII: 059QF0KO0R) | |
| CETYL ALCOHOL (UNII: 936JST6JCN) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| STEARAMIDO PRO PYL PRO PYLENE GLYCO L-DIMO NIUM CHLO RIDE PHO SPHATE (UNII: W6000 VEI5Y) | |
| STEARYL ALCOHOL (UNII: 2KR89I4H1Y) | |
| CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S) | |
| POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY) | |
| DISTEARYLDIMO NIUM CHLO RIDE (UNII: OM9573ZX3X) | |
| PETROLATUM (UNII: 4T6H12BN9U) | |
| STEARETH-21 (UNII: 53J3F32P58) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4) | |
| METHYLPARABEN (UNII: A218 C7H19 T) | |
| PROPYLPARABEN (UNII: Z8IX2SC1OH) | |
| STEARETH-2 (UNII: V56 DFE46J5) | |
| ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X) | |
| .ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0) | |
| BUTYLENE GLYCOL (UNII: 3XUS85K0RA) | |
| PENTYLENE GLYCOL (UNII: 50 C130 7 PZG) | |
| HYDRO XYPHENYL PRO PAMIDO BENZO IC ACID (UNII: 25KRT26H77) | |
| XYLITYLGLUCO SIDE (UNII: O0 IEZ166FB) | |
| ANHYDRO XYLITOL (UNII: 8 XWR7NN42F) | |
| XYLITOL (UNII: VCQ006KQ1E) | |
| EDETATE DISO DIUM (UNII: 7FLD9 1C8 6 K) | |
| TROLAMINE (UNII: 9O3K93S3TK) | |

| l | Packaging | | | | |
|---|-----------|-----------------|---|-----------------------------|--------------------|
| l | # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| l | 1 N | DC:0363-8410-11 | 396 mL in 1 BOTTLE; Type 0: Not a Combination Product | | |

| Marketing Information | | | |
|-----------------------|--|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC monograph final | part347 | 09/01/2014 | |
| | | | |

Labeler - Walgreen Company (008965063)

Revised: 9/2014 Walgreen Company