

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 Sunscreen Gel SPF 15 - Instant Medium 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

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 blue no. 1, 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

Instant Medium Color



Drug Facts

| Active Ingredients | Purpose |
|---------------------------------|-----------|
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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 reach of children. If 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, after towel drying and at least every 2 hours
 • children under 6 months: Ask a doctor

Inactive ingredients

ammonium acryloyldimethyltaurate/copolymer, red no. 33, blue no. 1, yellow no. 5, glycerin, imidurea, laureth-7, limonene, (+)-, linalool, dl-, methylchloroisothiazolinone, methylisothiazolinone, parfum, phenoxyethanol, triethylamine, water

Other Information

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Questions or comments?

call 305.672.9486 / info@rayitodesolus.com

Manufactured for: Suncare de Argentina SA - Res. 33559 - Est. Bah. #129
 Distributed by: EJI Holdings - Miami, FL

RAYITO DE SOL
 2-IN-1 SPORT BRONZING



Made in Argentina



2 in 1 Sport Bronzing
Sunscreen Gel

Instant Cooling

15
spf

Instant Medium Color

7.05 oz e 200 g

Drug Facts

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Questions or comments?

call 305. 672.9486 or send an email to: info@rayitodesolus.com

www.rayitodesolus.com PATENT PENDING

Manufactured for: Siscom de Argentina SA (Uruguay 775
Zero B, CABA, Argentina) · Res. 155/98 · Est. Elab. # 129
NDC # 20367-133-01

Made in Argentina
Distributed by:
BLIII Holdings
Miami, FL



RAYITO DE SOL

ensulizole, sulisobenzone gel

Product Information

| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:20367-133 |
|-------------------------|----------------|--------------------|---------------|
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|--------------|
| ENSULIZOLE (UNII: 9YQ9D1I42) (ENSULIZOLE - UNII:9YQ9D1I42) | ENSULIZOLE | 4 g in 200 g |
| SULISOBENZONE (UNII: 1W6L629B4K) (SULISOBENZONE - UNII:1W6L629B4K) | SULISOBENZONE | 4 g in 200 g |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| Water (UNII: 059QF0K00R) | |
| AMMONIUM ACRYLOYLDIMETHYLTAURATE/VP COPOLYMER (UNII: W59H9296ZG) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| TROLAMINE (UNII: 9O3K93S3TK) | |
| LAURETH-7 (UNII: Z95S6G8201) | |
| IMIDUREA (UNII: M629807ATL) | |
| PHENOXYETHANOL (UNII: HIE492ZZ3T) | |
| FD&C YELLOW NO. 5 (UNII: I753WB2F1M) | |
| D&C RED NO. 33 (UNII: 9DBA0SBB0L) | |
| FD&C BLUE NO. 1 (UNII: HBR47K3TBD) | |
| LINALOOL, DL- (UNII: D81QY6I88E) | |
| LIMONENE, (+/-)- (UNII: 9MC3I34447) | |
| METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN) | |
| METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:20367-133-01 | 200 g in 1 BOTTLE | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part352 | 12/24/2012 | |

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

Revised: 12/2012

Siscom de Argentina S.A.