

REMEDY CALAZIME SKIN PROTECTANT- calamine, menthol, white petrolatum, zinc oxide paste
Medline Industries, LP

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.

165 REMEDY Calazime Skin Protectant

Active ingredient

Calamine 3.5%

Menthol 0.2%

White Petrolatum 69%

Zinc Oxide 16.5%

Purpose

Protectant

Protectant

Prot

Protectant

Uses

- Provides temporary relief from skin irritations, itching and discomfort in the perianal area
- For the temporary relief of pain
- May provide a cooling sensation

Warnings

For External Use Only

Do not use

- in the eyes
- on deep or puncture wounds
- on animal bites
- on serious burns.

When using this product

- do not exceed the recommended daily dosage unless directed by a doctor
- do not put this product into the rectum by using fingers or any mechanical device or

applicator

- Certain persons can develop allergic reactions to ingredients in this product. If the symptom being treated does not subside or if redness, irritation, swelling, pain, or other symptoms develop or increase, stop use and consult a doctor

Stop use and ask a doctor if

- condition worsens or does not improved within 7 days
- you experience bleeding

Keep out of reach of children.

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

Directions

Adults

- Cleanse the affected area with Remedy No-rinse cleanser
- Gently dry
- Apply externally to the affected area up to 6 times daily
- For peri-G tubes, cleanse as directed, apply thin layer and secure with drain sponge or product as directed.

Children under 12 years of age

- Consult a doctor

Other information

- Protect from freezing, Avoid excessive heat.

Inactive ingredients

Aloe Barbadensis Leaf Juice, Ascorbic Acid, Ascorbyl Palmitate, Carthamus Tinctorius (Safflower) Seed Oil, Cholecalciferol, Citric Acid, Citrus Aurantium Dulcis Peel Oil, Citrus Grandis Peel Oil, Glycine, Helianthus Annuus (Sunflower) Seed Oil, Hydroxytyrosol, L-proline, L-aurine, Methylparaben, Modified Corn Starch, Methylsulfonmethane, N-acetyl-L-cysteine, Niacinamide, Olea Europaea (Olive) Fruit Oil, PEG-8, Pyridoxine Hydrochloride, Retinyl Palmitate, Tapioca Starch Polymethylsilsesquioxane, Tocopherol, Vanillin, Zea Mays (Corn) Oil.

Medline Remedy is a registered trademark of Medline Industries, Inc.

Olivamine is a registered trademark of McCord Research, Inc. Manufactured for Medline Industries, Inc., Mundelein, IL 60060 **www.medline.com**

1-800-MEDLINE

Package Label



Remedy is a well-balanced meal for skin cells. Nourished with Olivamine®: A blend of potent antioxidants, amino acids, vitamins and MSM.

Drug Facts

Active ingredients	Purpose
Calamine 3.5%	Protectant
Menthol 0.2%	Analgesic
White Petrolatum 69%	Protectant
Zinc Oxide 16.5%	Protectant

Uses ■ Provides temporary relief from skin irritations, itching and discomfort in the perianal area ■ For the temporary relief of pain ■ May provide a cooling sensation

Warnings

For External Use Only

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

When using this product ■ do not exceed the recommended daily dosage unless directed by a doctor ■ do not put this product into the rectum by using fingers or any mechanical device or applicator ■ Certain persons can develop allergic reactions to ingredients in this product. If the symptom being treated does not subside or if redness, irritation, swelling, pain, or other symptoms develop or increase, stop use and consult a doctor.

Stop use and ask a doctor if ■ condition worsens or does not improve within 7 days ■ you experience bleeding

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

Directions

Adults ■ Cleanse the affected area with Remedy No-rinse cleanser ■ Gently dry ■ Apply externally to the affected area up to 6 times daily ■ For perit-G tubes, cleanse as directed, apply a thin layer and secure with drain sponge or product as directed.

Children under 12 years of age ■ Consult a doctor

Other information ■ Avoid excessive heat. Protect from freezing.

Inactive ingredients Aloe barbadensis leaf juice, ascorbic acid, ascorbyl palmitate, carthamus tinctorius (safflower) seed oil, cholecalciferol, citric acid, citrus aurantium dulcis peel oil, citrus grandis peel oil, glycine, helianthus annuus (sunflower) seed oil, hydroxytyrosol, L-proline, L-leucine, methylparaben, modified corn starch, methylsulfonylmethane, n-acetyl-L-cysteine, niacinamide, olea europaea (olive) fruit oil, PEG-8, pyroxidine hydrochloride, retinyl palmitate, tapioca starch polymethylsilsesquioxane, tocopherol, vanillin, zea mays (corn) oil.

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Olivamine is a registered trademark of McCord Research, Inc. Manufactured for Medline Industries, Inc., Mundelein, IL 60060 www.medline.com
1-800-MEDLINE RL15EIK

REF MSC094544



OLIVAMINE®



RECYCLE

MEDLINE

N 53329-165-44

REMEDY®

WITH OLIVAMINE®

CALAZIME®

SKIN
PROTECTANT PASTE

Helps protect irritation and relieve pain associated with diaper rash.

Nourishes skin.

NON-ALLERGENIC
NON-SENSITIZING



REMEDY CALAZIME SKIN PROTECTANT

calamine, menthol, white petrolatum, zinc oxide paste

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53329-165
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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FERRIC OXIDE RED (UNII: 1K09F3G675) (FERRIC OXIDE RED - UNII:1K09F3G675)	FERRIC OXIDE RED	0.5 g in 100 g
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.2 g in 100 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	19.5 g in 100 g
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	69 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
SAFFLOWER OIL (UNII: 65UEH262IS)	
CHOLECALCIFEROL (UNII: 1C6V77QF41)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
ORANGE OIL (UNII: AKN3KSD11B)	
CITRUS MAXIMA FRUIT RIND OIL (UNII: 8U3877WD44)	
GLYCINE (UNII: TE7660XO1C)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
HYDROXYTYROSOL (UNII: QEU0NE4O90)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
MODIFIED CORN STARCH (1-OCTENYL SUCCINIC ANHYDRIDE) (UNII: 461P5CJN6T)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
ACETYLCYSTEINE (UNII: WYQ7N0BPYC)	
NIACINAMIDE (UNII: 25X51I8RD4)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
VANILLIN (UNII: CHI530446X)	
CORN OIL (UNII: 8470G57WFM)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53329-165-44	113 g in 1 TUBE; Type 0: Not a Combination Product	03/14/2018	03/21/2024
2	NDC:53329-165-96	144 in 1 BOX	03/14/2018	12/13/2023
2		4 g in 1 PACKET; Type 0: Not a Combination Product		
3	NDC:53329-165-02	3 in 1 BAG	07/01/2021	
3	NDC:53329-165-44	113 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
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Category	Citation	Date	Date
OTC monograph final	part347	03/23/2012	

Labeler - Medline Industries, LP (025460908)

Registrant - Medline Industries, LP (025460908)

Revised: 8/2023

Medline Industries, LP