

**PORCELANA DAY SKIN LIGHTENING- hydroquinone and octinoxate cream**  
**Ultimark Products LLC**

*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.*

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**Porcelana Day Skin Lightening Cream**

***Active Ingredient***

Hydroquinone U.S.P. 2%

***Purpose***

Skin Lightener

***Active Ingredient***

Octinoxate 2.5%

***Purpose***

Sunscreen

***Uses:***

- Lightens dark spots, blemishes, freckles and discolorations of the skin caused by sun exposure, age, acne, pregnancy and the use of oral contraceptives.
- Contains a sunscreen to keep darkening from reoccurring.

***Warnings***

**For External use only.** Avoid contact with eyes. Some users of this product may experience a mild skin irritation. If skin irritation becomes severe, stop use and consult a doctor.

**Do Not use on**

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

**Keep out of the reach of children.**

If swallowed, get medical help or contact a Poison Control Center right away. **If pregnant or breast-feeding**, ask a doctor before use.

***Questions or Comments?***

**Call 1-800-820-8717**

Monday - Friday 9:00 - 6:00 EST or visit us at: [www.nicenebrands.com](http://www.nicenebrands.com)

**¿Las Preguntas o Comentarios? Llame al 1-800-820-8717**

Lunes - Viernes 9:00 - 6:00 EST, o visítenos en:

### Directions

- Adults: 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.
- Children under 12 years of age: do not use unless directed by a doctor
- 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 in order to prevent darkening from reoccurring.

### Inactive Ingredients

Water, Mineral Oil, Glyceryl Stearate, Cetyl Alcohol, Isopropyl Palmitate, PEG-100 Stearate, Propylene Glycol, Emulsifying Wax NF, Stearic Acid, Hydroxyethylcellulose, Tocopheryl Acetate, Magnesium Ascorbyl Phosphate, Beta-Carotene, Disodium EDTA, C13-14 Isoparaffin, Sodium Meta-Bisulfite, Citric Acid, BHT, Methylparaben, Propylparaben, Diazolidinyl Urea, Fragrance.

### PRINCIPAL DISPLAY PANEL

**PORCELANA®**  
**FOR BALANCED SKIN TONE**  
**DAY**  
**SKIN LIGHTENING CREAM**  
**FADES DARK SPOTS    EVENS SKIN TONE**  
**Protects With**  
**Anti-Oxidants & Sunscreen    Net Wt 3 oz/85 g**

 <p><b>PORCELANA®</b> FOR BALANCED SKIN TONE</p> <p><b>DAY</b> SKIN LIGHTENING CREAM FADES DARK SPOTS • EVENS SKIN TONE</p>							
<p><b>Drug Facts</b></p> <table border="1"> <tr> <th>Active Ingredients</th> <th>Purpose</th> </tr> <tr> <td>Hydroquinone U.S.P. 2% Octyl methoxycinnamate 2.5%</td> <td>Skin Lightener Sunscreen</td> </tr> </table> <p><b>Uses</b> For the gradual fading of dark spots in the skin such as liver and age spots. Contains a sunscreen to help prevent darkening from reoccurring.</p> <p><b>Warnings</b> 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.</p> <p><b>Questions or Comments?</b> • Call toll-free: 1-888-881-1840 • Visit us at: <a href="http://www.porcelana.com">www.porcelana.com</a></p>	Active Ingredients	Purpose	Hydroquinone U.S.P. 2% Octyl methoxycinnamate 2.5%	Skin Lightener Sunscreen	<p><b>Drug Facts (continued)</b></p> <p><b>Directions</b> Adults apply a small amount as a thin layer on the affected area(s) twice daily 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><b>Other Information</b> • This product is not for use in the prevention of sunburn. • Lightening effect of this product may not be noticeable when used on very dark skin. • 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> <p><b>Inactive Ingredients</b> Water, Mineral Oil, Glyceryl Stearate, Cetyl Alcohol, Isopropyl Palmitate, PEG-100 Stearate, Propylene Glycol, Emulsifying Wax NF, Stearic Acid, Hydroxyethylcellulose, Tocopheryl Acetate, Magnesium Ascorbyl Phosphate, Beta-Carotene, Disodium EDTA, C13-14 Isoparaffin, Sodium Meta-bisulfite, Citric Acid, BHT, Methylparaben, Propylparaben, Diazolidinyl Urea, Fragrance</p> <p><small>©2011 Distributed by: Ulmark Products™ Plymouth Meeting, PA 19462 • Made in USA</small></p>	<p><b>PORCELANA®</b> FOR BALANCED SKIN TONE</p> <p><b>DAY</b> SKIN LIGHTENING CREAM FADES DARK SPOTS • EVENS SKIN TONE</p> <p>Protects With Anti-Oxidants &amp; Sunscreen</p> <p>Net Wt 3 oz/85 g</p>	<p>Do you know why Porcelana® is known for Balancing Skin Tone? For over 40 years, its innovative blend of the highest quality ingredients has delivered proven results for fading blemishes and discolored skin. Take the advice of generations of women who have trusted Porcelana® to give them the look of flawless skin.</p> <p>Porcelana® Day fades away dull, uneven skin tones and lets radiant, flawless skin shine through. Formulated with Hydroquinone, the most effective lightening ingredient, Porcelana® Day fades discolorations, blemishes and dark spots caused by sun exposure, acne, pregnancy or oral contraceptives. Light enough to wear under makeup or alone, it contains anti-oxidants and a sunscreen to help protect skin from daytime environmental damage. Your skin will look clearer, more even and ready to face a new day. Use with Porcelana® Night for optimal results.</p>
Active Ingredients	Purpose						
Hydroquinone U.S.P. 2% Octyl methoxycinnamate 2.5%	Skin Lightener Sunscreen						

hydroquinone and octinoxate cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:51545-110
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROQUINONE (UNII: XV74C1N1AE) (HYDROQUINONE - UNII:XV74C1N1AE)	HYDROQUINONE	0.02 g in 1 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.025 g 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)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
MAGNESIUM ASCORBYL PHOSPHATE (UNII: 0R822556M5)	
.BETA.-CAROTENE (UNII: 01YAE03M7J)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51545-110-03	1 in 1 BOX	12/14/2017	
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	04/01/2011	

**Labeler** - Ultimark Products LLC (964734078)

**Registrant** - Humco Holding Group, Inc. (825672884)

Revised: 12/2017

Ultimark Products LLC