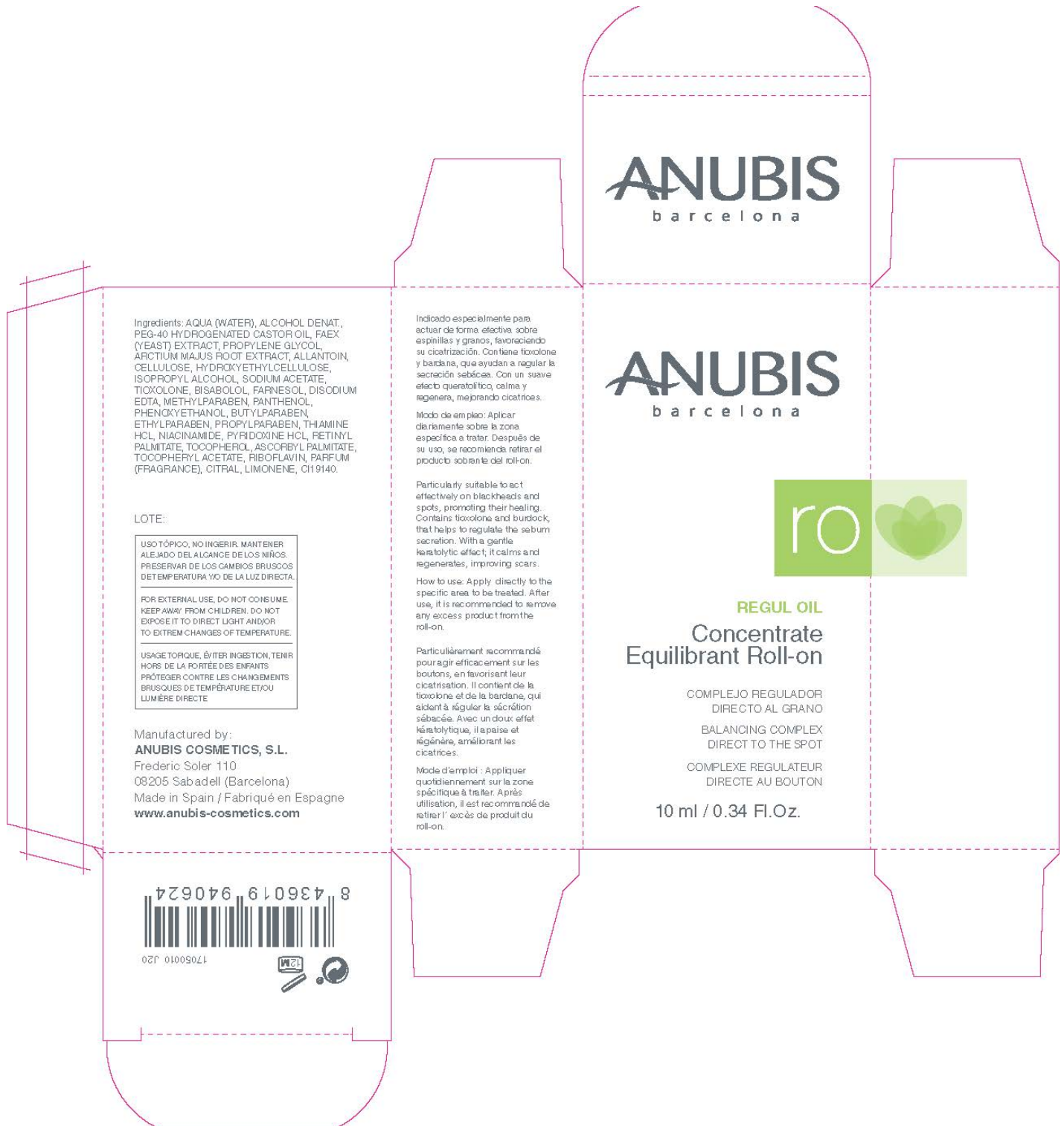


**ANUBIS BARCELONA REGUL OIL- peg-40 hydrogenated castor oil, propylene glycol, arctium majus root extract concentrate**  
**ANUBIS COSMETICS SL**

*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.*



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**REGUL OIL**  
**Concentrate**  
**Equilibrant Roll-on**

COMPLEJO REGULADOR  
DIRECTO AL GRANO

BALANCING COMPLEX  
DIRECT TO THE SPOT

COMPLEXE REGULATEUR  
DIRECTE AU BOUTON

10 ml / 0.34 Fl.Oz.

Ingredients: AQUA (WATER), ALCOHOL DENAT., PEG-40 HYDROGENATED CASTOR OIL, FAEX (YEAST) EXTRACT, PROPYLENE GLYCOL, ARCTIUM MAJUS ROOT EXTRACT, ALLANTOIN, CELLULOSE, HYDROXYETHYLCELLULOSE, ISOPROPYL ALCOHOL, SODIUM ACETATE, TIOXOLONE, BISABOLOL, FARNESOL, DISODIUM EDTA, METHYLPARABEN, PANTHENOL, PHENOKYETHANOL, BUTYLPARABEN, ETHYLPARABEN, PROPYLPARABEN, THIAMINE HCL, NIACINAMIDE, PYRIDOXINE HCL, RETINYL PALMITATE, TOCOPHEROL, ASCORBYL PALMITATE, TOCOPHERYL ACETATE, RIBOFLAVIN, PARFUM (FRAGRANCE), CITRAL, LIMONENE, CI 19140.

LOTE:

USO TÓPICO. NO INGERIR. MANTENER ALEJADO DEL ALCANCE DE LOS NIÑOS. PRESERVAR DE LOS CAMBIOS BRUSCOS DE TEMPERATURA Y/O DE LA LUZ DIRECTA.

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USAGE TOPIQUE. ÉVITER INGESTION, TENIR HORS DE LA PORTÉE DES ENFANTS. PROTÉGER CONTRE LES CHANGEMENTS BRUSQUES DE TEMPÉRATURE ET/OU LUMIÈRE DIRECTE.

Manufactured by:  
**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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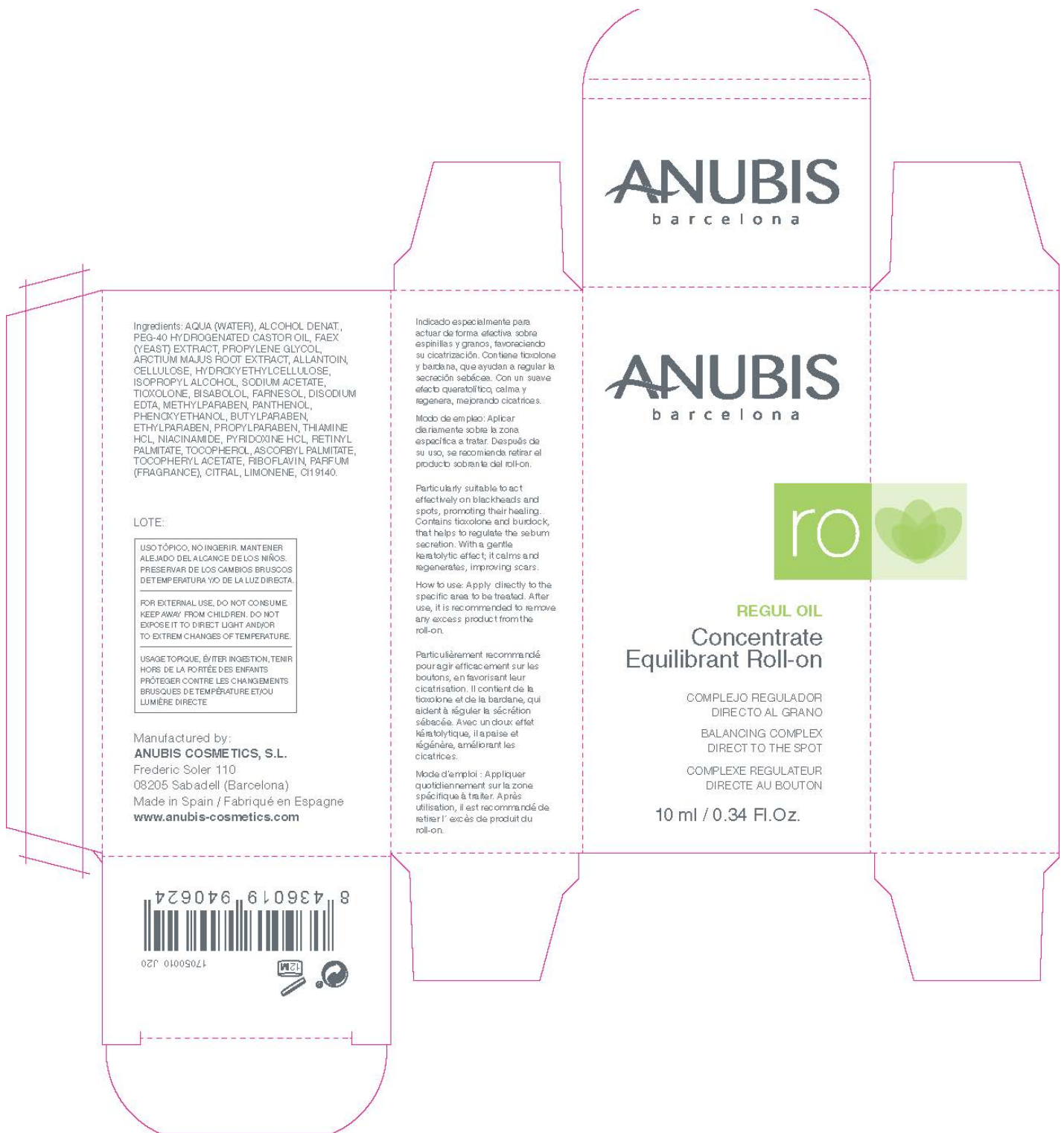
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## ANUBIS BARCELONA REGUL OIL

peg-40 hydrogenated castor oil, propylene glycol, arctium majus root extract concentrate

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:83021-624
<b>Route of Administration</b>	TOPICAL		

<b>Active Ingredient/Active Moiety</b>		
<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>ALCOHOL</b> (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	3.512 mL in 10 mL
<b>POLYOXYL 40 HYDROGENATED CASTOR OIL</b> (UNII: 7YC686GQ8F) (POLYOXYL 40 HYDROGENATED CASTOR OIL - UNII:7YC686GQ8F)	POLYOXYL 40 HYDROGENATED CASTOR OIL	0.04 g in 10 mL
<b>YEAST, UNSPECIFIED</b> (UNII: 3NY3SM6B8U) (YEAST, UNSPECIFIED - UNII:3NY3SM6B8U)	YEAST, UNSPECIFIED	0.0345 g in 10 mL
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3) (PROPYLENE GLYCOL - UNII:6DC9Q167V3)	PROPYLENE GLYCOL	0.0138 g in 10 mL
<b>ARCTIUM LAPPA ROOT</b> (UNII: 597E9BI3Z3) (ARCTIUM LAPPA ROOT - UNII:597E9BI3Z3)	ARCTIUM LAPPA ROOT	0.00007 g in 10 mL
<b>ALLANTOIN</b> (UNII: 344S277G0Z) (ALLANTOIN - UNII:344S277G0Z)	ALLANTOIN	0.025 g in 10 mL
<b>POWDERED CELLULOSE</b> (UNII: SMD1X3XO9M) (POWDERED CELLULOSE - UNII:SMD1X3XO9M)	POWDERED CELLULOSE	0.0006 g in 10 mL
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH) (PROPYLPARABEN - UNII:Z8IX2SC1OH)	PROPYLPARABEN	0.0000002 g in 10 mL
<b>TOCOPHEROL</b> (UNII: R0ZB2556P8) (TOCOPHEROL - UNII:R0ZB2556P8)	TOCOPHEROL	0.000002 g in 10 mL
<b>FRAGRANCE 13576</b> (UNII: 5EM498GW35) (FRAGRANCE 13576 - UNII:5EM498GW35)	FRAGRANCE 13576	0.02 g in 10 mL
<b>ETHYLPARABEN</b> (UNII: 14255EXE39) (ETHYLPARABEN - UNII:14255EXE39)	ETHYLPARABEN	0.0000003 g in 10 mL
<b>ASCORBYL PALMITATE</b> (UNII: QN83US2B0N) (ASCORBYL PALMITATE - UNII:QN83US2B0N)	ASCORBYL PALMITATE	0.0001 g in 10 mL
<b>WATER</b> (UNII: 059QF0K00R) (WATER - UNII:059QF0K00R)	WATER	6.2503117 mL in 10 mL
<b>TIOXOLONE</b> (UNII: S0FAJ1R9CD) (TIOXOLONE - UNII:S0FAJ1R9CD)	TIOXOLONE	0.02 g in 10 mL
<b>LEVOMENOL</b> (UNII: 24WE03BX2T) (LEVOMENOL - UNII:24WE03BX2T)	LEVOMENOL	0.009 g in 10 mL
<b>HYDROXYETHYL CELLULOSE, UNSPECIFIED</b> (UNII: T4V6TWG28D) (HYDROXYETHYL CELLULOSE, UNSPECIFIED - UNII:T4V6TWG28D)	HYDROXYETHYL CELLULOSE, UNSPECIFIED	0.034 g in 10 mL
<b>ISOPROPYL ALCOHOL</b> (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	0.0012 g in 10 mL
<b>FARNESOL</b> (UNII: EB41QIU6JL) (FARNESOL - UNII:EB41QIU6JL)	FARNESOL	0.001 g in 10 mL
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T) (METHYLPARABEN - UNII:A2I8C7HI9T)	METHYLPARABEN	0.0100013 g in 10 mL
<b>PANTHENOL</b> (UNII: WW9CM0O67Z) (PANTHENOL - UNII:WW9CM0O67Z)	PANTHENOL	0.005 g in 10 mL
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T) (PHENOXYETHANOL - UNII:HIE492ZZ3T)	PHENOXYETHANOL	0.000006 g in 10 mL
<b>BUTYLPARABEN</b> (UNII: 3QPI1U3FV8) (BUTYLPARABEN - UNII:3QPI1U3FV8)	BUTYLPARABEN	0.0000005 g in 10 mL
<b>NIACINAMIDE</b> (UNII: 25X5118RD4) (NIACINAMIDE - UNII:25X5118RD4)	NIACINAMIDE	0.0002 g in 10 mL
<b>RIBOFLAVIN</b> (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR)	RIBOFLAVIN	0.000006 g in 10 mL
<b>CITRAL</b> (UNII: T7EU0O9VPP) (CITRAL - UNII:T7EU0O9VPP)	CITRAL	0.000194 g in 10 mL
<b>LIMONENE, (+)-</b> (UNII: GFD7C86Q1W) (LIMONENE, (+)- - UNII:GFD7C86Q1W)	LIMONENE, (+)-	0.00419 g in 10 mL
<b>FD&amp;C YELLOW NO. 5</b> (UNII: I753WB2F1M) (FD&C YELLOW NO. 5 - UNII:I753WB2F1M)	FD&C YELLOW NO. 5	0.00002 g in 10 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>THIAMINE HYDROCHLORIDE</b> (UNII: M572600E5P)	0.0006 g in 10 mL
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	0.005 g in 10 mL
<b>PYRIDOXINE HYDROCHLORIDE</b> (UNII: 68Y4CF58BV)	0.0001 g in 10 mL
<b>VITAMIN A PALMITATE</b> (UNII: 1D1K0N0VVC)	0.000098 g in 10 mL
<b>SODIUM ACETATE</b> (UNII: 4550K0SC9B)	0.003 g in 10 mL
<b>EDETATE DISODIUM ANHYDROUS</b> (UNII: 8NLQ36F6MM)	0.01 g in 10 mL

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83021-624-10	10 mL in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product	10/21/2022	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M006	10/21/2022	07/07/2027

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

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

## Establishment

Name	Address	ID/FEI	Business Operations
ANUBIS COSMETICS SL		468680293	manufacture(83021-624)

Revised: 9/2023

ANUBIS COSMETICS SL