AVAR-E GREEN - sulfacetamide sodium and sulfur cream

Mission Pharmacal Company

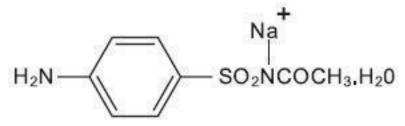
RX ONLY

FOR EXTERNAL USE ONLY.

NOT FOR OPHTHALMIC USE.

DESCRIPTION:

Each gram of AVAR TM -e Green Cream (sodium sulfacetamide 10% and sulfur 5%) color corrective emollient cream contains 100 mg of sodium sulfacetamide and 50 mg of colloidal sulfur in an emollient cream vehicle containing benzyl alcohol, cetyl alcohol, chromium oxide green, dimethicone, disodium EDTA, emulsifying wax, fragrance, glycerine, glyceryl stearate (and) PEG-100 stearate, isostearyl palmitate, nicotinamide, phenoxyethanol, purified water, sodium lactate, sodium thiosulfate and zinc oxide. Sodium sulfacetamide is a sulfonamide with antibacterial activity while sulfur acts as a keratolytic agent. Sodium sulfacetamide is $C_8H_9N_2NaO_3S\cdot H_2O$ with molecular weight of 254.24. Chemically, it 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:

AVARTM-e Green Cream is indicated for use in the topical control of acne vulgaris, acne rosacea and seborrheic dermatitis.

CONTRAINDICATIONS:

AVARTM-e Green Cream is contraindicated for use by patients having known hypersensitivity to sulfonamides, sulfur or any other component of this preparation. AVARTM-e Green Cream 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.

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. In one of these cases, there was a fatal outcome. **KEEP OUT OF REACH OF CHILDREN.**

PRECAUTIONS:

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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.

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 AVARTM-e Green Cream. It is also not known whether AVARTM-e Green Cream can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. AVARTM-e Green Cream 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 AVARTM-e Green Cream. However, small amounts of orally administered sulfonamides have been reported to be excreted in human milk. In view of this and because many drugs are excreted in human milk, caution should be exercised when AVARTM-e Green Cream 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. You should call your doctor for medical advice about side effects. To report a serious adverse event, call 1-800-298-1087.

DOSAGE AND ADMINISTRATION:

Wash hands. Cleanse affected area. Apply a thin layer 1 to 3 times daily or as directed by a physician. Massage the cream completely and uniformly into the skin.

HOW SUPPLIED:

AVARTM-e Green Cream is supplied in a 45 g (1.6 oz.) tube, NDC 0178-0460-45 and in 5 g sample packets, NDC 0178-0460-05. 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 exposures 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.

Note: Protect from freezing and excessive heat. The product may tend to darken slightly on storage. Slight discoloration does not impair the efficacy or safety of the product. Keep tube or packet tightly closed.

Occasionally, a slight yellowish discoloration may occur when an excessive amount of the product is used and comes in contact with white fabrics. This discoloration, however, presents no problem as it is readily removed by ordinary laundering without bleaches. Distributed by:

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NDC 0178-0460-45 R ONLY



Net wt. 45 g (1.6 oz.)

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INDICATIONS: For the topical control of acne vulgaris, acne rosacea and seborrheic dermatitis.

DIRECTIONS: Wash hands. Cleanse affected area. Apply a thin layer 1 to 3 times daily or as directed by a physician. Massage the cream completely and uniformly into the skin. See patient information for full prescribing details.

WARNING: FOR EXTERNAL USE ONLY. NOT FOR OPHTHALMIC USE. KEEP OUT OF REACH OF CHILDREN. Keep tube tightly closed.

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).

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> > Patent Pending v1 Rev. 03/2012



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