

MEDLINE- menthol, white petrolatum, zinc oxide paste
Medline Industries, LP

156 Remedy Specialized Zinc Oxide Paste

Active ingredients

Menthol 0.44% w/w

White petrolatum 53% w/w

Zinc oxide 20.6% w/w

Purpose

Analgesic

Protectant

Protectant

Uses

- for the temporary relief of anorectal itching and discomfort in the perianal area associated with anorectal inflammation
- temporarily forms a protective coating over inflamed tissues to help prevent drying of tissues
- temporarily protects irritated areas
- temporarily relieves burning
- provides temporary relief from skin irritations
- temporarily protects the inflamed irritated anorectal surface to help make bowel movements less painful
- temporarily protects inflamed perianal skin
- temporarily relieves the symptoms of perianal skin irritation
- may provide a cooling sensation

Warnings

For external use only

Allergy Alert: 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, discontinue use and consult a doctor

Do not use on

- deep or puncture wounds
- animal bites
- serious burns

When using this product

- do not get into eyes
- 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 applicator

Stop use and ask a doctor if

- condition worsens
- symptoms last more than 7 days or clear up and occur again within a few days
- in case of bleeding

Keep out of reach of children.

In case of accidental ingestion, get medical help or contact a Poison Control Center right away.

Directions

- **adults:** when practical, cleanse the affected area with mild soap and warm water and rinse thoroughly. Gently dry by patting or blotting with toilet tissue or a soft cloth before application of this product. Apply to the affected area up to 6 times daily
- **Children under 12 years of age:** consult a doctor

Other information

- protect from freezing
- avoid excessive heat
- not made with Natural rubber Latex

Inactive ingredients

7-dehydrocholesterol, algae extract (aphanizomenon flos-aquae), beeswax, bisabolol, brassica campestris (rapeseed) sterols, calamine, camellia sinensis (green tea) leaf extract, caprylic/capric triglycerides, carthamus tinctorius (safflower) seed oil, cetylhydroxyproline palmitamide, cholecalciferol, cocos nucifera (coconut) oil, dimethicone, eugenia caryophyllus (clove) flower extract, glycerin, hexyldecanol, hydrolyzed soy protein, manuka honey, olea europaea (olive) oil, phospholipids, phytonadione, simmondsia chinensis (jojoba) seed oil, stearic acid, tocopheryl acetate, water, yeast ferment extract, zea mays (corn) oil, zea mays (corn) starch.

Manufacturing information

Manufactured for:

Medline Industries, LP

Three Lakes Drive, Northfield, IL 60093 USA

Made in USA of domestic and imported materials

1-800-MEDLINE (633-5463)

V1 RJ22PUA

REF: MSC092554PACK

Package Label

<p>Drug Facts</p> <table><thead><tr><th>Active ingredients</th><th>Purpose</th></tr></thead><tbody><tr><td>Menthol 0.44% w/w</td><td>Analgesic</td></tr><tr><td>White petrolatum 53% w/w</td><td>Protectant</td></tr><tr><td>Zinc oxide 20.6% w/w</td><td>Protectant</td></tr></tbody></table> <p>Uses</p> <p>■ for the temporary relief of anorectal itching and discomfort in the perianal area associated with anorectal inflammation ■ temporarily forms a protective coating over inflamed tissues to help prevent drying of tissues ■ temporarily protects irritated areas ■ temporarily relieves burning ■ provides temporary relief from skin irritations ■ temporarily protects the inflamed irritated anorectal surface to help make bowel movements less painful ■ temporarily protects inflamed perianal skin ■ temporarily relieves the symptoms of perianal skin irritation ■ may provide a cooling sensation</p> <p>Warnings</p> <p>For external use only</p> <p>Allergy Alert: 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, discontinue use and consult a doctor</p> <p>Do not use on ■ deep or puncture wounds ■ animal bites ■ serious burns</p> <p>When using this product ■ do not get into eyes ■ 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</p> <p>Stop use and ask a doctor if ■ condition worsens ■ symptoms last more than 7 days or clear up and occur again within a few days ■ in case of bleeding</p> <p>Keep out of reach of children. In case of accidental ingestion, get medical help or contact a Poison Control Center right away.</p> <p>Directions</p> <p>■ adults: when practical, cleanse the affected area with mild soap and warm water and rinse thoroughly. Gently dry by patting or blotting with toilet tissue or a soft cloth before application of this product. Apply to the affected area up to 6 times daily ■ children under 12 years of age: consult a doctor</p> <p>Other information ■ protect from freezing ■ avoid excessive heat ■ not made with Natural Rubber Latex</p> <p>Inactive ingredients 7-dehydrocholesterol, algae extract (aphanizomenon flos-aquae), beeswax, bisabolol, brassica campestris (rapeseed) sterols, calamine, camellia sinensis (green tea) leaf extract, caprylic/capric triglycerides, carthamus tinctorius (safflower) seed oil, cetyl hydroxyproline palmitamide, cholecalciferol, cocos nucifera (coconut) oil, dimethicone, eugenia caryophyllus (clove) flower extract, glycerin, hexyldecyl alcohol, hydrolyzed soy protein, manuka honey, olea europaea (olive) oil, phospholipids, phytonadione, simmondsia chinensis (jojoba) seed oil, stearic acid, tocopheryl acetate, water, yeast ferment extract, zea mays (corn) oil, zea mays (corn) starch.</p>	Active ingredients	Purpose	Menthol 0.44% w/w	Analgesic	White petrolatum 53% w/w	Protectant	Zinc oxide 20.6% w/w	Protectant	<p>NDC 53329-156-96</p> <p>MEDLINE REMEDY</p> <p>SPECIALIZED</p> <p>PROTECT</p> <p>Zinc Oxide Paste Skin Protectant</p> <p>with Menthol</p> <p>For skin exposed to prolonged moisture</p> <p>ZnO</p> <p>CHG Compatible Paraben Free Hypoallergenic</p> <p>Unscented</p> <p>144 - 0.14 OZ (4 g) Packets</p>
Active ingredients	Purpose								
Menthol 0.44% w/w	Analgesic								
White petrolatum 53% w/w	Protectant								
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REF MSC092554PACK

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See box for complete Drug Facts

Active Ingredients
Menthol 0.44% w/w
White petrolatum 53% w/w
Zinc oxide 20.8% w/w

Directions: Apply as needed

Inactive Ingredients
7-dehydrocholesterol, algae extract (phanzomenon flos-aquae), beeswax, bisabolol, brassica campestris (rapeseed) sterols, calamine, camellia sinensis (green tea) leaf extract, caprylic/capric triglycerides, carthamus tinctorius (safflower) seed oil, cetylhydroxyproline palmitamide, cholecalciferol, cocos nucifera (coconut) oil, dimethicone, eugenia caryophyllus (clove) flower extract, glycerin, hexyldecanol, hydrolyzed soy protein, manuka honey, olea europaea (olive) oil, phospholipids, phytonadione, simmondsia chinensis (jojoba) seed oil, stearic acid, tocopheryl acetate, water, yeast ferment extract, zea mays (corn) oil, zea mays (corn) starch.

Warnings: For External Use Only
Keep out of Reach of Children.
Do not use if packet is damaged.

 REF: MSC092554PACK
Manufactured for Medline Industries, LP, Three Lakes Drive, Northfield, IL 60093 USA.
Made in USA of domestic and imported materials. V1 RJ22PUA

NDC 53329-156-83

MEDLINE
REMEDY

SPECIALIZED
PROTECT
Zinc Oxide Paste
Skin Protectant
with Menthol

For skin exposed to prolonged moisture



CHG Compatible
Paraben Free
Hypoallergenic

Unscented

0.14 OZ (4 g)

MEDLINE

menthol, white petrolatum, zinc oxide paste

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53329-156
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	206 mg in 1 g
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	4.4 mg in 1 g
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	530 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
HYDROLYZED SOY PROTEIN (ENZYMATIC; 2000 MW) (UNII: 1394NXB9L6)	

PHYTONADIONE (UNII: A034SE7857)
YEAST, UNSPECIFIED (UNII: 3NY3SM6B8U)
CORN OIL (UNII: 8470G57WFM)
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
CHOLECALCIFEROL (UNII: 1C6V77QF41)
COCONUT OIL (UNII: Q9L0O73W7L)
GLYCERIN (UNII: PDC6A3C0OX)
HEXYLDECANOL (UNII: 151Z7P1317)
HONEY (UNII: Y9H1V576FH)
OLIVE OIL (UNII: 6UYK2W1W1E)
JOJOBA OIL (UNII: 724GKU717M)
STEARIC ACID (UNII: 4ELV7Z65AP)
WATER (UNII: 059QF0KO0R)
GREEN TEA LEAF (UNII: W2ZU1RY8B0)
CETYLHYDROXYPROLINE PALMITAMIDE (UNII: 74ONU0S62G)
APHANIZOMENON FLOSAQUAE (UNII: 49VG1X560X)
YELLOW WAX (UNII: 2ZA36H0S2V)
RAPESEED STEROL (UNII: B46B6DD20U)
FERRIC OXIDE RED (UNII: 1K09F3G675)
STARCH, CORN (UNII: O8232NY3SJ)
7-DEHYDROCHOLESTEROL (UNII: BK1IU07GKF)
LEVOMENOL (UNII: 24WE03BX2T)
SAFFLOWER OIL (UNII: 65UEH262IS)
DIMETHICONE (UNII: 92RU3N3Y1O)
CLOVE (UNII: K48IKT5321)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53329-156-83	4 g in 1 PACKET; Type 0: Not a Combination Product	04/01/2023	
2	NDC:53329-156-96	144 in 1 BOX	04/01/2023	
2	NDC:53329-156-83	4 g in 1 PACKET; Type 0: Not a Combination Product		
3	NDC:53329-156-14	57 g in 1 TUBE; Type 0: Not a Combination Product	01/01/2024	
4	NDC:53329-156-44	113 g in 1 TUBE; Type 0: Not a Combination Product	01/01/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M015	04/01/2023	

Labeler - Medline Industries, LP (025460908)

