

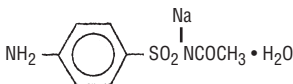
Rx Only

ROSULA®

(Sodium Sulfacetamide 10% and Sulfur 5% in a Urea vehicle)

Aqueous

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



Each mL of ROSULA® (Sodium Sulfacetamide 10% and Sulfur 5% in a Urea vehicle) Aqueous Cleanser contains 100 mg of Sodium Sulfacetamide and 50 mg of Sulfur in an emulsion base containing Urea 10%, sodium methyl cocoyl taurate, disodium oleamido MEA sulfosuccinate, sodium cocoyl isethionate, cetyl alcohol, glyceryl stearate and PEG 100 stearate, stearyl alcohol, magnesium aluminum silicate, xanthan gum, methylparaben, di-sodium EDTA, butylated hydroxytoluene, sodium thiosulfate, fragrance, propylparaben, and purified water.

Each mL of ROSULA® (Sodium Sulfacetamide 10% and Sulfur 5% in a Urea vehicle) Aqueous Gel contains 100 mg of Sodium Sulfacetamide and 50 mg of Sulfur in an emulsion base containing Urea 10%, propylene glycol, isopropyl myristate, mineral oil, polysorbate 60, sorbitan monostearate, cetyl alcohol, cocoglycerides, stearyl alcohol, benzyl alcohol, glyceryl stearate and PEG 100 stearate, dimethicone, fragrance, disodium EDTA, xanthan gum, zinc ricinoleate, sodium thiosulfate and purified water.

CLINICAL PHARMACOLOGY: The most widely accepted mechanism of action of sulfonamides is the Woods-Fildes theory,

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Aqueous Gel

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: ROSULA® Aqueous Cleanser and ROSULA® Aqueous Gel are indicated in the topical control of acne vulgaris, acne rosacea and seborrheic dermatitis.

CONTRAINDICATIONS: ROSULA® Aqueous Cleanser and ROSULA® Aqueous Gel are contraindicated for use by patients having known hypersensitivity to sulfonamides, sulfur or any other component of this preparation. ROSULA® Aqueous Cleanser and ROSULA® Aqueous Gel are 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.

FOR EXTERNAL USE ONLY. Keep away from eyes. **Keep out of reach of children.** Keep tube tightly closed.

PRECAUTIONS: General - If irritation develops, use of the product should be discontinued and appropriate therapy instituted. 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 the epidermis. These side effects are not unusual in the treatment of acne vulgaris, but patients should be cautioned about the possibility.

Information for Patients - Avoid contact with eyes, eyelids, lips and mucous membranes. If accidental contact occurs, rinse with water. If excessive irritation develops, discontinue use and consult your physician.

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 ROSULA[®] Aqueous Cleanser and ROSULA[®] Aqueous Gel. It also is not known whether ROSULA[®] Aqueous Cleanser and ROSULA[®] Aqueous Gel can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. ROSULA[®] Aqueous Cleanser and ROSULA[®] Aqueous Gel 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 ROSULA[®] Aqueous Cleanser and ROSULA[®] Aqueous Gel. 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 ROSULA[®] Aqueous Cleanser and ROSULA[®] Aqueous Gel are 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:

ROSULA[®] Aqueous Cleanser: Wash affected area once or twice daily or as directed by your physician. Avoid contact with eyes or mucous membranes. Wet skin and liberally apply to areas to be cleansed, massage gently into skin for 10-20 seconds, working into a full lather, rinse thoroughly and pat dry. If drying occurs, it may be controlled by rinsing off cleanser sooner or using less often.

ROSULA[®] Aqueous Gel: Cleanse affected areas. Apply a thin layer into affected areas 1 to 3 times daily, or as directed by a physician.

HOW SUPPLIED: ROSULA[®] Aqueous Gel is available in a 1.5 fl. oz. (45 mL) tube, NDC 10337-661-45. ROSULA[®] Aqueous Cleanser is available in a 355 mL bottle, NDC 10337-662-12.

Store ROSULA[®] Aqueous Gel at 15°-30° C (59°-86° F).

Store ROSULA[®] Aqueous Cleanser at 15°-25° C (59°-77° F).

Protect from freezing.

Manufactured for:

 **DOAK DERMATOLOGICS**
A SUBSIDIARY OF BRADLEY PHARMACEUTICALS, INC.

Our Speciality is Dermatology

383 Route 46 West
Fairfield, NJ 07004-2402 USA
www.doakderm.com



Manufactured by:
Groupe PARIMA, Inc.
Montreal, QC H4S 1X6 CANADA

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