

HIPOGLOS- zinc oxide and lanolin ointment
Laboratorios Andromaco S.A.

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.

Hipoglós® Ointment

Active ingredient

Lanolin USP 15%

Zinc Oxide 15%

Purpose

Skin Protectant

Uses

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

Warnings

For external use only

When using this product - do not get into eyes

Stop use and ask a doctor if:

- Conditions worsen.
- Symptoms last more than 7 days or clear up and occur again within a few days.

Do not use on:

- Deep or puncture wounds
- Animal Bites
- Serious Burns

Keep out of reach of children

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

Directions

- Change wet or soiled diapers promptly.
- Clean 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 at 59° to 86° F (15 ° to 30° C)

Inactive ingredients

Alcohol, Benzethonium Chloride, Cod Liver Oil (contains vitamin A and D), Lavender Fragrance, Mineral Oil, Petrolatum, Sorbitan Monostearate, Talc, Vanillin, and Water.

Propósito

Protector dérmico

Usos

- Ayuda a tratar y prevenir las irritaciones producidas por el pañal.
- Protege la piel irritada debido a las rozaduras de pañal.
- Ayuda a mantener la piel seca.

Warnings

Para uso externo

*Cuando use este producto no aplicar en los ojos.

Descontinuar su uso y preguntar al médico si:

- la condición empeora
- Los síntomas permanecen por más de 7 días o si desaparecen y vuelven a aparecer luego de pocos días.

No usar en:

- Heridas profundas y punzantes.
- Mordeduras de animales
- Quemaduras graves

Mantener fuera del alcance de los niños

* Si son ingeridos, consiga ayuda médica o acuda al Centro de Control de Envenenamiento inmediatamente.

Indicaciones de uso

- Cambiar pañales mojados o sucios rápidamente.
- Limpie la zona del pañal.
- Deje secar.
- Aplicar ungüento libremente de acuerdo a necesidad, con cada muda del pañal, especialmente a la hora de dormir o cuando la exposición a pañales mojados se prolongue más de lo habitual.

Otra información

*Almacenar entre 59° y 86° F (15 y 30°C).

Excipientes

alcohol, cloruro de bencetonio, aceite de hígado de bacalao (contiene vitaminas A y D), esencia de lavanda, aceite mineral, petrolato blanco, monoestearato de sorbitan, talco, vainillina, agua.

Principal Display Panel - Carton Label

Carton Label

Manufactured by Laboratorios Andrómaco S.A.
 Av. Quilín 5273, Peñalolén, Santiago.
 www.hipoglos.cl
 www.laboratoriosandromaco.cl
 Made in Chile, Reg. Exp. I.S.P. N° FX-5/12
 Dist. by Victus, Inc.
 4918 S.W. 74 Court, Miami, FL 33155
 www.victus.com

Cód de barra:
UPC USA
810112020007
 Imp. Negro

NDC 50145-2929-05
 Helps treat and prevent diaper rash
 Ayuda a tratar y prevenir la irritación del pañal

HIPOGLÓS®

SKIN PROTECTANT OINTMENT

Free Sample
 Muestra Gratis

HELPS TREAT AND
 PREVENT
 DIAPER RASH

AYUDA A TRATAR
 Y PREVENIR LA
 IRRITACIÓN
 DEL PAÑAL

Net wt. **0.18 Oz**
 (5 g)

Helps treat and prevent diaper rash
 Ayuda a tratar y prevenir la irritación del pañal
HIPOGLÓS
 SKIN PROTECTANT OINTMENT
 TAMPER EVIDENT: DO NOT USE IF TUBE
 SEAL UNDER CAP IS BROKEN OR MISSING

125 x 31 x 31

Drug Facts
Active ingredients Purpose
 Lanolin USP 15% Skin Protectant
 Zinc Oxide 15% Skin Protectant
Uses
 - Helps treat and prevent diaper rash.
 - Protects chafed skin due to diaper rash.
 - Helps seal out wetness.
Warnings
 For external use only
 - When using this product do not get into eyes.
Stop use and ask a doctor if:
 - Conditions worsen.
 - Symptoms last more than 7 days or get worse, up and occur again within a few days.
Do not use on:
 - Deep or puncture wounds
 - Animal bites
 - Serious burns.
Keep out of reach of children
 - If swallowed, get medical help or contact a Poison Control Center right away.
Directions
 - Apply to clean or soiled diapers promptly.
 - Clean 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 at 68° to 86° F (15° to 30° C).
Inactive ingredients Alcohol, Benzethonium Chloride, Cod Liver Oil (contains vitamin A and D), Lavender Fragrance, Mineral Oil, Petroleum, Sorbitan Monostearate, Talc, Vanillin and Water.

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 Laboratorios Andrómaco S.A.

205703-6

Helps treat and prevent diaper rash
 Ayuda a tratar y prevenir la irritación del pañal
HIPOGLÓS
 SKIN PROTECTANT OINTMENT
 TAMPER EVIDENT: DO NOT USE IF TUBE
 SEAL UNDER CAP IS BROKEN OR MISSING

Datos del medicamento
Ingredientes activos
Propósito
 Lanolin USP 15% Skin Protectant
 Zinc Oxide 15% Skin Protectant
Usos
 - Ayuda a tratar y prevenir las irritaciones producidas por el pañal.
 - Protege la piel irritada debido a las rozaduras de pañal.
 - Ayuda a mantener la piel seca.
Precauciones de empleo
 Para uso externo
 - Cuando use este producto no aplicar en los ojos.
Discontinuar su uso y preguntar al médico si:
 - La condición empeora.
 - Los síntomas permanecen por más de 7 días o si desaparecen y vuelven a aparecer luego de pocos días.
No usar en:
 - Heridas y quemaduras.
 - Quemaduras graves.
Mantener fuera del alcance de los niños
 - Si son ingeridos, consiga ayuda médica o acuda al Centro de Control de Envenenamiento inmediatamente.
Indicaciones de uso
 - Cambiar pañales mojados o sucios rápidamente.
 - Limpiar la zona del pañal.
 - Deje secar.
 - Aplicar ungüento libremente de arriba a abajo, con cada cambio de pañal.
 - Evite exponer a la piel a la humedad de dormir o cuando la exposición a pañales mojados se prolongue más de lo habitual.
Otra información
 - Almacenar entre 68° y 86° F (15 y 30° C).
Excipientes Alcohol, Cloruro de bencetonio, Aceite de hígado de bacalao (contiene vitaminas A y D), Esencia de Lavanda, Aceite mineral, Peróxido blanco, Monostearato de sorbitano, talco, Vanilina, Agüa.

Descripción: Est Hipoglos Ointment 5g MM		Código: 205703	MM: 26306	Check-list Des. Envases:	Check-list A. Regulatorios:
Tacas: 18 mm	Medidas: 125x31x31	Versión: 6	ST: 0198	1R <input checked="" type="checkbox"/> 2R <input type="checkbox"/>	<input type="checkbox"/> N° de Registro
Colores: P. 369 P. Warm Red CYK	Cód de barra: UPC USA 810112020007/ Imp. Negro	Escala: 1:1		<input checked="" type="checkbox"/> Código ME	<input checked="" type="checkbox"/> Nom. Comercial
	Firma A. Regulatorios: <i>[Signature]</i>	Firma A. Regulatorios: <i>[Signature]</i>	Firma D. Envases: <i>[Signature]</i>	<input type="checkbox"/> Código barra	<input checked="" type="checkbox"/> Nom. Princ. Activo
Instructivo Código:	Firma Stg. Producto: <i>[Signature]</i>	Firma Depto. Diseño: <i>[Signature]</i>	Firma D. Técnico: <i>[Signature]</i>	<input type="checkbox"/> Registro	<input checked="" type="checkbox"/> Nom. Excipientes
	Fecha último V°B°: <i>[Signature]</i>	Fecha último V°B°: <i>[Signature]</i>	Fecha último V°B°: <i>[Signature]</i>	<input type="checkbox"/> Texto	<input checked="" type="checkbox"/> U. Concentración
Código reemplazo: Versión 5	Firma Stg. Producto: <i>[Signature]</i>	Firma Depto. Diseño: <i>[Signature]</i>	Firma D. Técnico: <i>[Signature]</i>	<input type="checkbox"/> Versión	<input checked="" type="checkbox"/> Cond. Almacenam.
	Fecha último V°B°: <i>[Signature]</i>	Fecha último V°B°: <i>[Signature]</i>	Fecha último V°B°: <i>[Signature]</i>	<input type="checkbox"/> Tacas	<input checked="" type="checkbox"/> Cond. Venta
Otros:	Historial de cambio: Cambio cod. barras UPC			<input type="checkbox"/> Dimensiones	<input checked="" type="checkbox"/> Frases por Resol.
				<input type="checkbox"/> Colores	<input checked="" type="checkbox"/> Fab.- Distrib.
				<input type="checkbox"/> Presentación	<input checked="" type="checkbox"/> Form. Farmacéutica
				<input type="checkbox"/> Posicion S:V	
				Responsable V°B° Digital: Jacqueline Jara A.	

Helps prevent and treat diaper rash, skin irritation

Net wt. 4.2 oz (120 g)

Principal Display Panel - Tube Label

2:1

Helps treat and prevent diaper rash
Ayuda a tratar y prevenir la irritación del pañal

HIPOGLÓS®

SKIN PROTECTANT OINTMENT

Free Sample - Muestra Gratis

NDC 50145-222-05

TAMPER EVIDENT - DO NOT USE IF TUBE SEAL UNDER CAP IS BROKEN OR MISSING NO USAR SI EL SELLO DEL TUBO BAJO LA TAPA ESTÁ ROTO O AUSENTE

Drug Facts	Warnings	Directions	Other information
<p>Active Ingredients</p> <ul style="list-style-type: none"> Zinc Oxide 15% Zinc Diolate 15% <p>Helps treat and prevent diaper rash. Protects child's skin from further rash. Helps soothe sore skin.</p>	<p>When used as directed:</p> <ul style="list-style-type: none"> Apply a thin layer to the affected area. Apply after each diaper change. Do not use on cuts, scrapes, or other broken skin. Do not use on children under 2 years of age. Do not use on children with known hypersensitivity to any of the ingredients. Do not use on children with known hypersensitivity to any of the ingredients. 	<p>Apply a thin layer to the affected area after each diaper change, especially at bedtime or after a bath.</p> <p>Apply after each diaper change.</p> <p>Do not use on cuts, scrapes, or other broken skin.</p> <p>Do not use on children under 2 years of age.</p> <p>Do not use on children with known hypersensitivity to any of the ingredients.</p>	<p>Other information:</p> <p>Keep out of reach of children. If swallowed, get medical help or contact Poison Control Center right away. Changes in color or smell indicates spoilage. Keep out of reach of children. If swallowed, get medical help or contact Poison Control Center right away. Changes in color or smell indicates spoilage. Keep out of reach of children. If swallowed, get medical help or contact Poison Control Center right away. Changes in color or smell indicates spoilage.</p>
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Manufactured by Laboratorios Andrómaco S.A., Av. Quilín 5273, Peñalolén, Santiago. www.hipoglos.cl www.laboratoriosandromaco.cl

Dist. by Victus, Inc., 4918 S.W. 74 Court, Miami, FL 33155 www.victus.com

HELPS TREAT AND PREVENT DIAPER RASH

AYUDA A TRATAR Y PREVENIR LA IRRITACIÓN DEL PAÑAL

Net wt. 0.18 Oz (5 g)

HELPS TREAT AND PREVENT DIAPER RASH

AYUDA A TRATAR Y PREVENIR LA IRRITACIÓN DEL PAÑAL

Net wt. 0.18 Oz (5 g)

026599-9

1:1

Helps treat and prevent diaper rash
Ayuda a tratar y prevenir la irritación del pañal

HIPOGLÓS

SKIN PROTECTANT OINTMENT

Free Sample - Muestra Gratis

NDC 50145-222-05

TAMPER EVIDENT - DO NOT USE IF TUBE SEAL UNDER CAP IS BROKEN OR MISSING NO USAR SI EL SELLO DEL TUBO BAJO LA TAPA ESTÁ ROTO O AUSENTE

Drug Facts	Warnings	Directions	Other information
<p>Active Ingredients</p> <ul style="list-style-type: none"> Zinc Oxide 15% Zinc Diolate 15% <p>Helps treat and prevent diaper rash. Protects child's skin from further rash. Helps soothe sore skin.</p>	<p>When used as directed:</p> <ul style="list-style-type: none"> Apply a thin layer to the affected area. Apply after each diaper change. Do not use on cuts, scrapes, or other broken skin. Do not use on children under 2 years of age. Do not use on children with known hypersensitivity to any of the ingredients. Do not use on children with known hypersensitivity to any of the ingredients. 	<p>Apply a thin layer to the affected area after each diaper change, especially at bedtime or after a bath.</p> <p>Apply after each diaper change.</p> <p>Do not use on cuts, scrapes, or other broken skin.</p> <p>Do not use on children under 2 years of age.</p> <p>Do not use on children with known hypersensitivity to any of the ingredients.</p>	<p>Other information:</p> <p>Keep out of reach of children. If swallowed, get medical help or contact Poison Control Center right away. Changes in color or smell indicates spoilage. Keep out of reach of children. If swallowed, get medical help or contact Poison Control Center right away. Changes in color or smell indicates spoilage.</p>
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HELPS TREAT AND PREVENT DIAPER RASH

AYUDA A TRATAR Y PREVENIR LA IRRITACIÓN DEL PAÑAL

Net wt. 0.18 Oz (5 g)

HELPS TREAT AND PREVENT DIAPER RASH

AYUDA A TRATAR Y PREVENIR LA IRRITACIÓN DEL PAÑAL

Net wt. 0.18 Oz (5 g)

026599-9

Descripción: Po Hipoglós Ointment 5g(0.18oz) MM		Código: 205699	MM: 26306	Ccheck-list Des. Envases:	Ccheck-list A. Regulatorios:
Tacas:	Medidas: Ø18 x L75 mm	Versión: 6	ST: 0198	1R <input checked="" type="checkbox"/> 2R <input type="checkbox"/>	<input type="checkbox"/> N° de Registro
Colores: P. 369 P. Warm Red CYK	Cód de barra:	Firma A/Regulatorios:	Escala: 1:1	<input type="checkbox"/> Código ME	<input type="checkbox"/> Nom. Comercial
	Fecha última V°B°:	Fecha último V°B°:	Fecha último V°B°:	<input type="checkbox"/> Código 2 de 5	<input type="checkbox"/> Nom. Princ. Activo
Instructivo Código:	Firma Gte. Producto:	Firma Depto. Diseño:	Firma D. Técnico:	<input type="checkbox"/> Registro	<input type="checkbox"/> Nom. Excipientes
	Fecha último V°B°:	Fecha último V°B°:	Fecha último V°B°:	<input type="checkbox"/> Texto	<input type="checkbox"/> U. Concentración
Código reemplazo: Versión 4	Historial de cambio: Agranda texto	Fecha último V°B°:	Fecha último V°B°:	<input type="checkbox"/> Versión	<input type="checkbox"/> Cond. Almacenam.
		Fecha último V°B°:	Fecha último V°B°:	<input type="checkbox"/> Dimensiones	<input type="checkbox"/> Cond. Venta
Otros:				<input type="checkbox"/> Colores	<input type="checkbox"/> Frases por Resol.
				<input type="checkbox"/> Presentación	<input type="checkbox"/> Fab.- Distrib.
					<input type="checkbox"/> Form. Farmacéutica
				Responsable V°B° Digital: Jacqueline Jara A.	

Tube Label

Hipoglós® Ointment

Helps prevent and treat diaper rash, skin irritation

Net wt. 4.2 oz (120 g)

HIPOGLOS

zinc oxide and lanolin ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50 145-222
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	15 g in 100 g
LANOLIN (UNII: 7EV65EAW6H) (LANOLIN - UNII:7EV65EAW6H)	LANOLIN	15 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
BENZETHONIUM CHLORIDE (UNII: PH41D05744)	
COD LIVER OIL (UNII: BBL281NWFG)	
ENGLISH LAVENDER OIL (UNII: ZBP1YXW0H8)	
MINERAL OIL (UNII: T5L8T28FGP)	
PETROLATUM (UNII: 4T6H12BN9U)	
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)	
TALC (UNII: 7SEV7J4R1U)	
VANILLIN (UNII: CHI530446X)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50 145-222-01	1 in 1 CARTON		
1		120 g in 1 TUBE		
2	NDC:50 145-222-02	1 in 1 CARTON		
2		100 g in 1 TUBE		
3	NDC:50 145-222-03	1 in 1 CARTON		
3		72 g in 1 TUBE		
4	NDC:50 145-222-04	1 in 1 CARTON		
4		60 g in 1 TUBE		
5	NDC:50 145-222-05	1 in 1 CARTON		
5		5 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	11/03/2010	

Labeler - Laboratorios Andromaco S.A. (980106538)

Registrant - Laboratorios Andromaco S.A. (980106538)

Establishment

Name	Address	ID/FEI	Business Operations
Laboratorios Andromaco S.A.		980106538	manufacture(50 145-222)

Revised: 11/2013

Laboratorios Andromaco S.A.