8029017-9093

SUNPROTECT SPF 50

(Octinoxate, Avobenzone, Oxybenzone, Octocrylene And Zinc Oxide Lotion)

Composition:

Octinoxate U.S.P. 7.5 % w/w Avobenzone U.S.P. 2.0 % w/w Oxybenzone U.S.P. 3.0 % w/w Octocrylene U.S.P. 3.0 % w/w Zinc Oxide I.P. 2.0 % w/w Methyl Paraben I.P. (As Preservative) 0.2 % w/w Propvl Paraben I.P. (As Preservative) 0.02 % w/w

Excipients

SUNPROTECT SPF 50 is an advanced photostable sunscreen to provide complete broad spectrum sun protection for sensitive skin & suitable to all skin types. It is indicated to provide protection from UVB rays & deep penetrating UVA rays to prevent tanning, sun burn & premature ageing of the skin.

Pharmacology:

SUNPROTECT SPF 50 consists of four organic sunscreen molecules which share a common basic mechanism of action. The active ingredients in SUNPROTECT SPE 50 are Octinoxate, 7.5%; Avobenzone, 2%; Oxybenzone, 3% and Octoorvlene, 3.0%. The molecules are raised to a state of higher state of energized orbital on absorption of photons from UV radiation. This energized state is highly unstable and is rapidly converted to a more stable form by loosing energy and attaining ground state. The energy released is of a longer wavelength (lower energy) that does not damage biological structures. The molecule in ground state can again be recycled for UV rays absorption.

Octinoxate isomerizes in the exited state, releases energy and gets stabilized in ground state. Avobenzone reaches a higher state energy level on absorption of UV rays and is subjected to photochemical reaction which leads to structural change releasing energy and stabilizing the molecule. In addition to UV protection, oxybenzone also acts as a quencher and photostablizer for avobenzone because of its singlet stage quenching.

Octinoxate protects in the range of 290 to 320 nm (UVB protection), avobenzone in the 320 to 420 nm range (UVA protection) and oxybenzone in the 270 to 350 nm range, which covers both UVA and UVB. The extended conjugation of the acrylate portion of the Octocrylene absorbs UVB and short-wave UVA rays with wavelengths from 280 to 320 nm, protecting the skin from direct DNA damage. The ethylhexanol portion is a fatty alcohol, adding emollient and oil - like (water resistant) properties. SUNPROTECT SPF 50 contains Zinc Oxide as the physical sunscreen agent.

Thus, an effective combination of physical sunscreen with chemical sunscreen that blocks UV rays provides very high protection to the skin against UVA & UVB.

Indications:

A sunscreen lotion for prevention of sunburn skin.

Direction for use:

Squeeze desired amount of lotion & apply evenly and liberally on face, neck and exposed area of the skin 15-30 minutes prior to sun exposure. Adults and children above 6 months of age should apply to exposed areas of the skin before sun exposure. There is no recommended dosage for children below 6 months of age except under the supervision of the doctor.

SPF 50:

Provides 50 times more natural protection.

Water Resistance:

Provides sun protection even after 40 minutes of continuous water activity.

Broad Spectrum:

Protects against both UVA & UVB rays.

Although not all side effects may occur, however if they do please contact your doctor immediately.

Rare: Acne, burning, itching or stinging of skin, early appearance of redness or swelling of the skin, late appearance of rash with or without weeping blisters that become crusted, especially in sun exposed areas and may extend to unexposed areas of skin, pain in hairy areas, pus in hair follicles. Other side effects may occur that usually do not require medical attention. These side effects may disappear as your body adjusts to the product. However check with vour doctor if these become bothersome.

More common side effects: dryness Contraindications:

- · Avoid prolonged exposure to sun. Sun-sensitive persons particularly should exercise caution.
- If irritation or sensitization occurs, discontinue use.
- · Do not use sunscreens on eczematous or inflamed skin.
- · Vitamin D deficiency: May occur in elderly patients; sunscreens that block UV-B may block cutaneous vitamin D synthesis. SUNPROTECT SPF 50

Warnings and Precautions:

- · Avoid contact with eyes.
- · Flush water immediately in case of accidental contact.
- Do not swallow
- · Rinse with water to remove.
- Reapply after swimming, sweating, physical activity or advised.
- · Discontinue use, if signs of irritation or rash appear.
- · Wear protective eye covering or sunglasses. UV can cause corneal damage.
- · Keep out of reach of children.
- · Prolonged exposure to the sun is harmful.
- · Shake well before use.
- · Use under medical supervision.
- · Keep the cap tightly closed after used.
- · For external use only.

Information for Patients

What is SUNPROTECT SPF 50 ?

SUNPROTECT SPF 50 is a sunscreen lotion that will protect your skin from the harmful rays of the sun. Sunscreens provide either a chemical or a physical barrier to sunlight. These agents help to prevent sunburn, premature aging, photosensitivity reactions. SUNPROTECT SPF 50 contains a mixture of physical and chemical sunscreen agents to give you optimum protection from sun rays.

What is SPF?

SPF stands for Sun Protection Factor. All sunscreen products include SPF ratings. This factor indicates the amount of increased resistance to sun burning the product provides, relative to unprotected skin. The SPF value is based on a numerical index designed to tell how much protection from the sun a product will provide. Higher the SPF more is the protection. The Skin Cancer Foundation recommends an SPF of at least 15 for most individuals.

How should I use SUNPROTECT SPF 50 ?

Squeeze desired amount of lotion & apply evenly and liberally on face, neck and exposed area of the skin 15-30 minutes prior to sun exposure. Adults and children above 6 months of age should apply to exposed areas of the skin before sun exposure. There is no recommended dosage for children below 6 months of age except under the supervision of the doctor.

What are the side effects that I can see with SUNPROTECT SPF 50 ?

Although not all side effects may occur, however if they do please contact your doctor immediately. Rare side effects that will need the attention of your doctor include: Acne, burning, itching or stinging of skin, early appearance of redness or swelling of the skin, late appearance of rash with or without weeping blisters that become crusted, especially in sun exposed areas and may extend to unexposed areas of skin, pain in hairy areas, pus in hair follicles. Other side effects may occur that usually do not require medical attention. These side effects may disappear as your body adjusts to the product. However check with your doctor if these become bothersome.

The contraindications include;

- Avoid prolonged exposure to sun. Sun-sensitive persons particularly should exercise caution.
- If irritation or sensitization occurs, discontinue use.
- · Do not use sunscreens on eczematous or inflamed skin.
- · Vitamin D deficiency: May occur in elderly patients; sunscreens that block UV-B may block cutaneous vitamin D

Can I use SUNPROTECT SPF 50 if I am pregnant or breast feeding?

As there is no data on the safety of SUNPROTECT SPF 50 in the above mentioned conditions, it should be avoided. How should I store SUNPROTECT SPF 50 ?

Store below 30°C. Protect from light.

Expiry:

Do not use later than the date of expiry.

SUNPROTECT SPF 50 is available in 60 ml tube.

torrent Marketed by :

TORRENT PHARMACEUTICALS LTD. Indrad-382 721, Dist. Mehsana, INDIA.

Manufactured in India by : Aurochem Laboratories (I) Pvt. Ltd. 8. Palghar Taluka Indl. Co-op Est. Ltd. Palghar-401404, Dist-Thane, Maharashtra.

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