

TEATRICAL PRO-ACLARANT SKIN LIGHTENING- hydroquinone cream
Genomma Lab USA

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.

Teatrical® Pro-Aclarant Skin Lightening Cream

Drug Facts

Active ingredient

Hydroquinone 2%

Purpose

Skin Lightener

Use

Lightens dark (brownish) spots, blotches, freckles and discolorations of the skin.

Warnings

For external use only

Do not use on children under 12 years of age unless directed by a doctor.

When using this product

- you may experience mild skin irritation
- avoid contact with eyes.

Stop use and consult a doctor if skin irritation becomes severe.

If pregnant or breast-feeding, ask a doctor before use.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

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.
- Exposure to the sun should be limited by using a sunscreen agent, sun blocking agent or protective clothing to cover bleached skin when using and after treatment is completed in order to prevent darkening from reoccurring.

Other information

- Keep tightly closed.
- Store at room temperature.

Inactive ingredients

water, mineral oil, glyceryl stearate, cetyl alcohol, isopropyl myristate, PEG-100 stearate, propylene glycol, cetearyl alcohol, polysorbate 60, sodium metabisulfite, stearic acid, tocopheryl acetate, beta-carotene, diazolidinyl urea, iodopropynyl butylcarbamate, fragrance

Questions or comments?

Call toll free **1-877-994-3666**

Distributed by:

Genomma Lab USA Inc., Houston,
TX 77027

PRINCIPAL DISPLAY PANEL - 48 g Tube Carton

teatrical®

PRO-ACLARANT
SKIN LIGHTENING

NIGHT
CREAM

HYDROQUINONE 2%

Lightens dark spots

NET WT 1.7 OZ (48 g)


Teatrical
PRO-ACLARANT
 SKIN LIGHTENING


Teatrical
PRO-ACLARANT
 SKIN LIGHTENING

**NIGHT
 CREAM**

**CREMA ACLARADORA
 DE NOCHE**

**HYDROQUINONE 2%
 HIDROQUINONA 2%**

Lightens dark spots
 A clara las manchas oscuras

NET WT 1.7 OZ (48 g)

**Información
 del Medicamento (cont.)**

- Niños menores de 12 años de edad: No se utilice a menos que sea indicado por su médico.
- La exposición al sol deberá de ser limitada mediante el uso de un protector solar, bloqueador solar o ropa protectora para cubrir la piel aclarada durante el tratamiento y después de terminarlo para prevenir el oscurecimiento recurrente.

Información Adicional

- Manténgase cerrada herméticamente.
- Almacenar a temperatura ambiente.

Ingredientes inactivos agua, ácido mineral, estearato de glicerilo, alcohol cetílico, minixtrato de isopropilo, PEG-100 estearato, propilenglicol, alcohol cetílico, polisorbato 80, metabisulfito de sodio, ácido esteárico, acetato de tocoferol, beta-caroteno, diazolidinil urea, iodopropinil butilcarbamato, fragancia

¿Preguntas o comentarios?
 Llame al 1-877-994-3666

Este producto desvanece gradualmente las manchas oscuras y decoloraciones.

Su piel lucirá más clara y uniforme. Formulada con hidroquinona, un eficaz ingrediente aclarador de piel. Esta crema es lo suficientemente ligera para usarla sin maquillaje o con él.



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Drug Facts

Active ingredient *Purpose*
 Hydroquinone 2%.....Skin Lightener

Use Lightens dark (brownish) spots, blotches, freckles and discolorations of the skin.

Warnings

For external use only

Do not use on children under 12 years of age unless directed by a doctor.

When using this product

- you may experience mild skin irritation
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Stop use and consult a doctor if skin irritation becomes severe.

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• Exposure to the sun should be limited by using a sunscreen agent, sun blocking agent or protective clothing to cover bleached skin when using and after treatment is completed in order to prevent darkening from recurring.

Other information

- Keep tightly closed.
- Store at room temperature.

Inactive ingredients water, mineral oil, glyceryl stearate, cetyl alcohol, isopropyl myristate, PEG-100 stearate, propylene glycol, cetearyl alcohol, polysorbate 80, sodium metabisulfite, stearic acid, tocopheryl acetate, beta-carotene, diazolidinyl urea, iodopropinyl butylcarbamate, fragrance

Questions or comments?

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**Información
 del Medicamento**

Ingrediente Activo *Propósito*
 Hidroquinona 2%...Aclarador dérmico

Uso Aclara las manchas oscuras, paño, pecas y decoloraciones de la piel.

Advertencias

Únicamente para uso externo

No la utilice en niños menores de 12 años a menos que sea indicado por un médico.

Cuando utilice este producto

- puede experimentar una leve irritación dérmica.
- Evite el contacto con los ojos.

Suspenda el uso y consulte a su médico si la irritación se vuelve severa.

En caso de embarazo o lactancia, consulte a su médico antes de utilizarlo.

Manténgase fuera del alcance de los niños. En caso de ser ingerida, obtenga ayuda médica o contacte al Centro de Control de Envenenamientos de manera inmediata.

Indicaciones

• Adultos: Aplicar una pequeña cantidad en forma de una capa delgada sobre el área afectada dos veces al día, o úsela de acuerdo a las indicaciones del médico. Si no observa mejoría después de 3 meses de tratamiento, deberá de suspender el uso de este producto. El efecto de aclaración de este producto puede no ser notable cuando se usa sobre piel muy oscura.

This cream gradually fades dark (brownish) spots and discolorations.

Your skin will look clearer. Formulated with the effective skin lightening ingredient hydroquinone, this cream is light enough to use under makeup or alone.



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TEATRICAL PRO-ACLARANT SKIN LIGHTENING

hydroquinone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50066-072
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

Inactive Ingredients

Ingredient Name	Strength
Mineral oil (UNII: T5L8T28FGP)	
Isopropyl myristate (UNII: 0RE8K4LNJS)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Cetyl alcohol (UNII: 936JST6JCN)	
Polysorbate 60 (UNII: CAL22UVI4M)	
PEG-100 stearate (UNII: YD01N1999R)	

Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50066-072-01	1 in 1 CARTON	04/22/2020	
1		48 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	04/22/2020	

Labeler - Genomma Lab USA (832323534)