

COMPLEXION ENHANCER SPF15- titanium dioxide and zinc oxide cream
Omorovicza Kozmetikai Kft.

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.

Complexion Enhancer SPF15

DRUG FACTS

ACTIVE INGREDIENTS	PURPOSE
Titanium Dioxide 1.5%	Sunscreen
Zinc Oxide 3.2%	Sunscreen

USES

Protects from UVA/B sunrays

WARNING

For external use only; do not swallow.

Stop use if rash or irritation occurs.

DIRECTIONS

Apply evenly to face and neck.

INGREDIENTS

Aqua (Hungarian Thermal Water), Caprylic/Capric Triglyceride, Zinc Oxide, Squalane, Cetearyl Ethylhexanoate, Glycerin, Corundum (Pro Ruby Crystal), Stearyl Heptanoate, Cetearyl Alcohol, Cetearyl Oliviate, Sorbitan Oliviate, Titanium Dioxide, Butyrospermum Parkii (Shea) Butter, Prunus Armeniaca (Apricot) Kernel Oil, Phenoxyethanol, Ethylhexylglycerin, Galactoarabinan, Lactic Acid, Pyrus Malus, Pectin, Chlorella Vulgaris/Lupinus Albus Protein Ferment, Parfum (Fragrance), Geraniol, Citronellol, Linalool, Malpighia Punicifolia (Acerola) Fruit Extract, Zinc gluconate, Magnesium aspartate, Copper gluconate, Mannitol, Yeast Extract, Hydrolyzed Soy Protein, Mica, Silica, Xanthan Gum, Tocopherol (Vitamin E), Disodium EDTA, CI 77492/ CI 77491/ CI 77499 (Iron Oxides)

PRINCIPAL DISPLAY PANEL - 50ml Bottle Carton

COMPLEXION ENHANCER

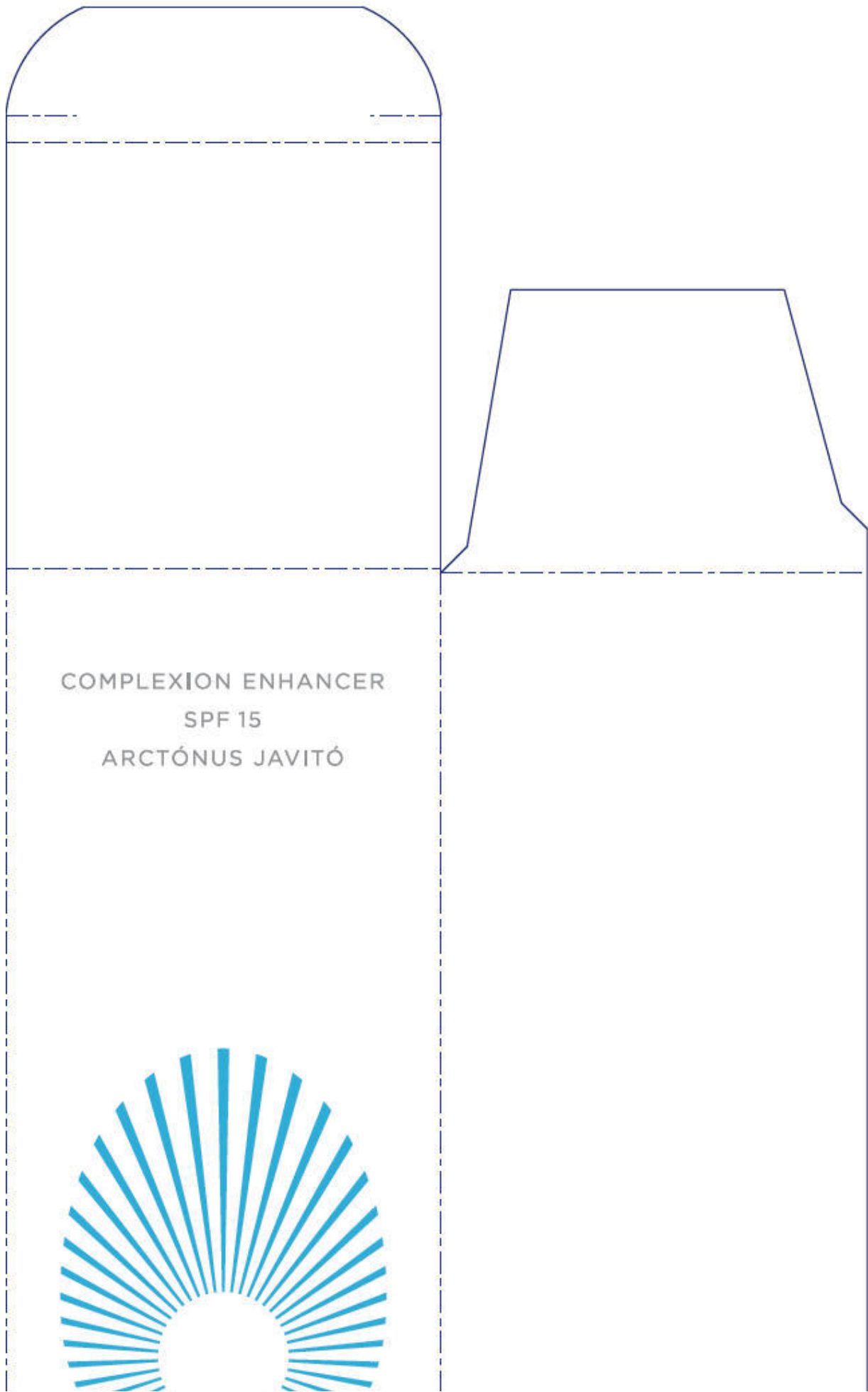
SPF 15

ARCTÓNUS JAVITÓ

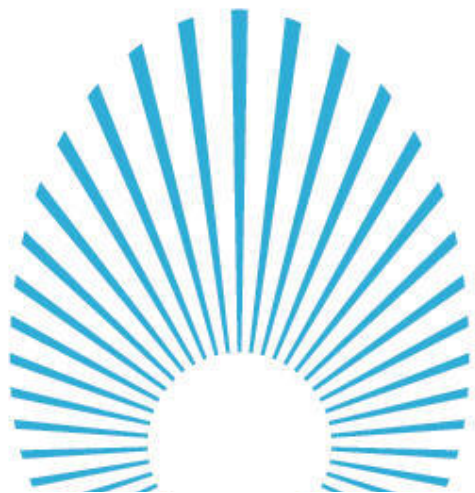
Omorovicza

BUDAPEST

e 1.7 fl oz 50ml



COMPLEXION ENHANCER
SPF 15
ARCTÓNUS JAVITÓ





Omorovicza,
BUDAPEST

e 1.7 fl oz 50ml

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110

Omorovicza,
SUBLIMATEUR DE TEINT

MINERAL COSMETOLOGY™, a patent protected mineral delivery system developed by Omorovicza Cosmetics, enables an unprecedented level of absorption of minerals by the epidermis and the dermis for firmer, suppler and younger looking skin.

Beauty editors' favourite stealth foundation. This tinted complexion enhancer conceals imperfections and gives the skin an even matte finish, whilst protecting from UVA/B rays and preventing premature ageing.

n°30

ÁSVÁNYI KOZMETOLÓGIA™, az Omorovicza által kifejlesztett, és szabadalmaztatott, innovatív rendszer, mely az ásványok szállítását végzi, hangsúlyozva a Magyar termál vízből nyert ásványok bőrbe való felszívódását, a puhább, simább bőrért.

A szépségipari szerkesztők kedvenc titkos alapozója. Ez a színezett arctónus javító elrejtő a szépséghibákat és egy egyenletes, matt felületet ad a bőrnek, míg védi az UVA/UVB sugarak ellen és meggátolja annak idő előtti öregedését.

DERMATOLOGICALLY TESTED

DRUG FACTS

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Product of Hungary

www.omorovicza.com

Omorovicza Kft, 2 Andrássy Ut, 1061 Budapest



COMPLEXION ENHANCER SPF15

titanium dioxide and zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41442-110
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Titanium dioxide (UNII: 15FIX9V2JP) (Titanium dioxide - UNII:15FIX9V2JP)	Titanium dioxide	0.75 mL in 50 mL
Zinc oxide (UNII: SOI2LOH54Z) (Zinc oxide - UNII:SOI2LOH54Z)	Zinc oxide	1.6 mL in 50 mL

Inactive Ingredients

Ingredient Name	Strength
Caprylic/Capric Mono/Diglycerides (UNII: U72Q2I8C85)	
Squalane (UNII: GW89575KF9)	
Cetearyl Ethylhexanoate (UNII: 9M64UO4C25)	
Glycerin (UNII: PDC6A3C0OX)	
Aluminum Oxide (UNII: LMI26O6933)	
Stearyl Heptanoate (UNII: 2M4UGL1NCN)	
Cetostearyl Alcohol (UNII: 2DMT128M1S)	
Cetearyl Olivatate (UNII: 58B69Q84JO)	
Sorbitan Olivatate (UNII: MDL271E3GR)	
Shea Butter (UNII: K49155WL9Y)	
Apricot Seed Oil (UNII: 54JB35T06A)	
Phenoxyethanol (UNII: HIE492ZZ3T)	
Ethylhexylglycerin (UNII: 147D247K3P)	
Lactic Acid (UNII: 33X04XA5AT)	
Apple (UNII: B423VGH5S9)	
Pectin (UNII: 89NA02M4RX)	
Geraniol (UNII: L837108USY)	
.BETA.-CITRONELLOL, (+/-)- (UNII: 565OK72VNF)	
LINALOOL, (+)- (UNII: F4VNO44C09)	
Acerola (UNII: XDD2WEC9L5)	
Zinc Gluconate (UNII: U6WSN5SQ1Z)	
Magnesium Aspartate (UNII: R17X820ROL)	
Copper Gluconate (UNII: RV823G6G67)	
Mannitol (UNII: 3OWL53L36A)	
Yeast (UNII: 3NY3SM6B8U)	
Soy Protein (UNII: R44IWB3RN5)	
Mica (UNII: V8A1AW0880)	
Silicon Dioxide (UNII: ETJ7Z6XBU4)	
Xanthan Gum (UNII: TTV12P4NEE)	
Alpha-Tocopherol (UNII: H4N855PNZ1)	

Edetate Disodium (UNII: 7FLD91C86K)	
Ferrosoferric Oxide (UNII: XM0M87F357)	

Product Characteristics

Color	BROWN	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41442-110-01	1 in 1 BOX		
1		50 mL in 1 BOTTLE, GLASS		
2	NDC:41442-110-02	125 mL in 1 BOTTLE, PUMP		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	03/01/2011	

Labeler - Omorovicza Kozmetikai Kft. (525432105)

Establishment

Name	Address	ID/FEI	Business Operations
Omorovicza Kozmetikai Kft.		525432105	LABEL, MANUFACTURE

Revised: 3/2011

Omorovicza Kozmetikai Kft.