#### RAYITO DE SOL - ensulizole, sulisobenzone gel Siscom de Argentina S.A.

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.

-----

#### Rayito de Sol® 2-in-1 Sport Bronzing Susncreen Gel SPF 15 - Natural Color

#### **Drug Facts**

#### **Active Ingredients**

Ensulizole 4%, Sulisobenzone 4%

#### Purpose

Sunscreen

#### Uses

• helps prevent sunburn

#### Warnings

**Skin Cancer/Skin Aging Alert**: Spending time in the sun increases your risk of skin cancer and early skin aging.

This product has been shown only to prevent sunburn, **not** skin cancer or early skin aging. **For external use only** 

Do not use on damaged or broken skin

#### When using this product

keep out of eyes. Rinse with water to remove.

#### Stop use and ask a doctor

if rash occurs

#### Keep out of the reach of children

If product is swallowed, get medical help or contact a Poison Control Center right away.

#### Directions

• apply liberally 15 minutes before sun exposure

- reapply:
  - after swimming or sweating

- immediately after towel drying
- at least every 2 hours
- children under 6 months: Ask a doctor

#### **Inactive Ingredients**

ammonium acryloyldimethyltaurate/vp copolymer, D and C red no. 33, FD and C yellow no. 5, glycerin, imidurea, laureth-7, limonene, (+)-, linalool, dl-, methylchloroisothiazolinone, methylisothiazolinone, parfum, phenoxyethanol, trolamine, water

#### **Other Information**

- protect this product from excessive heat and direct sun
- avoid contact with clothing to avoid staining. If staining does occur, launder within 12 hours

#### **Questions or Comments?**

call 305.672.9486 or send an email to: info@rayitodesolus.com

### **Principal Display Panel**

RAYITO DE SOL 2-in-1 SPORT BRONZING SUNSCREEN GEL INSTANT COOLING SPF15 Natural Color

# 2-IN-1 SPORT BRONZING SUNSCREEN GEL

RAYITO DE SOL



## Natural Color

7.05 OZ (200 g)

#### **Drug Facts**

Active Ingredients Ensulizate 4%, Sulisaberizane 4%. Purpose ... Sunscreen beips prevent sunburn

Warnings Skin Cancer/Skin Aging Alert: Spending time in the sun Increases your risk of skin cancer and early skin aging. This product has been shown only to prevent surburn, The product has been shown only as provide solution mot skin cancer or early skin aging. For external use only Do not use on damaged or broken skin When using this product keep out of eyes. Rinse with when using this product keep out of eyes. Rinse with

Note to bang this product keep of the eyes. In see whith subor to remove. Stop use and ask a doctor if rash occurs Keep out of reach of children. If swallowed, get medical help or contact a Poison Centrol Center right away.

Directions before sun exposure sweating, after towel drying and at least every 2 hours • children under 6 months: Ask a doctor

Inactive ingredients amonium acryloyldimethytaurate/vp copolymer, red no. 33, yellow no. 5, glycerin, imidurea, laureth-7, ilimonene, (+)-, linalool, dI-, methylchforolso-thiazolinone, methylisothiazolinone, parlum, phenoxyethanol, trolamine, water

Other Information - protect this product from excessive heat and cirect sun - avoid contact with clothing to avoid staining. If staining does occur, launder within 12 hours Questions or comments?

call 305.672.9486 / info@rayitodesolus.com



Active Ingredients	Purpose
the second se	
Uses	
<ul> <li>helps prevent sunburn</li> </ul>	
Warnings	
AND AND A REAL PROPERTY AN	nding time in the sun increases your
risk of skin cancer and early skin a only to prevent sunburn, not skin o	ging. This product has been shown
For external use only	ancer or early skin aging.
Do not use on damaged or broken	eldn
	of syes. Rinse with water to remove.
Stop use and ask a doctor if rash o	
Keep out of reach of children. If pr	
help or contact a Poison Control C	enter right away.
Directions	
apply liberally 15 minutes before	sun exposure
<ul> <li>reapply:</li> </ul>	
<ul> <li>after swimming or sweating</li> <li>immediately after towal drying</li> </ul>	
<ul> <li>at least every 2 hours</li> </ul>	
· children under 6 months: Ask a	doctor
Inactive ingredients	
ammonium acryloyldimethyltaura	te/vp copolymer, d&c red no. 33,
	erin, imiduree, laureth-7, limonene,
phanoxysthanol, trolamina, water	hiszolinone, methylisothiszolinone,
Other Information	
<ul> <li>protect this product from excess</li> </ul>	ive heat and direct sun
	old staining. If staining does occur,
launder within 12 hours	
Questions or comments	6?
call 305. 872.9486 or send an ema	ail to: info@rayitodesolus.com
ww.rayitodesolus.co	DIT PATENT PENDIN
anufactured for: Siscom d	le Argentina SA (Uruguay 775
ero B, CABA, Argentina) - Res.	155/98 · Est. Elab. # 129
DC # 20367-132-01	and and a second se
lade in Argentina	
Distributed by:	
BLIII Holdings	

# **RAYITO DE SOL**

ensulizole, sulisobenzone gel

**Product Information** 

Product Type	HUMAN OTC DRUG	Item Code (Sour	Item Code (Source) NDC:20	
Route of Administratio	n TOPICAL			
Active Ingredient/A	active Moiety			
Ingredient Name			Basis of Strength	
ENSULIZOLE (UNII: 9 YQ9 DI1W42) (ENSULIZOLE - UNII:9 YQ9 DI1W42)		Q9DI1W42)	ENSULIZOLE	4 g in 200 g
SULISOBENZONE (UNII: 1W6L629B4K) (SULISOBENZONE - UNII:1W6L629B		- UNII:1W6L629B4K)	4K) SULISOBENZONE	
Inactive Ingredient	s			
	Ingredient	Name		Strength
Water (UNII: 059QF0KO0	PR)			
AMMO NIUM ACRYLO Y	LDIMETHYLTAURATE/VP COPOI	L <b>YMER</b> (UNII: W59H9296ZG)		
GLYCERIN (UNII: PDC6A	3C0OX)			
TROLAMINE (UNII: 903)	K93S3TK)			
LAURETH-7 (UNII: Z9556	5G8201)			
IMIDUREA (UNII: M62980	)7ATL)			
PHENOXYETHANOL (UI	NII: HIE492ZZ3T)			
FD&C YELLOW NO.5 (U	JNII: I753WB2F1M)			
D&C RED NO.33 (UNII: 9	DBA0SBB0L)			
LINALOOL, DL- (UNII: D	08 1Q Y6 I8 8 E)			
L IMO NENE, (+/-)- (UNII:	9 MC3I34447)			
METHYLCHLOROISOT	HIAZOLINONE (UNII: DEL7T5QRP	N)		
METHYLISOTHIAZOLI	<b>NONE</b> (UNII: 229 D0 E1QFA)			
Packaging				
# Item Code	Package Description	Marketing Start D	ate Market	ting End Date
1 NDC:20367-132-01	200 g in 1 BOTTLE			0
Marketing Infor	mation			
Marketing Category	Application Number or Monog	graph Citation Marketi	ng Start Date Ma	rketing End Date
OTC monograph final	part352	12/24/2012	)	

Labeler - Siscom de Argentina S.A. (974736332)

Revised: 12/2012

Siscom de Argentina S.A.