

DERMAHAUS- lice treatment shampoo shampoo

Laboratorio Salutec, S.A. de C.V.

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.

Coconut Oil

Camphor

Purpose: Pediculicide, Lice treatment

Lice treatment shampoo kills lice and eliminates nits. Used to prevent and treat head lice infections and their eggs.

For external use only. Keep out of reach of children.

When using this product keep out of eyes, ears and mouth. In case of contact with eyes rinse thoroughly with water.

If swallowed, get medical help or contact poison control center right away.

Stop use and ask a doctor if irritation or rash occurs.

On open skin wounds.

In children less than 2 months of age.

Do not wash your head with cosmetic shampoo for 24 hours after applying this product, to maintain residual efficacy.

Keep out of reach of children. If swallowed, get medical help or contact poison control center right away.

Treatment- Moisten hair 1 time with this shampoo and repeat 1 week later, to ensure the total removal of lice or nits.

Prevention - Wash hair once a week with this shampoo, avoid new infestations.

How to apply - Moisten the hair and apply a sufficient amount of shampoo on the hair and scalp. Leave in contact for 10 minutes, detangle the hair with a special comb and rinse with warm water. Dry the hair and remove the parasites and nits with the fine comb. Do not wash your head with cosmetic shampoo for 24 hours after applying this product, to maintain residual efficacy. As prevention, repeat the treatment after 7 days.

Store between 15-30C (59-86F)

Avoid freezing and excessive heat above 40C (104F)

PEG-150 Distearate

Sodium Cocoyl Isethionate

Triethanolamine Lauryl Sulfate

Tromlamine

Coco-Betaine

Hydroxypropyl Cellulose (TypeM)

Methylchloroisothiazolinone

Water

DERMAHAUS[®]

LICE



TREATMENT
SHAMPOO
TRATAMIENTO AUXILIAR
PARA PIOJOS

ULTRA
STRENGTH • FUERZA



KILLS LICE
ELIMINA PIOJOS
ELIMINATES NITS
ELIMINA LIENDRES
GIVES STRENGTH
SHINE & SILKINESS
DA FUERZA, BRILLO
Y SEDOSIDAD

4.2 FL OZ (125 ML)

Drug Facts / Datos del Medicamento

Active Ingredient/ Ingredientes Activos

Camphor.....0.1% w/w
/Alcanfor.....0.1% p/p

Purpose/ Propósito

Podiculicide/Podiculicida

Traditionally used to prevent and treat head lice infections and their eggs (nits) on the scalp /Tradicionalmente utilizado para prevenir y tratar las infecciones de piojos y sus huevos (liendres) en cuero cabelludo.

Warnings: For external use only. Precauciones: Uso externo solamente.

Do not use / No utilice • in children less than 2 months of age / en niños menores de 2 meses • on open skin wounds / en heridas abiertas de la piel

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water / Cuando use este producto, evite contacto con ojos, oídos y boca. En caso de contacto con los ojos, enjuague bien los ojos con agua.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition. / Suspender su uso y consulte a un médico si se produce irritación o sarpullido. Estos pueden ser signos de una afección grave.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away / Mantener fuera del alcance de los niños. En caso de ingestión, obtenga ayuda médica o comuníquese con un Centro de Control de Envenenamiento de inmediato.

Directions / Instrucciones Treatment: Wash hair 1 time with this shampoo and repeat 1 week later, to ensure the total removal of lice or nits. Prevention: Wash hair once a week with this shampoo, to avoid new infestations. / Modo de Empleo: Tratamiento: Lave el cabello por 1 vez con este shampoo y repita 1 semana más tarde, para asegurarse de la eliminación total de piojos o liendres. Prevención: Lavar el cabello 1 vez a la semana con este shampoo, para evitar nuevas infestaciones.

How to apply: Moisten the hair and apply a sufficient amount of shampoo on the hair and scalp. Leave in contact for 10 minutes, detangle the hair with a special comb and rinse with warm water. Dry the hair and remove the parasites and nits with the fine comb. Do not wash your head with cosmetic shampoo for 24 hours after applying this product, to maintain residual efficacy. As prevention, repeat the treatment after 7 days. Modo de aplicación: Humedecer el cabello y aplicar suficiente cantidad de shampoo sobre el cabello y el cuero cabelludo. Dejar en contacto durante 10 minutos, desenredar el cabello con un peine especial y enjuagar con agua tibia. Secar el cabello y remover los parásitos y las liendres con el peine fino. No lavarse la cabeza con shampoo cosmético hasta 24 horas después de la aplicación de este producto, para no anular su efecto residual. Como prevención, repetir el tratamiento a los 7 días.

Inactive Ingredients: Water, triethanolamine lauryl sulfate, peg-150 diesterate, coco-betaine, triethanolamine, sodium cocoyl isethionate, hydroxypropyl cellulose (type m), methylchloroisothiazolinone, coconut oil. /Ingredientes inactivos: Agua, lauril sulfato de trietanolamina, peg-150 diesterato, cocobetaina, trietanolamina, isetonato de cocoilo de sodio, hidroxipropilcelulosa (tipo m), metilcloroisotiazolinona, aceite de coco.

MADE IN MEXICO BY / HECHO EN MÉXICO POR:

Laboratorio Salutes S.A. de C.V.
Tel. 52(55)51605969

LOTE/CAD:



7506344000292

125 mL NDC:

79289-005-01

DERMAHAUS

lice treatment shampoo shampoo

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:79289-005

Route of Administration		TOPICAL		
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)		CAMPHOR (SYNTHETIC)	0.001 g in 100 mL	
Inactive Ingredients				
Ingredient Name		Strength		
COCONUT OIL (UNII: Q9L0O73W7L)		0.0002 g in 100 mL		
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)		0.1 g in 100 mL		
TRIETHANOLAMINE LAURYL SULFATE (UNII: E8458C1KAA)		37.09 g in 100 mL		
PEG-150 DISTEARATE (UNII: 6F36Q0I0AC)		4.5 g in 100 mL		
SODIUM COCOYL ISETHIONATE (UNII: 518XTE8493)		1 g in 100 mL		
WATER (UNII: 059QF0KO0R)		51.8 mL in 100 mL		
TROLAMINE (UNII: 9O3K93S3TK)		2 g in 100 mL		
COCO-BETAINE (UNII: 03DH2IZ3FY)		3 g in 100 mL		
HYDROXYPROPYL CELLULOSE (TYPE M) (UNII: U3JF91U133)		0.5 g in 100 mL		
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79289-005-01	125 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/01/2020	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final		part348	09/01/2020	

Labeler - Laboratorio Salutec, S.A. de C.V. (951580007)

Establishment			
Name	Address	ID/FEI	Business Operations
Laboratorio Salutec, S.A. de C.V.		951580007	manufacture(79289-005)