

SUNKISS 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.

SUNKISS
SPF 15
NAPVARÁZS

Drug Facts

ACTIVE INGREDIENTS	PURPOSE
Titanium Dioxide 1.35%	Sunscreen
Zinc Oxide 6%	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, Glycerin, Squalane, Titanium Dioxide, Corundum (Pro Ruby Crystal), Cetearyl Ethylhexanoate, Cetearyl Oliviate, Sorbitan Oliviate, Stearyl Heptanoate, Cetearyl Alcohol, Saccharomyces Ferment Extract, Phenoxyethanol, Polyhydroxystearic Acid, Isostearic Acid, Mica, Parfum (Fragrance), Geraniol, Citronellol, Linalool, Prunus Armeniaca (Apricot) Kernel Oil, Chlorella Vulgaris/Lupinus Albus Protein Ferment, Malpighia Punicifolia (Acerola) Fruit Extract, Pyrus Malus (Apple) Fruit Extract, Pectin, Phospholipids, Tocopherol, Disodium EDTA, Xanthan Gum, Ethylhexylglycerin, Lactic Acid, Galactoarabinan, Isopropyl Titanium Triisostearate, CI 77492/ CI 77491/ CI 77499 (Iron Oxides).

Product of Hungary

www.omorovicza.com

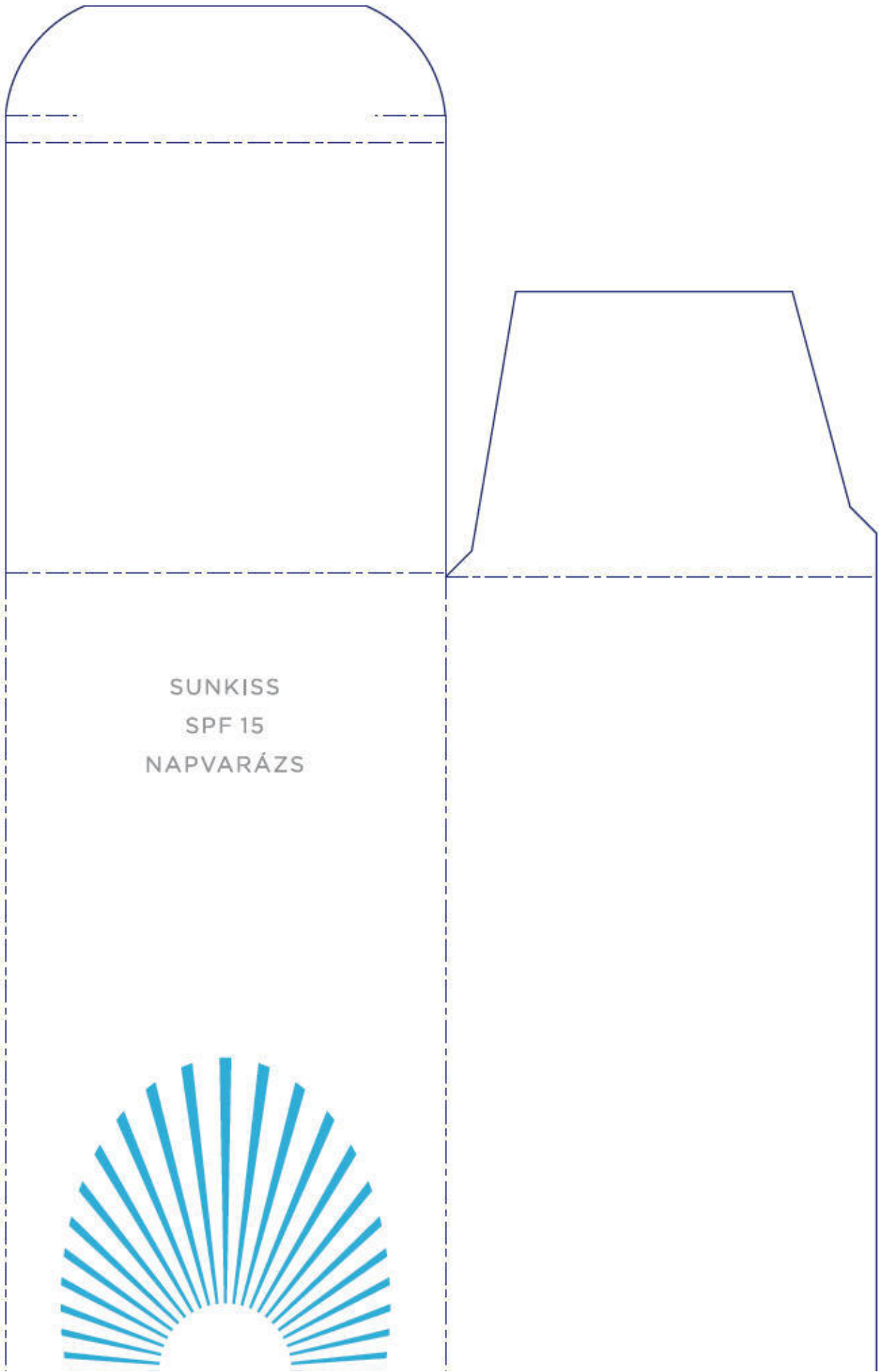
Omorovicza Kft, 2 Andrássy Ut, 1061 Budapest

PRINCIPAL DISPLAY PANEL - 50ml Bottle Carton

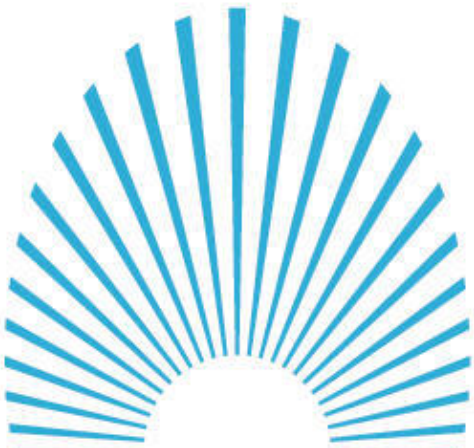
SUNKISS
SPF 15
NAPVARÁZS

Omorovicza
BUDAPEST

e 1.7 fl oz 50ml



SUNKISS
SPF 15
NAPVARÁZS





Omorovicza,
BUDAPEST

e 1.7 fl oz 50ml

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Omorovicza,
CARESSE DE SOLEIL

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.

This tan booster prolongs the life of your tan and gives an instant summer glow to your face. Sunkiss

n°39



conceals imperfections and gives the skin an even matte finish, whilst protecting from UVA/B rays and preventing premature ageing.

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.

Ez a barnulást segítő krém meghosszabbítja bőrünk napbarníttottságát, azonnal egy kellemes nyári színt kölcsönözve arcunknak. A Napvarázs kijavítja az apró hibákat, és ad arcunknak egy egyenletesen matt fedőréteget, miközben védelmet nyújt a nap UVA és B sugaraival szemben, és megelőzi az idő előtti öregedést.

DERMATOLOGICALLY TESTED

DRUG FACTS

ACTIVE INGREDIENTS

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Sunscreen

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SUNKISS SPF15

titanium dioxide and zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41442-133
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
titanium dioxide (UNII: 15FIX9V2JP) (titanium dioxide - UNII:15FIX9V2JP)	titanium dioxide	0.675 mL in 50 mL
zinc oxide (UNII: SOI2LOH54Z) (zinc oxide - UNII:SOI2LOH54Z)	zinc oxide	3 mL in 50 mL

Inactive Ingredients

Ingredient Name	Strength
CAPRYLIC/CAPRIC MONO/DIGLYCERIDES (UNII: U72Q2I8C85)	
glycerin (UNII: PDC6A3C0OX)	
squalane (UNII: GW89575KF9)	
aluminum oxide (UNII: LM26O6933)	
sorbitan olivate (UNII: MDL271E3GR)	
STEARYL ETHYLHEXANOATE (UNII: X8707A2274)	
cetostearyl alcohol (UNII: 2DMT128M1S)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
HYDROXYSTEARIC ACID (UNII: 933ANU3H2S)	
isostearic acid (UNII: X33R8U0062)	
mica (UNII: V8A1AW0880)	
geraniol (UNII: L837108USY)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
linalool, dl- (UNII: D81QY6I88E)	
APRICOT KERNEL OIL (UNII: 54JB35T06A)	
acerola (UNII: XDD2WEC9L5)	
apple (UNII: B423VGH5S9)	
pectin (UNII: 89NA02M4RX)	
alpha-tocopherol (UNII: H4N855PNZ1)	
Edetate Disodium (UNII: 7FLD91C86K)	
xanthan gum (UNII: TTV12P4NEE)	
ethylhexylglycerin (UNII: 147D247K3P)	
lactic acid (UNII: 33X04XA5AT)	
ferric oxide red (UNII: 1K09F3G675)	
ferric oxide yellow (UNII: EX438O2MRT)	
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:41442-133-01	1 in 1 BOX		
1		50 mL in 1 BOTTLE, GLASS		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	05/06/2011	

Labeler - Omorovicza Kozmetikai Kft (525432105)**Establishment**

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

Revised: 5/2011

Omorovicza Kozmetikai Kft