

DERMISA SKIN FADE VITAMIN C INFUSED- hydroquinone cream
Montani Cosmetics 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.

Drug Facts

Active Ingredient

Hydroquinone USP 2%

Octyl Dimethyl Paba 0.60%

Purpose

Skin Lightener

Uses

• For the gradual fading of dark (brownish) skin discolorations such as freckles, age and liver spots or uneven pigment that may occur due to sun overexposure, pregnancy or from the use of oral contraceptives.

Warnings

For external use only

Do not use

• On children under 12 years of age unless directed by a doctor • This product is not for use in the prevention of sunburn • On inflamed or broken skin

When using this product

• Avoid contact with the eyes • Some users of this product may experience a mild skin irritation, if skin irritation becomes severe **stop use and consult a doctor**

Keep out of reach of children

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

Directions

• **Adults** Apply a small amount as a thin layer to the affected areas twice daily or as directed by a doctor. If no improvement is seen after 3 months of treatment, use of this product should be discontinued. Lightening effect of this product may not be noticeable when used on very dark skin. • **Children under 12 years of age** Do not use unless directed by a doctor

• Sun exposure should be limited by using a sunscreen agent, or protective clothing to prevent bleached skin after treatment completed to prevent darkening from recurring

Other Information

• Store at room temperature • Tamper-evident tube • Contact us at contractar.en.info@dermisa.com

Inactive ingredients

Water (Aqua), Glycerin, Paraffinum Liquidum (Mineral Oil), Stearyl Alcohol, Petrolatum, Cetearyl Alcohol, Steareth-10, Propylene Glycol, Steareth-2, Sodium Sulfite, Citric Acid, Sodium Metabisulphate, Diazolidinyl Urea, Dicetyl Phosphate, Ceteth-10 Phosphate, Fragrance (Parfum), Methylparaben, Propylparaben, Ethylhexyl Methoxyinnamate, Limonene, Hydroxycitronellol, Ascorbic Acid (Vitamin C)

Package Label

PMS
280

PMS
3125



SKIN FADE CREAM



SKIN FADE CREAM

helps reduce the appearance of dark spots, freckles and skin discoloration

ANTIOXIDANT
VITAMIN C



crema
blanqueadora
crème
éclaircissante

NET WT 1.78oz (50g)

Drug Facts (continued)

Directions / Instrucciones
 • **Adults / Adultos:** Apply a small amount as a thin layer on the affected area twice daily, or use as directed by a doctor. If no improvement is seen after 3 months of treatment, use of this product should be discontinued. Lightening effect of this product may not be noticeable when used on very dark skin / Aplique una pequeña cantidad en una capaligera en el área afectada dos veces al día o sigalas instrucciones de su médico. Si no nota mejora después de 3 meses de tratamiento, debe discontinuar el uso de este producto. Efecto aclarante de este producto puede no ser notorio en piel muy oscura.
 • **Children under 12 years of age / Niños menores de 12 años de edad:** Do not use unless directed by a doctor / No usar sin ser indicado por un médico
 • Sun exposure should be limited by using a sunscreen agent, a sun blocking agent, or protective clothing to cover bleached skin after treatment is completed to prevent darkening from reoccurring / Se debe limitar exposición al sol aplicando una pantalla solar, un bloqueador solar o ropa para proteger la piel aclarada después del tratamiento para evitar que se vuelva a oscurecer.

Other Information / Otra Información
 • Store at room temperature / Conservar a temperatura de ambiente • Tamper-evident tube / Tubo contra prueba de violación
 • Contact us at / Nos puede contactar en info@dermisa.com

Inactive Ingredients / Ingredientes Inactivos
 Water (Aqua), Glycerin, Paraffinum Liquidum (Mineral Oil), Stearyl Alcohol, Petrolatum, Cetylalcohol, Steareth-10, Propylene Glycol, Steareth-2, Sodium Sulfite, Citric Acid, Sodium Metabisulfate, Diazolidinyl Urea, Dicyetyl Phosphate, Cetylth-10 Phosphate, Fragrance (Parfum), Methylparaben, Propylparaben, Ethylhexyl Methoxybenzoyl Sulfonate, Limonene, Hydroxycitronellol, Ascorbic Acid (Vitamin C)

Reg. San:
 Venezuela EF 31058 C.P.E. 020794881;
 Ecuador NSEC 0183909 02076194000;
 Panama 92980; Cuba Peca C 2283-07;
 Colombia NSC2004001 1398;
 El Salvador EC22751211

DRUG FACTS / DATOS MEDICINALES

Active Ingredient / Ingrediente Activo:
Hydroquinone 2%

Purpose / Propósito
Skin Lightener / Aclarador de Piel

Uses / Usos • For the gradual fading of dark (brownish) spots such as freckles, age and liver spots or an even pigmentation that may occur in pregnancy or from the use of oral contraceptives. / Para el aclarado gradual de manchas oscuras (marrones) causadas por la edad, pecas, manchas del hígado o pigmentación desigual que puede ocurrir durante el embarazo o con el uso de pastillas anticonceptivas. • Contains a sunscreen to help prevent darkening from recurring / Contiene un bloqueador solar para ayudar a prevenir la reaparición de oscurecimiento.

Warnings / Advertencias
For external use only / Solamente para uso externo

Do not use / No Usar
• On children under 12 years of age unless directed by a doctor / En niños menor de 12 años de edad sin que sea recetado por un médico • This product is not for use in the prevention of sunburn / Este producto no está indicado para la prevención de quemaduras de sol • On inflamed or broken skin / En piel irritada o con cortes.

When using this product / Al usar este producto
• Avoid contact with eyes / Evite el contacto con los ojos • Some users of this product may experience a mild skin irritation. If skin irritation becomes severe, stop use and consult a doctor. / Algunos usuarios de este producto pueden tener una leve irritación a la piel. Si la irritación se vuelve severa, deje de usarlo y consulte con un médico.

Keep out of the reach of children / Mantenga fuera del alcance de niños. If swallowed, get medical help or contact a Poison Control Center right away / Si lo ingerie, busque ayuda médica o contacte a un Centro de Control de Veneno inmediatamente.

Drug Facts (continued)

Dermisa® Skin Fade Cream is a non-oily formula designed to help gradually fade the appearance of dark (brownish) skin discolorations caused by overexposure to the sun, aging, pregnancy, minor scars and use of birth control pills. Contains antioxidant VITAMIN C to help fight free radicals. Can be used under make-up. Results may be seen in 4-6 weeks of treatment.

La Crema Blanqueadora Dermisa® es una fórmula no grasosa creada para aclarar gradualmente la apariencia de manchas oscuras (marrones), manchas de la edad y decoloraciones causadas por exposición al sol, envejecimiento natural, embarazo, cicatrices menores, pecas y pastillas anticonceptivas. Contiene **Vitamina C**, un antioxidante que ayuda a combatir los radicales libres. Se puede usar debajo del maquillaje. Podrá ver resultados en 4-6 semanas.

La Crème éclaircissante pour la peau Dermisa® est une formule légère et non grasse conçue pour progressivement éclaircir les décolorations foncées de la peau (mêlasmes) causées par la surexposition à u soleil, le vieillissement, les taches de rousseur, la grossesse, les petites cicatrices et les contraceptifs oraux. Elle contient l'antioxydant VITAMINE C pour aider à combattre les radicaux libres. Peut être appliquée sous le maquillage. Utiliser deux fois par jour pour les meilleurs résultats; amélioration visible après 4-6 semaines de traitement.

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www.dermisa.com

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hydroquinone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68343-005
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROQUINONE (UNII: XV74C1N1AE) (HYDROQUINONE - UNII:XV74C1N1AE)	HYDROQUINONE	2 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
DIHEXADECYL PHOSPHATE (UNII: 2V6E5WN99N)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
SODIUM SULFITE (UNII: VTK01UQK3G)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
OCTINOXATE (UNII: 4Y5P7MUD51)	
HYDROXYCITRONELLOL (UNII: R0B4U2I48W)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
MINERAL OIL (UNII: T5L8T28FGP)	
GLYCERIN (UNII: PDC6A3C0OX)	
STEARYL ALCOHOL (UNII: 2KR89I4HIY)	
PETROLATUM (UNII: 4T6H12BN9U)	
STEARETH-10 (UNII: FD0913P475)	
STEARETH-2 (UNII: V56DFE46J5)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETETH-10 PHOSPHATE (UNII: 4E05O5N49G)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68343-005-01	1 in 1 BOX	07/16/2018	
1	NDC:68343-005-50	50 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:68343-005-02	1 in 1 BOX	07/16/2018	
2	NDC:68343-005-25	25 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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Labeler - Montani Cosmetics Inc (124852331)

Revised: 7/2018

Montani Cosmetics Inc