

ACTIVE 4- hydroquinone cream
Vivier Pharma, 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.

Active 4

Active Ingredient

Hydroquinone USP (4%)

Indication

Skin Lightening

Indication

To gradually lighten hyperpigmentation of the skin such as age spots, liver spots, freckles or hyperpigmentation that can occur as a result of pregnancy or the use of oral contraceptives.

Precautions

For external use only. Use only on the advice of a physician. A mild transient stinging may occur for people with sensitive skin. Do not use on broken or irritated skin. Discontinue use if irritation or rash occurs. Avoid contact with eyes and mucous membranes. In case of contact, rinse thoroughly with water. Do not use on children under 12 years of age. Keep out of reach of children. Avoid usage around the eyes and lips.

Precautions

Keep out of reach of children.

Directions

Use fingertips to apply a thin layer to affected areas. Use both morning and night or as directed by a physician. Gradual lightening of the discolored area can be expected in most cases. Close cap securely after each use. Store at room temperature (15-30°C / 59-86°F).

Non-Medicinal Ingredients

Butylated Hydroxy Toluene, Cetearyl Alcohol, Cetyl Alcohol, Disodium EDTA, Ethoxydiglycol, Fragrance/Parfum, Glycerin, Lactic Acid, L-Ascorbic Acid USP, Methylparaben, Phenyl Trimethicone, PPG-2 Myristyl Ether Propionate, Propylparaben, Sodium Cetearyl Sulfate, Sodium Lauryl Sulfate, Sodium Metabisulfite, Tocopheryl Acetate, Triethanolamine Salicylate, Water/Eau.

Principal Display Panel

NDC 67226-2140-6



Active™ 4

Crème d'Hydroquinone (4 %)

Crème éclaircissante
pour la peau

Seulement
sur ordonnance†

60 mL
2 fl oz

INDICATION

To gradually lighten hyperpigmentation of the skin such as age spots, liver spots, freckles or hyperpigmentation that can occur as a result of pregnancy or the use of oral contraceptives.

DIRECTIONS

Use fingertips to apply a thin layer to affected areas. Use both morning and night or as directed by a physician. Gradual lightening of the discolored area can be expected in most cases. Close cap securely after each use. Store at room temperature (15–30°C / 59–86°F).

PRECAUTIONS

For external use only. Avoid contact with eyes. If contact occurs, rinse thoroughly with water. Keep out of reach of children. Use only on the advice of a physician. Contains Sodium Metabisulfite. See package insert for complete details.

ACTIVE INGREDIENT (w/w)

Hydroquinone USP (4%)

NON-MEDICINAL INGREDIENTS

INGRÉDIENTS NON-MÉDICINAUX

Butylated Hydroxy Toluene, Cetearyl Alcohol, Cetyl Alcohol, Disodium EDTA, Ethoxydiglycol, Fragrance/Parfum, Glycerin, Lactic Acid, L-Ascorbic Acid USP, Methylparaben, Phenyl Trimethicone, PPG-2 Myristyl Ether Propionate, Propylparaben, Sodium Cetearyl Sulfate, Sodium Lauryl Sulfate, Sodium Metabisulfite, Tocopheryl Acetate, Triethanolamine Salicylate, Water/Eau.

† « Rx only » applies to USA



NDC 67226-2140-6



Active™ 4

Hydroquinone Cream (4%)

Skin Lightening Cream

Rx only†

60 mL
2 fl oz

INDICATION

Pour l'éclaircissement graduel de l'hyperpigmentation de la peau telles les taches séniles, de vieillesse, de rousseur ou l'hyperpigmentation pouvant se manifester à la suite d'une grossesse ou de l'emploi de contraceptifs oraux.

MODE D'EMPLOI

En utilisant vos doigts, appliquer une mince couche sur la région affectée. Utiliser matin et soir ou selon l'avis d'un médecin. Avec une application continue, on peut constater un éclaircissement graduel de la peau dans la plupart des cas. Bien visser le bouchon après chaque usage. Conserver à la température ambiante (15–30 °C / 59–86 °F).

PRÉCAUTIONS

Pour usage externe seulement. Éviter tout contact avec les yeux. En cas de contact, bien vous les rincer avec de l'eau. Garder hors de portée des enfants. Utiliser seulement selon les recommandations d'un médecin. Contient du métabisulfite de sodium.

Pour tout renseignement, consulter l'info-feuille.

INGRÉDIENT ACTIF (p/p)

Hydroquinone USP (4 %)

† « Seulement sur ordonnance » ne s'applique qu'aux É.-U.

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Made in Canada
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DIN 02248851

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ACTIVE 4

hydroquinone cream

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:67226-2140 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|---------------|
| HYDROQUINONE (UNII: XV74C1N1AE) (HYDROQUINONE - UNII:XV74C1N1AE) | HYDROQUINONE | 4 g in 100 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K) | |
| CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S) | |
| CETYL ALCOHOL (UNII: 936JST6JCN) | |
| EDETATE DISODIUM (UNII: 7FLD91C86K) | |
| DIETHYLENE GLYCOL MONOETHYL ETHER (UNII: A1A118X02B) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| LACTIC ACID (UNII: 33X04XA5AT) | |

| | |
|--|--|
| ASCORBIC ACID (UNII: PQ6CK8PD0R) | |
| METHYL PARABEN (UNII: A2I8C7HI9T) | |
| PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R) | |
| PPG-2 MYRISTYL ETHER PROPIONATE (UNII: 88R97D8U8A) | |
| PROPYL PARABEN (UNII: Z8IX2SC1OH) | |
| SODIUM CETOSTEARYL SULFATE (UNII: 7ZBS06BH4B) | |
| SODIUM LAURYL SULFATE (UNII: 368GB5141J) | |
| SODIUM METABISULFITE (UNII: 4VON5FNS3C) | |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) | |
| TROLAMINE SALICYLATE (UNII: H8O4040BHD) | |
| WATER (UNII: 059QF0K00R) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:67226-2140-6 | 1 in 1 BOX | | |
| 1 | | 60 mL in 1 TUBE | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part358A | 05/30/2014 | |

Labeler - Vivier Pharma, Inc. (250996550)

Establishment

| Name | Address | ID/FEI | Business Operations |
|---------------------|---------|-----------|-------------------------|
| Vivier Pharma, Inc. | | 250996550 | manufacture(67226-2140) |

Revised: 11/2013

Vivier Pharma, Inc.