

**IDOLE BLACK - hydroquinone cream**  
**International Beauty Exchange**

*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**

Hydroquinone 2%

For external use only

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

Avoid contact with eyes

Skin Lightener

For the gradual fading of dark areas in the skin such as freckles, age and liver spots

Apply a small amount as a thin layer on the affected area twice daily, or use as directed by a doctor

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

WATER, ALCOHOL, GLYCERIN, CARBOMER COPOLYMER TYPE A, COCOA BUTTER, .ALPHA.-TOCOPHEROL ACETATE, D-, ASCORBIC ACID, SODIUM METABISULFITE, EDTATE DISODIUM, BUTYLATED HYDROXYTOLUENE, IRON OXIDES



La **CREME NOIR IDOLE** aide à éliminer les **MARQUES** et les **TACHES**.

**INDICATIONS:** Elle éclaircit les pigments foncés de la peau, tels que les taches de rousseur les taches de vieillissement ou les décolorations de la peau.

**AVERTISSEMENT:** Uniquement pour usage externe. Eviter le contact avec les yeux. En cas d'irritation, arrêter l'utilisation.

La **CREMA NEGRA IDOLE** ayuda a eliminar **MARCAS** y **MANCHAS**.

**INDICACIONES:** Aclara las pigmentaciones oscuras de la piel tales como las pecas, las manchas de envejecimiento o la decoloración de la piel.

**PRECAUCIONES:** Sólo para uso externo. Evitar el contacto con los ojos. En caso de irritación, interrumpir el uso.

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| <b>Drug Facts</b>   | <ul style="list-style-type: none"> <li>Some users of this product may experience a mild skin irritation. If skin irritation becomes severe, stop use and consult a doctor.</li> <li>Keep out of the reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</li> </ul>   |
| <b>Active ingredients</b><br>Hydroquinone 2% .....  | <b>Purpose</b><br>Skin Lightener  |
| <b>Uses:</b> Gradually fades skin discolorations such as age spots, freckles, scars.  | <b>Directions:</b> <ul style="list-style-type: none"> <li>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.</li> <li>Children under 12 years of age: Do not use unless directed by a doctor.</li> <li>Sun exposure should be limited by using a sunscreen agent, a sun blocking agent or protective clothing to cover bleached skin after treatment is complete in order to prevent darkening from reoccurring.</li> </ul> |
| <b>Warnings:</b> For external use only  | <b>Inactive ingredients:</b><br>Water (Aqua), Alcohol denat, Glycerin, TEA-Acrylates/C10-30 Alkyl acrylates crosspolymer, Theobroma Cacao (Cocoa Extract), Fragrance (Parfum), Tocopheryl Acetate, Ascorbic Acid, Sodium Metabisulfite, Disodium EDTA, BHT, Iron Oxides.  |
| <b>Do not use:</b> <ul style="list-style-type: none"> <li>On children under 12 years of age unless directed by a doctor.</li> </ul> |   |
| <b>When using this product:</b> <ul style="list-style-type: none"> <li>Avoid contact with eyes.</li> </ul>                          |   |

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| <b>IDOLE BLACK</b><br>hydroquinone cream |
| <b>Product Information</b>               |

|  |   |                             |                             |                           |
|--|---|-----------------------------|-----------------------------|---------------------------|
| <b>Product Type</b>  | HUMAN OTC DRUG                                  | <b>Item Code (Source)</b>   | NDC:66 129-412              |                           |
| <b>Route of Administration</b>                                   | TOPICAL   |                             |                             |                           |
| <b>Active Ingredient/Active Moiety</b>                           |   |                             |                             |                           |
| <b>Ingredient Name</b>   |   | <b>Basis of Strength</b>    | <b>Strength</b>             |                           |
| HYDROQUINONE (UNII: XV74C1N1AE) (HYDROQUINONE - UNII:XV74C1N1AE) |   | HYDROQUINONE                | 1 g in 50 g                 |                           |
| <b>Inactive Ingredients</b>                                      |   |                             |                             |                           |
| <b>Ingredient Name</b>   |   |                             | <b>Strength</b>             |                           |
| WATER (UNII: 059QF0KO0R)   |   |                             |                             |                           |
| ALCOHOL (UNII: 3K9958V90M)                                       |   |                             |                             |                           |
| GLYCERIN (UNII: PDC6A3C0OX)                                      |   |                             |                             |                           |
| CARBOMER COPOLYMER TYPE A (UNII: 71DD5V995L)                     |   |                             |                             |                           |
| COCOA BUTTER (UNII: 512OYT1CRR)                                  |   |                             |                             |                           |
| .ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)                |   |                             |                             |                           |
| ASCORBIC ACID (UNII: PQ6CK8PD0R)                                 |   |                             |                             |                           |
| SODIUM METABISULFITE (UNII: 4VON5FNS3C)                          |   |                             |                             |                           |
| EDETATE DISODIUM (UNII: 7FLD91C86K)                              |   |                             |                             |                           |
| BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)                      |   |                             |                             |                           |
| <b>Product Characteristics</b>                                   |   |                             |                             |                           |
| <b>Color</b>   | white   | <b>Score</b>                |                             |                           |
| <b>Shape</b>   |   | <b>Size</b>                 |                             |                           |
| <b>Flavor</b>  |   | <b>Imprint Code</b>         |                             |                           |
| <b>Contains</b>  |   |                             |                             |                           |
| <b>Packaging</b>   |   |                             |                             |                           |
| #  | <b>Item Code</b>                                | <b>Package Description</b>  | <b>Marketing Start Date</b> | <b>Marketing End Date</b> |
| 1  | NDC:66 129-412-31                               | 50 g in 1 TUBE              |                             |                           |
| <b>Marketing Information</b>                                     |   |                             |                             |                           |
| <b>Marketing Category</b>  | <b>Application Number or Monograph Citation</b> | <b>Marketing Start Date</b> | <b>Marketing End Date</b>   |                           |
| OTC monograph not final  | part358A  | 01/01/2011                  |                             |                           |

**Labeler** - International Beauty Exchange (966261273)

### Establishment

| Name             | Address | ID/FEI    | Business Operations |
|------------------|---------|-----------|---------------------|
| JABONES PARDO SA |         | 462018250 | manufacture         |

