

ROSAC® Cream

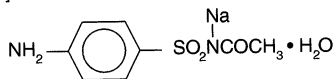
WITH  SUNSCREENS

(sodium sulfacetamide 10% and sulfur 5%)

Rx only

DESCRIPTION: Each gram of Rosac® Cream With Sunscreens contains 100 mg of sodium sulfacetamide and 50 mg of sulfur in a cream containing avobenzone, benzyl alcohol, C12-15 alkyl benzoate, cetostearyl alcohol, dimethicone, edetate disodium, emulsifying wax, monobasic sodium phosphate, octinoxate, propylene glycol, purified water, sodium thiosulfate, steareth-2, steareth-21.

Sodium sulfacetamide is a sulfonamide with antibacterial activity while sulfur acts as a keratolytic agent. Chemically, sodium sulfacetamide is N-[(4-aminophenyl) sulfonyl]-acetamide, monosodium salt, monohydrate. The structural formula is:



CLINICAL PHARMACOLOGY: The most widely accepted mechanism of action of sulfonamides is the Woods-Fildes theory which is based on the fact that sulfonamides act as competitive antagonists to para-aminobenzoic acid (PABA), an essential component for bacterial growth. While absorption through intact skin has not been determined, sodium sulfacetamide is readily absorbed from the gastrointestinal tract when taken orally and excreted in the urine, largely unchanged. The biological half-life has variously been reported as 7 to 12.8 hours.

The exact mode of action of sulfur in the treatment of acne is unknown, but it has been reported that it inhibits the growth of *Propionibacterium acnes* and the formation of free fatty acids.

INDICATIONS AND USAGE: Rosac Cream With Sunscreens is indicated in the topical control of acne vulgaris, acne rosacea and seborrheic dermatitis.

CONTRAINDICATIONS: Rosac Cream With Sunscreens is contraindicated for use by patients having known hypersensitivity to sulfonamides, sulfur or any other component of this preparation. This drug is not to be used by patients with kidney disease.

WARNINGS: Although rare, sensitivity to sodium sulfacetamide may occur. Therefore, caution and careful supervision should be observed when prescribing this drug for patients who may be prone to hypersensitivity to topical sulfonamides. Systemic toxic reactions such as agranulocytosis, acute hemolytic anemia, purpura hemorrhagica, drug fever, jaundice, and contact dermatitis indicate hypersensitivity to sulfonamides. Particular caution should be employed if areas of denuded or abraded skin are involved.

PRECAUTIONS: General — If irritation develops, use of the product should be discontinued and appropriate therapy instituted. For external use only. Keep away from eyes. Patients should be carefully observed for possible local irritation or sensitization during long-term therapy. The object of this therapy is to achieve desquamation without irritation, but sodium sulfacetamide and sulfur can cause reddening and scaling of epidermis. These side effects are not unusual in the treatment of acne vulgaris, but patients should be cautioned about the possibility. Keep out of reach of children.

Carcinogenesis, Mutagenesis and Impairment of Fertility — Long-term studies in animals have not been performed to evaluate carcinogenic potential.

Pregnancy — Category C. Animal reproduction studies have not been conducted with Rosac Cream with Sunscreens. It is also not known whether this drug can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. It should be given to a pregnant woman only if clearly needed.

Nursing Mothers — It is not known whether sodium sulfacetamide is excreted in human milk following topical use of Rosac Cream With Sunscreens. However, small amounts of orally administered sulfonamides have been reported to be eliminated in human milk. In view of this and because many drugs are excreted in human milk, caution should be exercised when this drug is administered to a nursing woman.

Pediatric Use — Safety and effectiveness in children under the age of 12 have not been established.

ADVERSE REACTIONS: Although rare, sodium sulfacetamide may cause local irritation.

DOSAGE AND ADMINISTRATION: Apply a thin film of Rosac® Cream With Sunscreens to affected areas 1 to 3 times daily.

HOW SUPPLIED: 45 g tubes (NDC 0145-2617-05)

Store at controlled room temperature 15°-30°C (59°-86°F).



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