

**LANSINOH BABY - dimethicone ointment**

**Lansinoh Laboratories, Inc.**

*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.*

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**ACTIVE INGREDIENTS**

DRUG FACTS DIMETHICONE 5.0% USP MODIFIED LANOLIN 15.5 % ZINC OXIDE 5.5 %

DATOS DEL MEDICAMENTO DIMETICONA 5.0% LANOLINA MODIFICADA 15.5%,  
CALIDAD USP OXIDO DE ZINC 5.5%

**INACTIVE INGREDIENT**

ALLANTOIN, BEESWAX, BISABOLO, CAPRYLIC/CAPRIC TRIGLYCERIDE, CHAMOMILLA RECUTITA (MATRICARIA)FLOWER EXTRACT, GLYCERIL BEHENATE/EICOSADIOATE, JOJOBA ESTERS, PETROLATUM, POLYDECENE, POLYETHYLENE, STEARYL GLYCYRRHETINATE, ZEA MAYS (CORN) STARCH

ALANTOINA, CERA DE ABEJAS, BISBOLOL, TRIGLICERIDO CAPRIILICO/CAPRICO, BEHENATO/EICOSADIOATO DE GLICERILO, JOJOBA ESTERES, EXTRACTO DE FLOR DE CHAMOMILLA RECUTITA (MATRICARIA), PETROLATO, POLIDECENO, POLIETILENO, GLICIRRETINATO DE ESTEARILO, ALMIDON DE ZEA MAYS (MAIZ)

**PURPOSE**

SKIN PROTECTANT

PROTECTOR DE LA PIEL

**WARNINGS**

FOR EXTERNAL USE ONLY WHEN USING THIS PRODUCT AVOID CONTACT WITH THE EYES STOP USE AND ASK A DOCTOR IF CONDITION WORSENS OR DOES NOT IMPROVE WITH IN 7 DAYS.

PARA USO EXTERNO SOLAMENTE CUANDO USE ESTE PRODUCTO EVITE EL CONTACTO CON LOS OJOS DEJE DE USARLO Y CONSULTE AL MEDICO SI EL PROBLEMA SE AGRAVA O NO MEJORA EN 7 DIAS

**KEEP OUT OF REACH OF CHILDREN**

KEEP OUT OF REACH OF CHILDREN. IF SWALLOWED, GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER RIGHT AWAY.

MANTENGA FUERA DEL ALCANCE DE LOS NINOS SI SE INGIERE, OBTENGA ATENCION MEDICA A LLAME AL INSTITUTO DE TOXICOLOGIA DE IMMEDIATO.

**DIRECTIONS**

CHANGE WET AND SOILED DIAPERS PROMPTLY CLEANSE THE DIAPER AREA ALLOW TO DRY APPLY OINTMENT LIBERALLY AS OFTEN AS NECESSARY, WITH EACH DIAPER CHANGE, ESPECIALLY AT BEDTIME OR ANY TIME WHEN EXPOSURE TO WET DIAPERS MAY BE PROLONGED

CAMBIE SIN DEMORS LOS PANALES MOJADOS O SUCIOS LIMPIE LA ZONA DEL PANAL DEJE SECAR APLIQUE ESTE UNGENTO ABUNDANTEMENTE Y TAN A MENUDO COMO SEA NECESARIO CUANDO CAMBIE EL PANAL, ESPECIALMENTE A LA HORA DE IR A DORMIR O EN CUALQUIER SITUACION EN QUE EL CONTACTO CON EL PANAL MOJADO PUDIERA SER PROLONGADO

#### **OTHER INFORMATION**

STORE BETWEEN 20 DEGREES TO 25 DEGREES C (68 DEGREES TO 77 DEGREES F)

GUARDE ENTRE LOS 20C Y 25 C (68 F A 77 F)

#### **QUESTIONS OR COMMENTS**

CALL 1-800-292-4794, WEEKDAYS.

LLAME AL 1-800-292-4794 DE LUNES A VIERNES.

#### **INDICATIONS AND USES**

TREATS DIAPER RASH PROTECTS SKIN PROMOTES HEALING

TRATA LA IRRITACION POR EL PANAL PROTEGE LA PIEL AYUDA A SANAR

#### **PACKAGE LABEL PRINCIPAL DISPLAY PANEL**

LANSINOH BABY LANSINOH 3-IN- 1 DIAPER RASH OINTMENT IS A UNIQUE BLEND OF THREE SPECIAL INGREDIENTS INCLUDING LANSINOH HPA LANOLIN - THE WORLD'S PUREST LANOLIN - TO HELP HEAL AND SOOTHE BABY'S BOTTOM AND HELP PREVENT IRRITATION FROM COMING BACK.

LANSINOH BABY LANSINOH 3-IN- 1 DIAPER RASH OINTMENT ES UNA COMBINACION EXCLUSIVA DE TRES INGREDIENTES ESPECIALES, ENTRE ELLOS LANSINOH HPA - LA LANOLINA MAS PURA DEL MUNDO - PARA CONTRIBUIR A SANAR Y SUAVIZAR EL PREVENIR QUE SE REPITA LA IRRITACION.

MANUFACTURED FOR: LANSINOH LABORATORIES, INC. ALEXANDRIA, VA 22314 800-292-4794 LANSINOH.COM LANSINOH R AND HPA R ARE REGISTERED TRADEMARKS OF LANSINOH LABORATORIES, INC. © 2010 LANSINOH LABORATORIES, INC. ALL RIGHTS RESERVED MADE IN USA

LANSINOH BABY 3-IN-1 DIAPER RASH OINTMENT TRATA LA IRRITACION POR EL PANAL PROTEGE LA PIEL AYUDA A SANAR HIPOALERGENICO, SIN FRAGANCIA, SIN PARABENO

LANSINOH BABY 3-IN-1 DIAPER RASH OINTMENT TREATS DIAPER RASH PROTECTS SKIN PROMOTES HEALING HYPOALLERGENIC FRAGRANCE FREE PARABEN FREE

IPARENTING MEDIA WINNER AWARD

NET WT 3 OZ (85G)

**3-in-1 DIAPER RASH OINTMENT**  
 Trata la irritación por el pañal  
 Protege la piel  
 Ayuda a sanar  
 Hipoalergénico, sin fragancia, sin parabeno

**Lansinoh baby**

Lansinoh 3-in-1 Diaper Rash Ointment is a unique blend of three special ingredients including Lansinoh HPA® Lanolin – the world’s purest lanolin – to help heal and soothe baby’s bottom and help prevent irritation from coming back.

Lansinoh 3-in-1 Diaper Rash Ointment es una combinación exclusiva de tres ingredientes especiales, entre ellos Lansinoh HPA – la lanolina más pura del mundo – para contribuir a sanar y suavizar el trasero del bebé y ayudar a prevenir que se repita la irritación.

Manufactured for:  
 Lansinoh Laboratories, Inc.  
 Alexandria, VA 22314  
 800-292-4794  
 Lansinoh.com  
 Lansinoh® and HPA® are registered trademarks of Lansinoh Laboratories, Inc.  
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**3-in-1 DIAPER RASH OINTMENT™**

Treats diaper rash  
 Protects skin  
 Promotes healing

Hypoallergenic  
 Fragrance free  
 Paraben free

**Lansinoh baby**

NET WT 3 OZ (85g)

IPARENTING MEDIA WINNER Award

76604 #3  
 LAN-C30000

**Drug Facts**

Active ingredients	Purpose
Dimethicone 5.0%.....	Skin Protectant
USP Modified Lanolin 15.5%.....	Skin Protectant
Zinc Oxide 5.5%.....	Skin Protectant

**Uses**

- Helps treat and prevent diaper rash
- Protects chafed skin due to diaper rash and helps seal out wetness

**Warnings**  
**For external use only**

**When using this product**

- Avoid contact with the eyes

**Stop use and ask 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**

- Change wet and soiled diapers promptly
- Cleanse the diaper area
- Allow to dry
- Apply ointment liberally as often as necessary, with each diaper change, especially at bedtime or any time when exposure to wet diapers may be prolonged

**Other information**

- Store between 20° to 25°C (68° to 77°F)

**Inactive ingredients** Allantoin, Beeswax, Bisabolol, Caprylic/Capric Triglyceride, Chamomilla Recutita (Matricaria) Flower Extract, Glyceril Behenate/ Eicosadioate, Jojoba Esters, Petrolatum, Polydecene, Polyethylene, Stearyl Glycyrhettinate, Zea Mays (Corn) Starch

**Questions or Comments?**  
 Call 1-800-292-4794, weekdays.

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**Datos del medicamento**

Ingredientes activos:	Propósito
Dimeticona 5.0%.....	Protector de la piel
Lanolina modificada 15.5%, calidad USP.....	Protector de la piel
Óxido de zinc 5.5%.....	Protector de la piel

**Usos**

- Tratamiento y prevención del exantema de pañal
- Protege la piel irritada por exantema de pañal y forma una barrera protectora contra la humedad

**Advertencias**  
**Para uso externo solamente**

**Cuando use este producto**

- evite el contacto con los ojos

**Deje de usarlo y consulte al médico si**

- el problema se agrava o no mejora en 7 días

**Mantenga fuera del alcance de los niños.** Si se ingiere, obtenga atención médica o llame al Instituto de Toxicología de inmediato.

**Instrucciones**

- Cambie sin demora los pañales mojados o sucios
- Limpie la zona del pañal
- Deje secar
- Aplique este ungüento abundantemente y tan a menudo como sea necesario cuando cambie el pañal, especialmente a la hora de ir a dormir o en cualquier situación en que el contacto con el pañal mojado pudiera ser prolongado

**Información adicional**

- Guarde entre los 20 °C y los 25 °C (68 °F a 77 °F)

**Ingredientes inactivos** Alantoína, cera de abejas, bisabolol, triglicérido caprílico/cáprico, behenato/eicosadiato de glicerilo, jojoba ésteres, extracto de flor de Chamomilla Recutita (Matricaria), petrolato, polideceno, polietileno, glicirretinato de estearilo, almidón de Zea Mays (maíz)

**¿Preguntas o comentarios?** Llame al 1-800-292-4794 de lunes a viernes.

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:53997-100
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	4.25 g in 85 g
LANOLIN (UNII: 7EV65EAW6H) (LANOLIN - UNII:7EV65EAW6H)	LANOLIN	13.17 g in 85 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	4.675 g in 85 g

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
ALLANTOIN (UNII: 344S277G0Z)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
LEVOMENOL (UNII: 24WE03BX2T)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
CHAMOMILE (UNII: FGL3685T2X)	
GLYCERYL BEHENATE (UNII: R8WTH25YS2)	
JOJOBA OIL (UNII: 724GKU717M)	
PETROLATUM (UNII: 4T6H12BN9U)	
HYDROGENATED POLYDECENE (550 MW) (UNII: U333RI6EB7)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
STEARYL GLYCYRRHETINATE (UNII: 3YYE6VJS0P)	
STARCH, CORN (UNII: O8232NY3SJ)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53997-100-01	85 g in 1 TUBE		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	01/01/2011	

**Labeler** - Lansinoh Laboratories, Inc. (181696907)**Registrant** - Lansinoh Laboratories, Inc. (181696907)**Establishment**

Name	Address	ID/FEI	Business Operations
Power Line Packaging, Inc		181099342	manufacture(53997-100)

