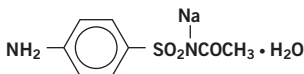




Rx Only
Sumadan[®]
(Sodium Sulfacetamide 9% & Sulfur 4.5%)
WASH In a Moisturizing
Novasome[®] Vehicle

DESCRIPTION: 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:



Each mL of **Sumadan[®] (sodium sulfacetamide 9% & sulfur 4.5%) Wash** contains 90 mg of sodium sulfacetamide and 45 mg of sulfur in a formulation consisting of: butylated hydroxytoluene, C12-15 alkyl benzoate, caprylyl glycol, cetyl alcohol, cholesterol, chrysanthemum dendranthema, dimethicone, disodium oleamido MIPA sulfosuccinate, edetate disodium, ethylene brassilate, glyceryl stearate, hexylene glycol, lemon oil, magnesium aluminum silicate, magnesium chloride, magnesium nitrate, methylchloroisothiazolinone, methylisothiazolinone, niacinamide, nonoxynol-20, octoxynol-5, purified water, PEG-100 stearate, phenoxyethanol, propylene glycol, sodium cocoyl isotheionite, sodium methyl cocoyl taurate, sodium thiosulfate, stearyl alcohol, xanthan gum.

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: **Sumadan[®] (sodium sulfacetamide 9% & sulfur 4.5%) Wash** is indicated for the topical control of acne vulgaris, acne rosacea and seborrheic dermatitis.

CONTRAINDICATIONS: **Sumadan[®] (sodium sulfacetamide 9% & sulfur 4.5%) Wash** are contraindicated for use by patients having known hypersensitivity to sulfonamides, sulfur or any other component of this preparation. **Sumadan[®] (sodium sulfacetamide 9% & sulfur 4.5%) Wash** 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.

FOR EXTERNAL USE ONLY. Keep away from eyes. Keep out of reach of children. Keep container 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 **Sumadan® (sodium sulfacetamide 9% & sulfur 4.5%) Wash**. It is also not known whether **Sumadan® (sodium sulfacetamide 9% & sulfur 4.5%) Wash** can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. **Sumadan® (sodium sulfacetamide 9% & sulfur 4.5%) Wash** should be given to a pregnant woman only if clearly needed.

NURSING MOTHERS: It is not known whether sodium sulfacetamide is excreted in the human milk following topical use of **Sumadan® (sodium sulfacetamide 9% & sulfur 4.5%) Wash**. 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 **Sumadan® (sodium sulfacetamide 9% & sulfur 4.5%) Wash** 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 **Sumadan® (sodium sulfacetamide 9% & sulfur 4.5%) Wash** once or twice daily to affected areas, or as directed by your physician. 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 **Sumadan® (sodium sulfacetamide 9% & sulfur 4.5%) Wash** sooner or using less often.

HOW SUPPLIED: **Sumadan® (sodium sulfacetamide 9% & sulfur 4.5%) Wash** is available in a 16 oz. (454 g) bottle, NDC 43538-190-16.

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

KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.

Manufactured for:



MEDIMETRIKS
PHARMACEUTICALS, INC.

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