



SulfaCleanse[®] 8/4

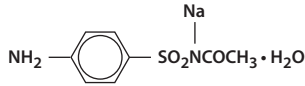
(sodium sulfacetamide 8% & sulfur 4%)

Rx Only

Topical Suspension in a vehicle containing Green Tea and Aloe

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 SulfaCleanse[®] 8/4 (sodium sulfacetamide 8% & sulfur 4%) contains 80 mg of sodium sulfacetamide and 40 mg of sulfur in a formulation consisting of: aloe, butylated hydroxytoluene, cetyl alcohol, disodium oleamide MEA sulfosuccinate, edetate disodium, fragrance, glyceryl stearate, green tea, magnesium aluminum silicate, methylparaben, PEG-100 stearate, propylparaben, purified water, sodium cocoyl isethionate, 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:

SulfaCleanse[®] 8/4 (sodium sulfacetamide 8% & sulfur 4%) is indicated for the topical control of acne vulgaris, acne rosacea and seborrheic dermatitis.

CONTRAINDICATIONS:

SulfaCleanse[®] 8/4 (sodium sulfacetamide 8% & sulfur 4%) is contraindicated for use by patients having known hypersensitivity to sulfonamides, sulfur or any other component of this preparation. SulfaCleanse[®] 8/4 (sodium sulfacetamide 8% & sulfur 4%) 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.

(continued on reverse side)



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 SulfaCleanse[®] 8/4 (sodium sulfacetamide 8% & sulfur 4%). It is also not known whether SulfaCleanse[®] 8/4 (sodium sulfacetamide 8% & sulfur 4%) can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. SulfaCleanse[®] 8/4 (sodium sulfacetamide 8% & sulfur 4%) 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 SulfaCleanse[®] 8/4 (sodium sulfacetamide 8% & sulfur 4%). 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 SulfaCleanse[®] 8/4 (sodium sulfacetamide 8% & sulfur 4%) is administered to a nursing woman.

PEDIATRIC USE:

Safety and effectiveness in children under the age of 12 has not been established.

ADVERSE REACTIONS:

Although rare, sodium sulfacetamide may cause local irritation.

DOSAGE AND ADMINISTRATION:

Apply SulfaCleanse[®] 8/4 (sodium sulfacetamide 8% & sulfur 4%) 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 SulfaCleanse[®] 8/4 (sodium sulfacetamide 8% & sulfur 4%) sooner or using less often.

HOW SUPPLIED:

SulfaCleanse[®] 8/4 (sodium sulfacetamide 8% & sulfur 4%) is available in a 16 fl. oz. (473 mL) bottle, NDC 42546-175-16.

Store at 20°C to 25°C (68°F to 77°F), excursions permitted between 15°C and 30°C (between 59°F and 86°F). Brief exposure to temperatures up to 40°C (104°F) may be tolerated provided the mean kinetic temperature does not exceed 25°C (77°F); however, such exposure should be minimized.

Protect from freezing.

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

Manufactured for:
Prugen Pharmaceuticals
18899 N Thompson Peak Pkwy
Scottsdale, AZ 85255



Rev.2.0

