

This insert contains basic prescribing information only. For more comprehensive information, a PROFESSIONAL BROCHURE is available to physicians on request.

## **SHADE\* UVA GUARD**

SPF 15 Sunscreen Lotion

### **DESCRIPTION**

**Active ingredients:** Octinoxate USP, 7.5%; Avobenzone USP, 3%; Oxybenzone USP, 3%.

**Other ingredients:** Benzyl alcohol, carbomer-941, dimethicone, edetate disodium, glyceryl stearate SE, isopropyl myristate, methylparaben, octadecena/MA copolymer, propylparaben, purified water, sorbitan monooleate, sorbitol, stearic acid and trolamine.

### **PHARMACOLOGY**

SHADE consists of 3 organic sunscreen molecules which share a common basic mechanism of action. The active ingredients in SHADE are Octinoxate, 7.5%; Avobenzone, 3%; Oxybenzone, 3%. 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 losing 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.

Octyl methoxycinnamate isomerizes in the excited 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 photostabilizer for avobenzone because of its singlet state quenching.

Octyl methoxycinnamate 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.

## **INDICATIONS AND USAGE**

Protection against sunburn, skin damage resulting in premature ageing and wrinkles.

## **DOSAGE AND ADMINISTRATION**

Shake well before using. Before sun exposure, apply evenly and liberally on all exposed areas and reapply after 40 minutes in the water or after excessive sweating. There is no recommended dosage for children under six (6) months of age except under the advise and supervision of a physician.

## **SIDE EFFECTS**

Allergy to octyl methoxycinnamate is rare. No reports of contact urticaria have been found in literature. No blood abnormalities have been reported with use of sunscreens. Contact allergy and photo-contact allergy to avobenzone have been reported. Most of them have been due to cross-reactivity caused by prior exposure to isopropyl derivatives. Some reports of photo-contact urticaria, contact urticaria and anaphylaxis are reported with use of oxybenzone. Irritation associated with burning or stinging sensation without objective erythema has also been reported with sunscreen usage.

## **SPECIAL FEATURES**

Water-resistant: Maintains its degree of protection (SPF-15) for 40 minutes or more in water.

Fragrance-free: Free of fragrance that may irritate those with sensitive skin.

Moisturizing: Moisturizing formula helps keep your skin feeling smooth and soft.

Non-comedogenic: Won't clog pores.

## **WARNINGS**

Do not use if sensitive to cinnamates, benzophenones or any other ingredient in this product. Avoid contact with the eyes, if contact occurs, rinse eyes thoroughly with water. For external use only, not to be swallowed. Discontinue use if signs of irritation or rash appear.

### **USE DURING PREGNANCY**

Safe use of the formulation during pregnancy has not been established.

### **CONTRAINDICATIONS**

The Product is contraindicated in patients who are hypersensitive to any of the ingredients of SHADE sunscreen.

### **STORAGE**

Store in a cool place. Do not freeze.

Keep out of reach of children.

### **PACKAGE**

SHADE UVA Guard is available as 40 and 100 ml bottle packs.

FOR EXTERNAL USE ONLY

Marketed by:

FULFORD (INDIA) LIMITED

A subsidiary of Schering-Plough

Eureka Towers, 8<sup>th</sup> floor, Mindspace, Malad (W), Mumbai – 400064, India.

Manufactured by:

ZYG Pharma Pvt. Ltd.

Plot no 810, Sector – III,

Industrial Area, Pithampur,

Dist. Dhar – 454775 (M. P.),

India