

DERMISA SKIN FADE- hydroquinone padimate o 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
Sunscreen

Use

- Lightens dark discolorations in the skin such as age spots, liver spots, freckles, minor scars and pigment in skin that may occur during pregnancy or from the use of oral contraceptives.
- Contains a sunscreen to help prevent darkening from reoccurring.

Warnings

- For external use only. Avoid contact with eyes. Some users of this product may experience a mild skin irritation. If irritation becomes severe, stop use and consult a doctor. Do not use on children under 12 years of age unless directed by a doctor. Sun exposure should be limited by using a sunscreen agent, a sunblocking agent or protective clothing to cover bleached skin after treatment to prevent darkening from recurring. This product is not for the use in the prevention of sunburn

Keep out of reach of children

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

Directions

- 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.
- Indications: For the gradual fading of dark age spots, liver spots, freckles and melasma (a condition caused during pregnancy or by the use of oral contraceptives)

Inactive ingredients

Water, Glyceryl Monostearate, Mineral Oil, Propylene Glycol, Cetyl Alcohol, Dimethicone, Sodium Lauryl Sulphate, Disodium EDTA, Ascorbic Acid (Vitamin C), Sodium Metabisulphite, Propylparaben, Fragrance, Allantoin

Package Label



DERMISA SKIN FADE

hydroquinone padimate o cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68343-001
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
PADIMATE O (UNII: Z11006CMUZ) (PADIMATE O - UNII:Z11006CMUZ)	PADIMATE O	0.6 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
MINERAL OIL (UNII: T5L8T28FGP)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	

ASCORBIC ACID (UNII: PQ6CK8PD0R)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
ALLANTOIN (UNII: 344S277G0Z)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68343-001-01	1 in 1 BOX	09/15/2011	
1	NDC:68343-001-50	50 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:68343-001-02	1 in 1 BOX	09/15/2011	
2	NDC:68343-001-25	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
OTC monograph not final	part358A	09/15/2011	

Labeler - Montani Cosmetics Inc (124852331)

Revised: 7/2018

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