

PORCELANA 24 HOUR SKIN LIGHTENING- hydroquinone, octinoxate cream
CCA Industries 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.

Porcelana 24 Hour Skin Lightening Cream

Drug Facts

Active Ingredient

Hydroquinone U.S.P. 2%

Octyl methoxycinnamate 2.5%

Purpose

Skin Lightener

Sun Screen

Uses:

For the gradual fading of dark spots in the skin such as age liver spots and pigment in the skin that may occur in 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.

Do not use

on children under 12 years of age unless directed by a doctor.

When using this product

some users may experience a mild skin irritation.

Stop use and ask a doctor

if skin irritation becomes severe.

Keep out of the reach of children.

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

This product is not for use in the prevention of sunburn,

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.

Directions

Adults apply a small amount as a thin layer on the affected area(s) as part of your daily routine or as directed by a doctor. If no improvement is seen after three months of treatment, use of this product

should be discontinued.

Other Information

- Lightening effect of this product may not be noticeable when used on very dark skin.

Inactive Ingredients

Water, Mineral Oil, Glyceryl Stearate, Cetyl Alcohol, Isopropyl Palmitate, PEG-100 Stearate, Propylene Glycol, Emulsifying Wax NF, Stearic Acid, Hydroxyethylcellulose, Disodium EDTA, Sodium Metabisulfite, Fragrance, Diazolidinyl Urea, Methylparaben, Propylparaben, BHT, Tocopheryl (Vitamin E) Acetate, Beta-Carotene, Magnesium Ascorbyl Phosphate, Citric Acid.

Questions or Comments?

- Call toll-free:1-800-595-6230
- Visit us at www.porcelana.com

Package Labeling:

	<p>2 ½ in</p>	 <p>PORCELANA®</p> <p>BEFORE</p> <ul style="list-style-type: none"> • FADES DARK SPOTS • EVENS SKIN TONE <p>AFTER</p> <p>DISCOVER YOUR INNER GLOW</p>															
<p>Drug Facts</p> <table border="1"> <tr> <th>Active Ingredients</th> <th>Purpose</th> </tr> <tr> <td>Hydroquinone U.S.P. 2%.....</td> <td>Skin Lightener</td> </tr> <tr> <td>Octyl methoxycinnamate 2.5%.....</td> <td>Sun Screen</td> </tr> </table> <p>Uses For the gradual fading of dark spots in the skin such as age and liver spots and pigment in the skin that may occur in pregnancy or from the use of oral contraceptives. Contains a sunscreen to help prevent darkening from reoccurring.</p> <p>Warnings For external use only. Avoid contact with eyes. Do not use on children under 12 years of age unless directed by a doctor. When using this product some users may experience a mild skin irritation. Stop use and ask a doctor if skin irritation becomes severe. Keep out of reach of children. If swallowed, seek medical help or contact a Poison Control Center right away. This product is not for use in the prevention of sunburn. 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.</p>	Active Ingredients	Purpose	Hydroquinone U.S.P. 2%.....	Skin Lightener	Octyl methoxycinnamate 2.5%.....	Sun Screen	<p>61150</p> <p>Drug Facts (continued)</p> <p>Directions Adults apply a small amount as a thin layer on the affected area(s) as part of your daily routine or as directed by a doctor. If no improvement is seen after three months of treatment, use of this product should be discontinued.</p> <p>Other Information • Lightening effect of this product may not be noticeable when used on very dark skin.</p> <p>Inactive Ingredients: Water, Mineral Oil, Glyceryl Stearate, Cetyl Alcohol, Isopropyl Palmitate, PEG-100 Stearate, Propylene Glycol, Emulsifying Wax NF, Stearic Acid, Hydroxyethylcellulose, Disodium EDTA, Sodium Metabisulfite, Fragrance, Diazolidinyl Urea, Methylparaben, Propylparaben, BHT, Tocopheryl (Vitamin E) Acetate, Beta-Carotene, Magnesium Ascorbyl Phosphate, Citric Acid</p> <p>Questions or Comments? • Call toll-free:1-800-595-6230 • Visit us at www.porcelana.com</p> <p><small>cca core care AMERICA Distributed by: CCA Industries Inc. 1099 Wall Street W. Lyndhurst, NJ 07071 1-800-595-6230 PD61150-01</small></p>	<p>PORCELANA®</p> <p>DISCOVER YOUR INNER GLOW</p> <p>CLINICAL  STRENGTH</p> <p>24 HOUR</p> <p>Skin Lightening Cream</p> <p>WITH UV FILTER</p> <p>FADES DARK SPOTS · EVENS SKIN TONE</p> <p>NET WT 3 OZ (85g)</p>	<p>FADES DARK SPOTS AND EVENS SKIN TONE DUE TO:</p> <table border="1"> <tr> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>AGE SPOTS</td> <td>ACNE SCARRING</td> <td>SUN SPOTS</td> <td>MELASMA (pregnancy mask)</td> </tr> </table> <p>New Porcelana 24 Hour Skin Lightening Cream includes a highly effective UV-B filter to slow the darkening process by day and includes antioxidants to protect from free radicals at night. It helps reduce the appearance of skin discolorations, leaving with you with a brighter, more even skin tone.</p>					AGE SPOTS	ACNE SCARRING	SUN SPOTS	MELASMA (pregnancy mask)
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 <p>8 55093 00300 7</p>		<p>2 ½ in</p> <p>4 color process & PMS8761</p>	<p>3 11/16 in</p>														

PORCELANA 24 HOUR SKIN LIGHTENING
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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61543-0000
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROQUINONE (UNII: XV74C1N1AE) (HYDROQUINONE - UNII:XV74C1N1AE)	HYDROQUINONE	20 mg in 1 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	25 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
MINERAL OIL (UNII: T5L8T28FGP)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
PEG-100 STEARATE (UNII: YD01N1999R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
BETA CAROTENE (UNII: 01YAE03M7J)	
MAGNESIUM ASCORBYL PHOSPHATE (UNII: 0R822556M5)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61543-0000-0	1 in 1 BOX	09/01/2018	
1		85 g in 1 JAR; 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	09/01/2018	

Labeler - CCA Industries Inc. (106771041)

