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

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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



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| Uses | |
| helps prevent sunburn | |
| 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. |
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| ammonium acryloyldimethyltaura | te/vp copolymer, d&c red no. 33, |
| | erin, imiduree, laureth-7, limonene, |
| phanoxysthanol, trolamina, water | hiszolinone, methylisothiszolinone, |
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| 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 YMER (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 | NONE (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.