

TEATRICAL PRO-ACLARANT DAY- avobenzone, octinoxate, and octocrylene 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 Day Cream

Drug Facts

<i>Active ingredients</i>	<i>Purpose</i>
Avobenzone 3.0%	Sunscreen
Octinoxate 7.0%	Sunscreen
Octocrylene 5.0%	Sunscreen

Use

- helps prevent sunburn

Warnings

For external use only

Do not use on damaged or broken skin

When using this product keep out of eyes. Rinse with water to remove.

Stop use and ask a doctor if rash occurs

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

Directions

For sunscreen use

- apply generously and evenly 15 minutes before sun exposure. Reapply at least every 2 hours
- use a water resistant sunscreen if swimming or sweating.

Sun Protection Measures

Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other skin protection measures including:

- limit time in the sun, especially from 10am to 2pm
- wear long-sleeved shirts, pants, hats and sunglasses
- children under 6 months of age: ask a doctor

Other information

- protect from excessive heat and direct sun.
- may stain some fabrics.
- keep this carton for future reference.

Inactive ingredients

WATER, CETYL ALCOHOL, CAPRYLIC/CAPRIC TRIGLYCERIDE, BUTYLENE GLYCOL, DIMETHICONE, GLYCERYL STEARATE, PEG-100 STEARATE, ISOPROPYL PALMITATE, POLYACRYLATE-13, POLYISOBUTENE, POLYSORBATE 20, BUTYROSPERMUM PARKII BUTTER, PANTHENOL, STEARETH-20, SODIUM HYALURONATE, NIACINAMIDE, TETRAHEXYLDECYL ASCORBATE, CAMELLIA SINENSIS LEAF EXTRACT, PHENOXYETHANOL, BENZOIC ACID, ETHYLHEXYLGLYCERIN.

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

WITH SUNSCREEN

teatrical®

PRO-ACLARANT
SKIN BRIGHTENING

DAY
CREAM

15
SPF BROAD SPECTRUM

VITAMIN B3 &
WHITE TEA EXTRACT

Helps unify skin tone
Prevents sun damage on skin

NET WT 1.7 OZ (48 g)

WITH SUNSCREEN / CON FILTRO SOLAR

Teatrical
PRO-ACLARANT
SKIN BRIGHTENING

WITH SUNSCREEN / CON FILTRO SOLAR

Teatrical
PRO-ACLARANT
SKIN BRIGHTENING

**DAY
CREAM**

CREMA ILUMINADORA
DE DIA

15 SPF BROAD SPECTRUM
FPS AMPLIO ESPECTRO

**VITAMIN B3 &
WHITE TEA EXTRACT**
VITAMINA B3 Y EXTRACTO DE TÉ BLANCO

Helps unify skin tone
Prevents sun damage on skin
Ayuda a unificar el tono de la piel
Previene del daño solar en la piel

NET WT 1.7 OZ (48 g)

hasta las 2:00 p. m.
• usar camisas de manga larga,
pantalones, sombrero y anteojos de
sol
• niños menores de 6 meses:
consultar al médico

Otra información
• proteger del calor excesivo y los
rayos directos del sol. • puede
manchar algunas telas. • guarde
este cartón para referencia futura.

Ingredientes Inactivos:
AGUA, ALCOHOL CETILICO,
TRIGLICERIDO CAPRICO/CAPRILICO,
BUTILEN GLICOL, DIMETICONA,
GLICERIL ESTEARATO, PEG-100
ESTEARATO, ISOPROPIL PALMITATO,
POLIACRILATO-13, POLIISOBUTENO,
POLISORBATO 20, MANTECA DE
BUTIROSPERMIUM PARKII,
PANTENOL, ESTEARETH-20,
HYALURONATO DE SODIO,
NIACINAMIDA, ASCORBATO DE
TETRAHEXILDECIL, EXTRACTO DE
CAMELLIA SINENSIS,
FENOXYETANOL, ACIDO BENZOICO,
ETILHEXIL GLICERINA.

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

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Datos del Medicamento

Principios activos	Propósito
Avobenzone 3.0%	Filtro solar
Octinoxato 7.0%	Filtro solar
Octocrileno 5.0%	Filtro solar

Uso • ayuda a prevenir las quemaduras solares

Precauciones

Para uso externo únicamente
No aplicar sobre la piel dañada o herida

Al usar este producto evitar el contacto con los ojos. Enjuagar con agua para retirar.

Suspender el uso y consultar al médico si aparecen sarpullidos

Mantener fuera del alcance de los niños. Si se ingiere, buscar ayuda médica o comunicarse con un centro de toxicología de inmediato.

Instrucciones

Para usar como filtro solar:

• aplicar de forma uniforme y abundante 15 minutos antes de exponerse al sol. Repetir la aplicación al menos cada 2 horas
• usar un filtro solar resistente al agua en caso de nadar o transpirar.

Medidas de protección contra el sol: Pasar tiempo al sol aumenta el riesgo de cáncer de piel y envejecimiento prematuro de la piel. Para disminuir este riesgo, use regularmente un filtro solar con valor FPS 15 de amplio espectro o mayor y otras medidas de protección de la piel, incluyendo: • limitar la exposición al sol, especialmente desde las 10:00 a.m.



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Lot/ Lote:
Exp:

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TEATRICAL PRO-ACLARANT DAY

avobenzone, octinoxate, and octocrylene cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50066-071
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Avobenzone (UNII: G63QQF2NOX) (Avobenzone - UNII:G63QQF2NOX)	Avobenzone	30 mg in 1 g
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	70 mg in 1 g
Octocrylene (UNII: 5A68WGF6WM) (Octocrylene - UNII:5A68WGF6WM)	Octocrylene	50 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
Cetyl alcohol (UNII: 936JST6JCN)	
PEG-100 stearate (UNII: YD01N1999R)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
Butylene Glycol (UNII: 3XUS85K0RA)	
Dimethicone (UNII: 92RU3N3Y1O)	

Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50066-071-01	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	part352	04/22/2020	

Labeler - Genomma Lab USA (832323534)