

R_x Only

ROSULA[®] NS

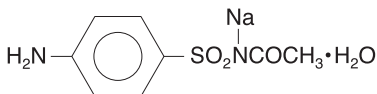
(Sodium Sulfacetamide 10% in a Urea vehicle)

Medicated Pads

FOR DERMATOLOGIC USE ONLY — NOT FOR OPHTHALMIC USE

DESCRIPTION: ROSULA[®] NS Medicated Pads contain a 10% solution of sodium sulfacetamide on a textured pad. Each gram of medicated solution contains 100 mg sodium sulfacetamide, urea (10%), purified water, sodium EDTA and sodium thiosulfate. ROSULA[®] NS Medicated Pads are greaseless and leave no residue when applied to the skin.

Sodium sulfacetamide is a sulfonamide with antibacterial activity. Chemically, sodium sulfacetamide is C₈H₉N₂NaO₃S•H₂O, with a molecular weight of 254.24. Chemically it is Acetamide, N- [(4 aminophenyl) sulfonyl]-, monosodium salt and monohydrate, with the following structural formula:



CLINICAL PHARMACOLOGY: Sodium sulfacetamide exerts a bacteriostatic effect against sulfonamide-sensitive gram-positive and gram-negative microorganisms including *P. acne* commonly isolated from secondary cutaneous pyogenic infections.

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 in humans 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.

INDICATIONS AND USAGE: ROSULA[®] NS Medicated Pads are indicated for the treatment of bacterial infections of the skin due to organisms susceptible to sulfonamides including *P. acne*. They are also intended for topical control of seborrheic dermatitis of the face and scalp.

CONTRAINDICATIONS: ROSULA[®] NS Medicated Pads are contraindicated in persons with known or suspected hypersensitivity to sulfonamides or to any of the ingredients of the preparation. ROSULA[®] NS Medicated Pads 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. Sulfonamides are known to cause Stevens-Johnson syndrome in hypersensitive individuals. Stevens-Johnson syndrome also has been reported following the use of sodium sulfacetamide topically. Cases of drug-induced systemic lupus erythematosus from topical sulfacetamide also have been reported.

PRECAUTIONS: *General:* Nonsusceptible organisms, including fungi, may proliferate with the use of this preparation. Hypersensitivity reactions may recur

when a sulfonamide is readministered, irrespective of the route of administration, and cross hypersensitivity between different sulfonamides may occur. If ROSULA[®] NS Medicated Pads produce signs of hypersensitivity or other untoward reactions, discontinue use of the preparation. Systemic absorption of topical sulfonamides is greater following application to large, infected, abraded, denuded, or severely burned areas. Under these circumstances, potentially any of the adverse effects produced by the systemic administration of these agents could occur, and appropriate observations and laboratory determinations should be performed.

INFORMATION FOR PATIENTS: Avoid contact with eyes, eyelids, lips and mucous membranes. If accidental contact occurs, rinse with water. Patients should discontinue the use of ROSULA[®] NS Medicated Pads if the condition becomes worse, or if a rash develops in the area being treated or elsewhere. ROSULA[®] NS Medicated Pads also should be discontinued promptly and the physician notified if any arthritis, fever, or sores in the mouth develop.

Drug Interactions: ROSULA[®] NS Medicated Pads are incompatible with silver preparations.

Carcinogenesis, Mutagenesis, and Impairment of Fertility: Long-term animal studies for carcinogenic potential have not been performed on ROSULA[®] NS Medicated Pads.

Pregnancy Category C: Animal reproduction studies have not been conducted with ROSULA[®] NS Medicated Pads. It also is not known whether ROSULA[®] NS Medicated Pads can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. ROSULA[®] NS Medicated Pads should be used by a pregnant woman only if clearly needed.

Nursing Mothers: It is not known whether this drug is excreted in human milk following topical use of ROSULA[®] NS Medicated Pads. Because many drugs are excreted in human milk, caution should be exercised when ROSULA[®] NS Medicated Pads are administered to a nursing woman.

Pediatric Use: Safety and effectiveness in children below the age of 12 years have not been established.

ADVERSE REACTIONS: Reports of irritation and hypersensitivity to sodium sulfacetamide are uncommon. The following adverse reactions, reported after administration of sterile ophthalmic sodium sulfacetamide, are noteworthy: instances of Stevens-Johnson syndrome and instances of local hypersensitivity, which progressed to a syndrome resembling systemic lupus erythematosus; in one case a fatal outcome has been reported (see **WARNINGS.**)

DOSAGE AND ADMINISTRATION: *Cutaneous Bacterial Infections:* Gently apply ROSULA[®] NS Medicated Pads to the affected areas 1 to 2 times daily or as directed by a physician until the infection has cleared.

Seborrheic dermatitis – Gently apply ROSULA[®] NS Medicated Pads to the skin or scalp 1 to 2 times daily or as directed by a physician.

HOW SUPPLIED: ROSULA[®] NS Medicated Pads NDC 10337-664-10 contain 30 Foil Pouches, each with a single-use medicated pad (2.5 mL each).

Note: **Store at controlled room temperature 15°-30° C (59°-86° F). Protect from freezing.** ROSULA[®] NS Medicated Pads may darken after prolonged storage. Slight discoloration does not impair the efficacy or safety of the product.

Manufactured for:



 **DOAK DERMATOLOGICS**

A SUBSIDIARY OF BRADLEY PHARMACEUTICALS, INC.

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