

**ANUBIS BARCELONA REGUL OIL- cetearyl ethylhexanoate, propylene glycol, glyceryl stearate se cream  
ANUBIS COSMETICS SL**

*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.*

Serum indicado en pieles grasas y/o acneicas. Equilibra, regula e hidrata. Formulado con PHYTO-TIOXOLONE, complejo exclusivo de Anubis, elimina eficazmente el exceso de brillo en la piel sin alterar el manto hidrolipídico y manteniendo el nivel óptimo de hidratación. Con propiedades astringentes y calmantes, regulan la secreción sebácea. Contiene filtro solar.

Modo de empleo: Con la piel limpia, aplicar en cara y cuello, mediante un ligero masaje hasta su total absorción.

Uso diario, mañana y/o noche.

Serum indicated for oily and/or acneic skins. It balances, normalizes and hydrates. Formulated with exclusive Anubis formula: PHYTO-TIOXOLONE, effectively removes excess shine from the skin without altering the hydrolipidic film and ensures the optimal level of hydration. Due to its astringent and soothing properties, it regulates sebum production. Contains sunscreen.

How to use: On clean skin, apply it to the face and neck, with a softly massaging until completely absorbed.

Daily use, day and/or night.

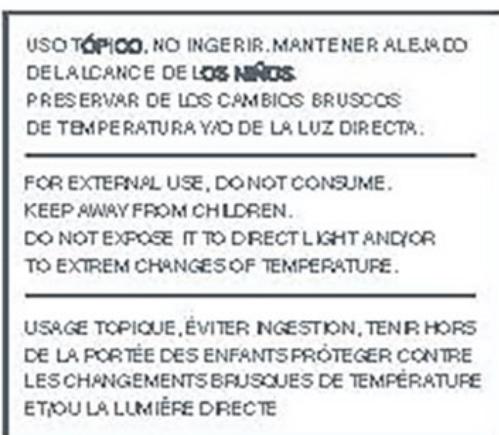
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Conseils d'utilisation : Appliquer sur le visage et le cou en massant légèrement jusqu'à pénétration complète.

Utilisation quotidienne, matin et/ou soir.

Ingredients: AQUA (WATER), CETEARYL ETHYLHEXANOATE, PROPYLENE GLYCOL, GLYCERYL STEARATE SE, C12-20 ACID PEG-8 ESTER, ETHYLHEXYL METHOXYCINNAMATE, ALCOHOL DENAT, PEG-40 HYDROGENATED CASTOR OIL, BENZOPHENONE-3, PHENOXYETHANOL, CARBOMER, TRIETHANOLAMINE, METHYLPARABEN, CETYL PHOSPHATE, PARFUM (FRAGRANCE), IMIDAZOLIDINYL UREA, TIOXOLONE, PROPYLPARABEN, ALLANTOIN, DISODIUM EDTA, HYDROXYETHYLCELLULOSE, BHT, FAEX EXTRACT, MELALEUCA ALTERNIFOLIA LEAF OIL, GLYCERIN, LIMONENE, PANthenol, CITRIC ACID, LINALOOL, NIACINAMIDE, CETYL ALCOHOL, THIAMINE HCL, CI 19140, CITRAL, CAMELLIA SINENSIS LEAF EXTRACT, HEXYL CINNAMAL, SODIUM ACETATE, BENZYL

BENZOATE, COUMARIN, ARCTIUM MAJUS ROOT EXTRACT, GERANIOL, ISOPROPYL ALCOHOL, PYRIDOXINE HCL, SODIUM CHLORIDE, CELLULOSE, POTASSIUM SORBATE, SODIUM BENZOATE, RIBOFLAVIN.  
CONTIENE / CONTAINS: BENZOPHENONE-3.



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**ANUBIS COSMETICS, S.L.**  
Frederic Soler 110  
08205 Sabadell (Barcelona)  
Made in Spain / Fabriqué en Espagne  
[www.anubis-cosmetics.com](http://www.anubis-cosmetics.com)

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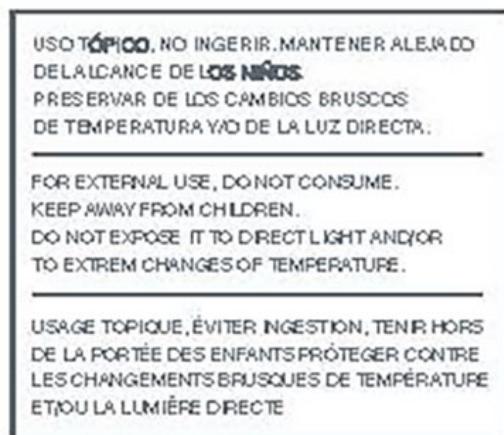
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Formulado para DENTRO TIPOLOGÍAS: COMPLEXION SEBOACNEICA - ACNEICA - SEBÁCEA.

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CONTIENE / CONTAINS: BENZOPHENONE-3.



LES CHANGEMENTS BRUSQUES DE TEMPERATURE  
ET LA LUMIÈRE DIRECTE

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CONTIENE / CONTAINS: BENZOPHENONE-3.

USO TÓPICO. NO INGERIR. MANTENER ALEJADO  
DE LA DEDICACIÓN DE LOS NIÑOS.

PRESERVAR DE LOS CAMBIOS BRUSCOS  
DE TEMPERATURA Y/O DE LA LUZ DIRECTA.

FOR EXTERNAL USE, DO NOT CONSUME.  
KEEP AWAY FROM CHILDREN.  
DO NOT EXPOSE IT TO DIRECT LIGHT AND/OR  
TO EXTREM CHANGES OF TEMPERATURE.

USAGE TOPIQUE, ÉVITER INGESTION, TENIR HORS  
DE LA PORTÉE DES ENFANTS PROTÉGER CONTRE  
LES CHANGEMENTS BRUSQUES DE TEMPÉRATURE  
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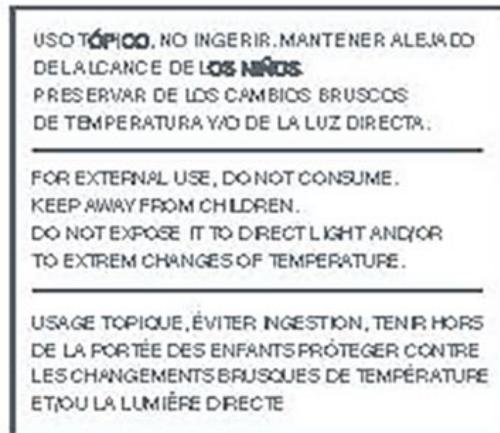
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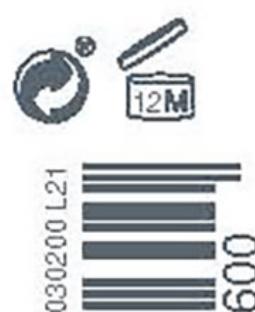
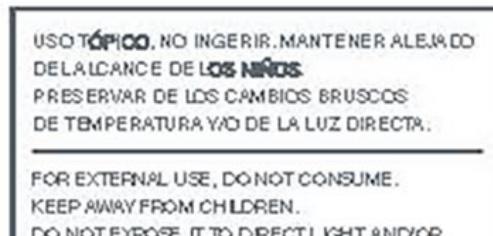
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TO EXTREM CHANGES OF TEMPERATURE.

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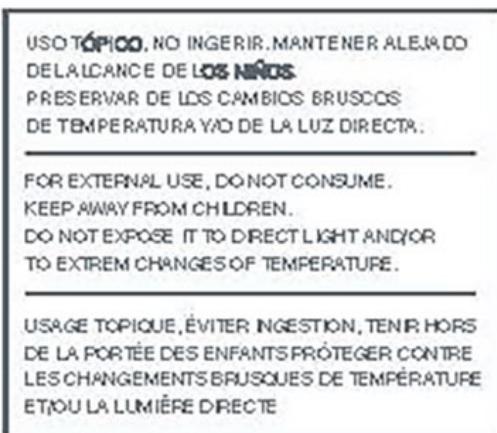
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skin and ensures the optimal level of hydration. Due to its astringent and soothing properties, it regulates sebum production. Contains sunscreen.

How to use: On clean skin, apply it to the face and neck, with a softly massaging until completely absorbed.

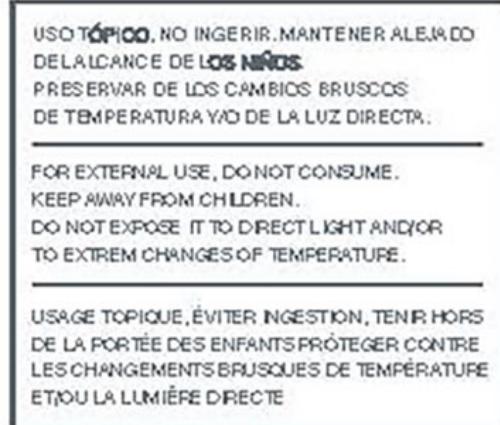
Daily use, day and/or night.

Sérum indiqué pour les peaux grasses et/ou acnéiques. Équilibre, régule et hydrate. Formulé avec PHYTO-TIOXOLONE, un complexe exclusif d'Anubis, qui élimine efficacement l'effet brillance sans altérer le film hydrolipidique tout en gardant une hydratation optimale. Propriétés astringentes et calmantes, qui régule la sécrétion sébacée. Contient filtre solaire.

Conseils d'utilisation : Appliquer sur le visage et le cou en massant légèrement jusqu'à pénétration complète.

Utilisation quotidienne, matin et/ou soir.

Ingredients: AQUA (WATER), CETEARYL ETHYLHEXANOATE, PROPYLENE GLYCOL, GLYCERYL STEARATE SE, C12-20 ACID PEG-8 ESTER, ETHYLHEXYL METHOXYCINNAMATE, ALCOHOL DENAT, PEG-40 HYDROGENATED CASTOR OIL, BENZOPHENONE-3, PHENOXYETHANOL, CARBOMER, TRIETHANOLAMINE, METHYLPARABEN, CETYL PHOSPHATE, PARFUM (FRAGRANCE), IMIDAZOLIDINYL UREA, TIOXOLONE, PROPYLPARABEN, ALLANTOIN, DISODIUM EDTA, HYDROXYETHYLCELLULOSE, BHT, FAEX EXTRACT, MELALEUCA ALTERNIFOLIA LEAF OIL, GLYCERIN, LIMONENE, PANthenol, CITRIC ACID, LINALOOL, NIACINAMIDE, CETYL ALCOHOL, THIAMINE HCL, CI 19140, CITRAL, CAMELLIA SINENSIS LEAF EXTRACT, HEXYL CINNAMAL, SODIUM ACETATE, BENZYL BENZOATE, COUMARIN, ARCTIUM MAJUS ROOT EXTRACT, GERANIOL, ISOPROPYL ALCOHOL, PYRIDOXINE HCL, SODIUM CHLORIDE, CELLULOSE, POTASSIUM SORBATE, SODIUM BENZOATE, RIBOFLAVIN.  
CONTIENE / CONTAINS: BENZOPHENONE-3.



Manufactured by:  
**ANUBIS COSMETICS, S.L.**  
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Made in Spain / Fabriqué en Espagne  
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**ANUBIS**  
barcelona

ro

REGUL OIL

Serum  
hydro-equilibrant

COMPLEJO REGULADOR  
PIELES GRASAS Y ACNÉICAS  
CON TIOXOLONA, ACEITE  
DE ÁRBOL DE TÉ Y BARDANA

BALANCING COMPLEX OILY  
AND ACNEIC SKIN WITH  
TIOXOLONE, TEA TREE OIL  
AND BURDOCK



## ANUBIS BARCELONA REGUL OIL

cetearyl ethylhexanoate, propylene glycol, glyceryl stearate se cream

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83021-742
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GLYCERIN (UNII: PDC6A3C0OX) (GLYCERIN - UNII:PDC6A3C0OX)	GLYCERIN	0.08784 g in 200 mL
GERANIOL (UNII: L837108USY) (GERANIOL - UNII:L837108USY)	GERANIOL	0.003398 g in 200 mL
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	0.002132 g in 200 mL
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	3.5436 mL in 200 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	1.6 g in 200 mL
PHENOXYETHANOL (UNII: HIE492ZZ3T) (PHENOXYETHANOL - UNII:HIE492ZZ3T)	PHENOXYETHANOL	1.3 g in 200 mL

<b>TEA TREE OIL</b> (UNII: VIF565UC2G) (TEA TREE OIL - UNII:VIF565UC2G)	TEA TREE OIL	0.1 g in 200 mL
<b>IMIDUREA</b> (UNII: M629807ATL) (IMIDUREA - UNII:M629807ATL)	IMIDUREA	0.4 g in 200 mL
<b>WATER</b> (UNII: 059QF0KO0R) (WATER - UNII:059QF0KO0R)	WATER	155.839258 mL in 200 mL
<b>GLYCERYL STEARATE SE</b> (UNII: FCZ5MH785I) (GLYCERYL STEARATE SE - UNII:FCZ5MH785I)	GLYCERYL STEARATE SE	6 g in 200 mL
<b>CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE</b> (UNII: 0A5MM307FC) (CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE - UNII:0A5MM307FC)	CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE	0.8 g in 200 mL
<b>TIOXOLONE</b> (UNII: S0FAJ1R9CD) (TIOXOLONE - UNII:S0FAJ1R9CD)	TIOXOLONE	0.3 g in 200 mL
<b>LINALOOL, (+/-)-</b> (UNII: D81QY6I88E) (LINALOOL, (+/-)- - UNII:D81QY6I88E)	LINALOOL, (+/-)-	0.026404 g in 200 mL
<b>FD&amp;C YELLOW NO. 5</b> (UNII: I753WB2F1M) (FD&C YELLOW NO. 5 - UNII:I753WB2F1M)	FD&C YELLOW NO. 5	0.01044 g in 200 mL
<b>BENZYL BENZOATE</b> (UNII: N863NB338G) (BENZYL BENZOATE - UNII:N863NB338G)	BENZYL BENZOATE	0.004 g in 200 mL
<b>PANTHENOL</b> (UNII: W9CM0O67Z) (PANTHENOL - UNII:W9CM0O67Z)	PANTHENOL	0.04 g in 200 mL
<b>COUMARIN</b> (UNII: A4VZ22K1WT) (COUMARIN - UNII:A4VZ22K1WT)	COUMARIN	0.003924 g in 200 mL
<b>C12-20 ACID PEG-8 ESTER</b> (UNII: 9M7A3K4339) (C12-20 ACID PEG-8 ESTER - UNII:9M7A3K4339)	C12-20 ACID PEG-8 ESTER	4 g in 200 mL
<b>ARCTIUM LAPPA ROOT</b> (UNII: 597E9BI3Z3) (ARCTIUM LAPPA ROOT - UNII:597E9BI3Z3)	ARCTIUM LAPPA ROOT	0.003512 g in 200 mL
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH) (PROPYLPARABEN - UNII:Z8IX2SC1OH)	PROPYLPARABEN	0.28 g in 200 mL
<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN) (CETYL ALCOHOL - UNII:936JST6JCN)	CETYL ALCOHOL	0.015 g in 200 mL
<b>YEAST, UNSPECIFIED</b> (UNII: 3NY3SM6B8U) (YEAST, UNSPECIFIED - UNII:3NY3SM6B8U)	YEAST, UNSPECIFIED	0.1 g in 200 mL
<b>RIBOFLAVIN</b> (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR)	RIBOFLAVIN	0.00012 g in 200 mL
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3) (PROPYLENE GLYCOL - UNII:6DC9Q167V3)	PROPYLENE GLYCOL	6.469044 g in 200 mL
<b>CETEARYL ETHYLHEXANOATE</b> (UNII: 9M64UO4C25) (CETEARYL ETHYLHEXANOATE - UNII:9M64UO4C25)	CETEARYL ETHYLHEXANOATE	10 g in 200 mL
<b>HYDROXYETHYL CELLULOSE, UNSPECIFIED</b> (UNII: T4V6TWG28D) (HYDROXYETHYL CELLULOSE, UNSPECIFIED - UNII:T4V6TWG28D)	HYDROXYETHYL CELLULOSE, UNSPECIFIED	0.12863 g in 200 mL
<b>BUTYLATED HYDROXYTOLUENE</b> (UNII: 1P9D0Z171K) (BUTYLATED HYDROXYTOLUENE - UNII:1P9D0Z171K)	BUTYLATED HYDROXYTOLUENE	0.104 g in 200 mL
<b>CITRAL</b> (UNII: T7EU0O9VPP) (CITRAL - UNII:T7EU0O9VPP)	CITRAL	0.01032 g in 200 mL
<b>GREEN TEA LEAF</b> (UNII: W2ZU1RY8B0) (GREEN TEA LEAF - UNII:W2ZU1RY8B0)	GREEN TEA LEAF	0.00679 g in 200 mL
<b>ALLANTOIN</b> (UNII: 344S277G0Z) (ALLANTOIN - UNII:344S277G0Z)	ALLANTOIN	0.2 g in 200 mL
<b>LIMONENE, (+)-</b> (UNII: GFD7C86Q1W) (LIMONENE, (+)- - UNII:GFD7C86Q1W)	LIMONENE, (+)-	0.061818 g in 200 mL
<b>NIACINAMIDE</b> (UNII: 25X51I8RD4) (NIACINAMIDE - UNII:25X51I8RD4)	NIACINAMIDE	0.02 g in 200 mL
<b>POWDERED CELLULOSE</b> (UNII: SMD1X3X09M) (POWDERED CELLULOSE - UNII:SMD1X3X09M)	POWDERED CELLULOSE	0.001066 g in 200 mL
<b>POLYOXYL 40 HYDROGENATED CASTOR OIL</b> (UNII: 7YC686GQ8F) (POLYOXYL 40 HYDROGENATED CASTOR OIL - UNII:7YC686GQ8F)	POLYOXYL 40 HYDROGENATED CASTOR OIL	1.8 g in 200 mL
<b>.ALPHA.-HEXYLCINNAMALDEHYDE</b> (UNII: 7X6O37OK2I) (.ALPHA.-	.ALPHA.-	0.00574 g

HEXYLCINNAMALDEHYDE - UNII:7X6O37OK2I)	HEXYLCINNAMALDEHYDE	in 200 mL
<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	3.996 g in 200 mL
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T) (METHYLPARABEN - UNII:A2I8C7HI9T)	METHYLPARABEN	0.6 g in 200 mL
<b>FRAGRANCE 13576</b> (UNII: 5EM498GW35) (FRAGRANCE 13576 - UNII:5EM498GW35)	FRAGRANCE 13576	0.5 g in 200 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>PYRIDOXINE HYDROCHLORIDE</b> (UNII: 68Y4CF58BV)	0.002 g in 200 mL
<b>CETYL PHOSPHATE</b> (UNII: VT07D6X67O)	0.585 g in 200 mL
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	0.000892 g in 200 mL
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	0.00156 g in 200 mL
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	0.03 g in 200 mL
<b>THIAMINE HYDROCHLORIDE</b> (UNII: M572600E5P)	0.012 g in 200 mL
<b>EDETADE DISODIUM ANHYDROUS</b> (UNII: 8NLQ36F6MM)	0.2 g in 200 mL
<b>TROLAMINE</b> (UNII: 9O3K93S3TK)	0.8 mL in 200 mL
<b>POTASSIUM SORBATE</b> (UNII: 1VPU26JZZ4)	0.000892 g in 200 mL
<b>SODIUM ACETATE</b> (UNII: 4550K0SC9B)	0.00462 g in 200 mL

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83021-742-01	200 mL in 1 TUBE; Type 0: Not a Combination Product	10/19/2022	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M006	10/19/2022	02/20/2027

**Labeler** - ANUBIS COSMETICS SL (468680293)

**Registrant** - GDC OF FLORIDA IMPORTS, INC. (807003988)

## Establishment

Name	Address	ID/FEI	Business Operations
ANUBIS COSMETICS SL		468680293	manufacture(83021-742)

Revised: 9/2023

ANUBIS COSMETICS SL