

MINERAL UV SHIELD SPF30- 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.

Mineral UV Shield SPF30

DRUG FACTS

ACTIVE INGREDIENTS	PURPOSE
Titanium Dioxide 1.5%	Sunscreen
Zinc Oxide 8.6%	Sunscreen

USES

Protects from UVA/B sunrays

WARNING

For external use only; do not swallow.

Stop use if rash or irritation occurs.

Keep out of reach for children.

When using this product keep out of eyes.

DIRECTIONS

Apply evenly to face and neck. Apply liberally 15 minutes before sun exposure. Reapply after 40 minutes of swimming or sweating or immediately after towel drying or at least every 2 hours.

INGREDIENTS

Aqua (Hungarian Thermal Water), Caprylic/Capric Triglyceride, Zinc Oxide, Silica, Squalane, Glycerin, Ethylhexyl dodecanol, Stearyl Heptanoate, Cetearyl Olivatate, Cetearyl Ethylhexanoate, Titanium Dioxide, Sorbitan Olivatate, Phenoxyethanol, Ascorbyl Tetraisopalmitate, Cetearyl Alcohol, Saccharomyces (Hungarian Thermal Water) Ferment Extract, Polyhydroxystearic Acid, Disodium EDTA, Alumina, Sodium Hyaluronate, Parfum (Fragrance), Prunus Armeniaca (Apricot) Kernel Oil, Tocopherol, Ethylhexylglycerin, Isostearic Acid, Lactic Acid, Xanthan Gum, Phospholipids, Linalool, Limonene, Citral.

Product of Hungary

www.omorovicza.com

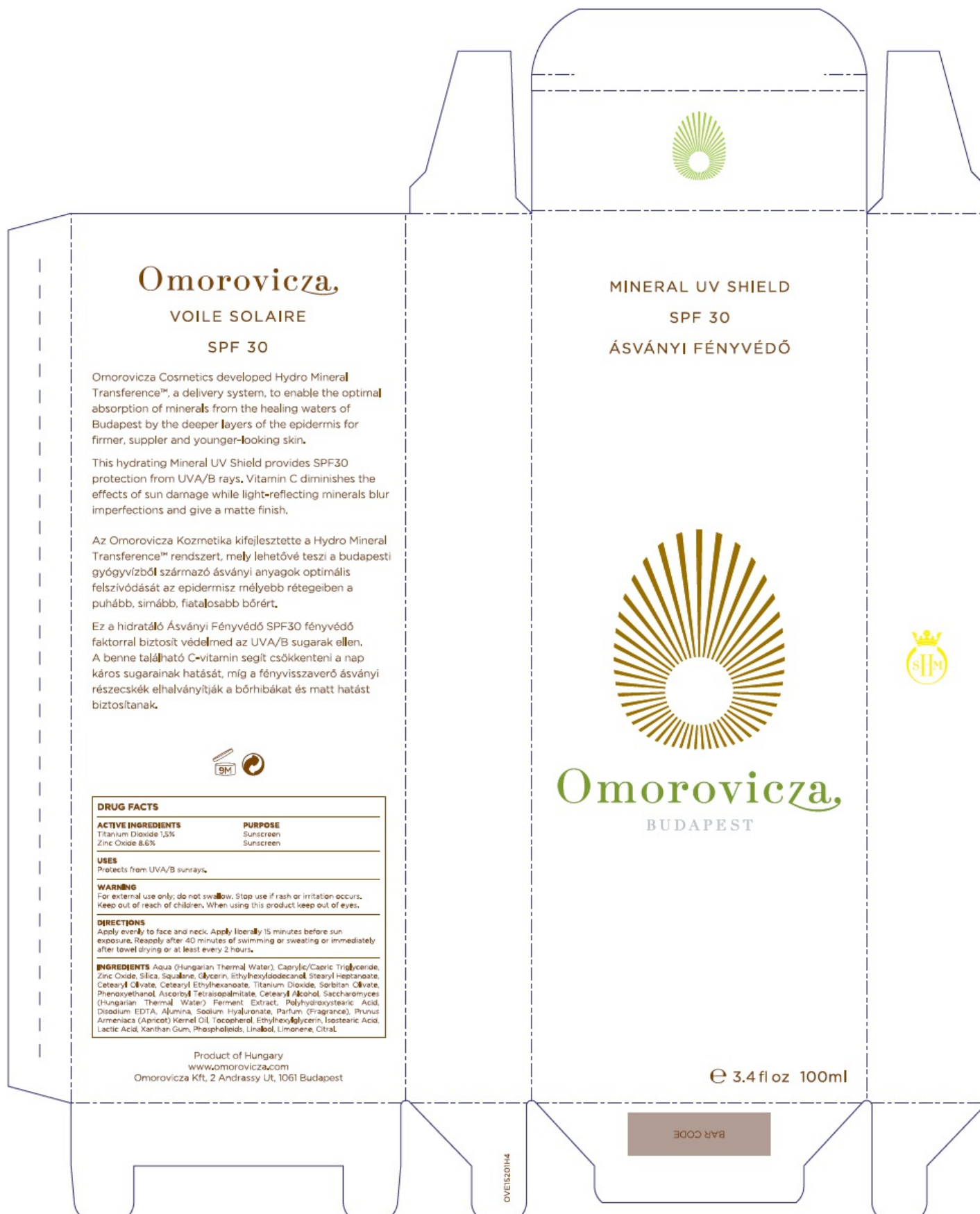
Omorovicza Kft, 2 Andrássy Ut, 1061 Budapest

PRINCIPAL DISPLAY PANEL - 100 ml Tube Box

MINERAL UV SHIELD
SPF 30

Omorovicza
BUDAPEST

e 3.4 fl oz 100ml



Omorovicza,

VOILE SOLAIRE

SPF 30

Omorovicza Cosmetics developed Hydro Mineral Transference™, a delivery system, to enable the optimal absorption of minerals from the healing waters of Budapest by the deeper layers of the epidermis for firmer, suppler and younger-looking skin.

This hydrating Mineral UV Shield provides SPF30 protection from UVA/B rays. Vitamin C diminishes the effects of sun damage while light-reflecting minerals blur imperfections and give a matte finish.

Az Omorovicza Kozmetika kifejlesztette a Hydro Mineral Transference™ rendszert, mely lehetővé teszi a budapesti gyógyvízből származó ásványi anyagok optimális felszívódását az epidermisz mélyebb rétegeiben a puhább, simább, fiatalosabb bőrért.

Ez a hidratáló Ásványi Fényvédő SPF30 fényvédő faktorral biztosít védelmet az UVA/B sugarak ellen. A benne található C-vitamin segít csökkenteni a nap káros sugarainak hatását, míg a fényvisszaverő ásványi részecskék elhalványítják a bőrhibákat és matt hatást biztosítanak.



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MINERAL UV SHIELD

SPF 30

ÁSVÁNYI FÉNYVÉDŐ



Omorovicza,

BUDAPEST



e 3.4 fl oz 100ml

BAR CODE

OVETSZ01H4

MINERAL UV SHIELD SPF30

titanium dioxide and zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41442-152
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	15 mg in 1 mL
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	86 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Medium-Chain Triglycerides (UNII: C9H2L21V7U)	
Silicon Dioxide (UNII: ETJ7Z6XBU4)	
Squalane (UNII: GW89575KF9)	
Glycerin (UNII: PDC6A3C0OX)	
Stearyl Heptanoate (UNII: 2M4UGL1NCN)	
Cetearyl Olivat (UNII: 58B69Q84JO)	
Cetearyl Ethylhexanoate (UNII: 9M64UO4C25)	
Sorbitan Olivat (UNII: MDL271E3GR)	
Phenoxyethanol (UNII: HIE492ZZ3T)	
Ascorbyl Tetraisopalmitate (UNII: 47143LT58A)	
Cetostearyl Alcohol (UNII: 2DMT128M1S)	
Polyhydroxystearic Acid (2300 MW) (UNII: YXH47AOU0F)	
Edetate Disodium (UNII: 7FLD91C86K)	
Aluminum Oxide (UNII: LMI26O6933)	
Hyaluronate Sodium (UNII: YSE9PPT4TH)	
Apricot Kernel Oil (UNII: 54JB35T06A)	
Tocopherol (UNII: R0ZB2556P8)	
Ethylhexylglycerin (UNII: 147D247K3P)	
Isostearic Acid (UNII: X33R8U0062)	
Lactic Acid (UNII: 33X04XA5AT)	
Xanthan Gum (UNII: TTV12P4NEE)	
Omega-3 Fatty Acids (UNII: 71M78END5S)	
Linalool, (+/-)- (UNII: D81QY6I88E)	
Citral (UNII: T7EU0O9VPP)	

Product Characteristics

Color	YELLOW	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41442-152-01	1 in 1 BOX		
1		100 mL in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	01/01/2015	

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

Name	Address	ID/FEI	Business Operations
Omorovicza Kozmetikai Kft.		525432105	LABEL(41442-152) , MANUFACTURE(41442-152)

Revised: 8/2014

Omorovicza Kozmetikai Kft.