

LANSINOH ANTI-ITCH- menthol 0.5% cream
Lansinoh Laboratories Inc

Lansinoh Anti Itch

| | |
|--------------------|-------------------|
| Active Ingredients | Purpose |
| Menthol 0.5% | Topical Analgesic |

Stop Use and ask a doctor

- **if condition worsens**
- **if symptoms persist for more than 7 days**
- **Or if symptoms clear up and occur again within a few days**

Do NOT use in or near mouth, or on breasts or nipples when breast feeding.

Pregnant women are advised to consult their physician before using any OTC drug product.

KEEP OUT OF REACH OF CHILDREN

if swallowed, get medical help or contact a Poison Control Center right away (1-800-222-1222)

For temporary relief of itching

Stop use and ask a doctor

- **If condition worsens**
- **If symptoms persists for more than 7 days**
- **Or if symptoms clear up and occur again within a few days**

Warnings

For external use only

Avoid contact with the eyes

Directions

- **For adults and children 2 years and older**
- **Apply externally to the affected area, no more than 3-4 times daily**

Inactive Ingredients:

Aloe Barbadosensis Leaf Juice, Avena Sativa (Oat) Meal Extract, Caprylyl Glycol, Carbomer, Cetearyl Oliviate, Cucumis Sativus Fruit Extract, Cyclopentasiloxane, Dimethicone, Dimethicone/Vinyl Dimethicone Crosspolymer, Glycerin, Hyaluronic Acid, Hydrolyzed Jojoba Esters, Hydroxyacetophenone, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Isopropyl Palmitate, Polysorbate 60, Prunus Armeniaca (Apricot Kernel Oil), Simmondsia Chinensis (Jojoba) Seed Oil, Sodium Benzoate, Potassium Sorbate, Sodium Chloride, Sodium Hydroxide, Sorbitan Isostearate, 1,2-Hexanediol, Sorbitan Oliviate, Squalane, Water (Eau, Aqua).

Uses

For temporary relief of itching

40*150mm



Lansinoh.

Itch Relief Serum

Topical Analgesic

Relieves itchy skin during pregnancy with soothing organic ingredients

Dermatologist tested

4.4 oz (125 ml) e

Drug Facts

| Active Ingredients | Purpose |
|--------------------|-------------------|
| Menthol 0.5%..... | Topical Analgesic |

Uses
For temporary relief of itching

Warnings
For external use only.
Avoid contact with the eyes.
Do NOT use in or near mouth, or on breasts or nipples when breastfeeding. Pregnant women are advised to consult their physician before using any OTC drug product.

KEEP OUT OF REACH OF CHILDREN.
If swallowed, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

Stop use and ask a doctor
■ If condition worsens
■ If symptoms persist for more than 7 days
■ Or if symptoms clear up and occur again within a few days

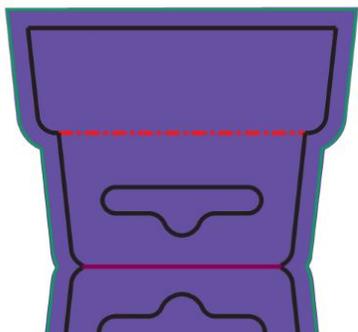
Directions
■ For adults and children 2 years and older.
■ Apply externally to the affected area, no more than 3 - 4 times daily

Inactive Ingredients:
Aloe Barbadensis Leaf Juice, Avena Sativa (Oat) Meal Extract, Caprylyl Glycol, Carbomer, Cetearyl Oliviate, Cucumis Sativus Fruit Extract, Cyclopentasiloxane, Dimethicone, Dimethicone/Vinyl Dimethicone Crosspolymer, Glycerin, Hyaluronic Acid, Hydrolyzed Jojoba Esters, Hydroxyacetophenone, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Isopropyl Palmitate, Polysorbate 60, Prunus Armeniaca (Apricot) Kernel Oil, Simmondsia Chinensis (Jojoba) Seed Oil, Sodium Benzoate, Potassium Sorbate, Sodium Chloride, Sodium Hydroxide, Sorbitan Isostearate, 1,2-Hexanediol, Sorbitan Oliviate, Squalane, Water (Eau, Aqua).

Distributed by: Lansinoh Laboratories, Inc.
Alexandria, VA 22314, USA
+1 800-292-4794 | Lansinoh.com

Lansinoh® is a registered trademark of Lansinoh Laboratories, Inc.
© 2024 Lansinoh Laboratories, Inc.
All rights reserved. Made in the USA.

A168700TB0224



NEW DIE



NO INK/ NO COAT

You've got this, mama

Moisturizes & relieves dry, itchy skin

Targeted relief for itchy skin

Fast absorbing, ultra-light formula

Made with cooling menthol & soothing organic ingredients

Perfect for dry skin & your growing belly



Safe for sensitive skin & hypoallergenic



We are with you

We were born from one mother's frustration that new moms often go without the support they need and deserve. We're on a mission to change that. We see you and are committed to making your journey a little easier.

Lansinoh.com

Alivia la picazón Analgésico tópico

Alivia la picazón en la piel durante el embarazo mediante ingredientes orgánicos calmantes.

Lansinoh®

Itch Relief Serum

Topical Analgesic

Relieves itchy skin during pregnancy with soothing organic ingredients

Dermatologist tested

4.4 oz (125 ml) e

Drug Facts

Active Ingredients Purpose

Menthol 0.5%.....Topical Analgesic

Uses

For temporary relief of itching

Warnings

For external use only.

Avoid contact with the eyes.

Do NOT use in or near mouth, or on breasts or nipples when breastfeeding. Pregnant women are advised to consult their physician before using any OTC drug product.

KEEP OUT OF REACH OF CHILDREN.

If swallowed, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

Stop use and ask a doctor

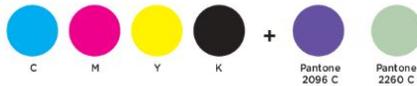
- If condition worsens
- If symptoms persist for more than 7 days
- Or if symptoms clear up and occur again within a few days

Directions

- For adults and children 2 years and older.
- Apply externally to the affected area, no more than 3 - 4 times daily

Inactive Ingredients:

Aloe Barbadensis Leaf Juice, Avena Sativa (Oat) Meal Extract, Caprylyl Glycol, Carbomer, Cetearyl Oliviate, Cucumis Sativus Fruit Extract, Cyclopentasiloxane, Dimethicone, Dimethicone/Vinyl Dimethicone Crosspolymer, Glycerin, Hyaluronic Acid, Hydrolyzed Jojoba Esters, Hydroxyacetophenone, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Isopropyl Palmitate, Polysorbate 60, Prunus Armeniaca (Apricot) Kernel Oil, Simmondsia Chinensis (Jojoba) Seed Oil, Sodium Benzoate, Potassium Sorbate, Sodium Chloride, Sodium Hydroxide, Sorbitan Isostearate, 1,2-Hexanediol, Sorbitan Oliviate, Squalane, Water (Eau, Aqua).



LANSINOH ANTI-ITCH

menthol 0.5% cream

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:53997-002 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|--------------------------|-----------------|
| MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A) | MENTHOL | 0.5 g in 100 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-----------------|
| CUCUMBER (UNII: YY7C30VXJT) | |
| POTASSIUM SORBATE (UNII: 1VPU26JZZ4) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |
| DIMETHICONE (UNII: 92RU3N3Y1O) | |
| CYCLOMETHICONE 5 (UNII: 0THT5PCI0R) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| SQUALANE (UNII: GW89575KF9) | |
| JOJOBA OIL (UNII: 724GKU717M) | |
| ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M) | |
| POLYSORBATE 60 (UNII: CAL22UVI4M) | |
| CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO) | |
| HYALURONIC ACID (UNII: S270N0TRQY) | |
| HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (45000 MPA.S AT 1%) (UNII: 86FQE96TZ4) | |
| CETEARYL OLIVATE (UNII: 58B69Q84JO) | |
| WATER (UNII: 059QF0KO0R) | |
| HYDROLYZED JOJOBA ESTERS (POTASSIUM SALTS) (UNII: CH428W5O62) | |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U) | |
| SORBITAN ISOSTEARATE (UNII: 01S2G2C1E4) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| SORBITAN OLIVATE (UNII: MDL271E3GR) | |
| APRICOT KERNEL OIL (UNII: 54JB35T06A) | |
| SODIUM BENZOATE (UNII: OJ245FE5EU) | |
| OATMEAL (UNII: 8PI54V663Y) | |
| HYDROXYACETOPHENONE (UNII: G1L3HT4CMH) | |
| DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (HARD PARTICLE) (UNII: H895X08VNO) | |
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | |
| 1,2-HEXANEDIOL (UNII: TR046Y3K1G) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|----------|------------------|---|-----------------------------|---------------------------|
| 1 | NDC:53997-002-02 | 1 in 1 CARTON | 05/15/2024 | |
| 1 | NDC:53997-002-01 | 125 mL in 1 TUBE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| OTC Monograph Drug | M017 | 05/15/2024 | |

Labeler - Lansinoh Laboratories Inc (181696907)

Establishment

| Name | Address | ID/FEI | Business Operations |
|--|---------|-----------|------------------------|
| Dhaliwal Pharmaceuticals Laboratories, LLC | | 116933772 | manufacture(53997-002) |

Revised: 12/2024

Lansinoh Laboratories Inc