

**AVAR - sulfacetamide sodium, sulfur emulsion**  
**Mission Pharmacal Company**

*Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.*

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**AVAR™ Cleanser (sodium sulfacetamide 10% and sulfur 5%)**

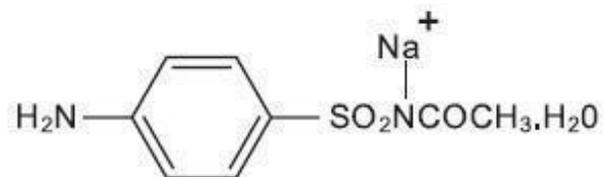
**Rx Only**

FOR EXTERNAL USE ONLY.  
NOT FOR OPHTHALMIC USE.

**DESCRIPTION:**

Each gram of AVAR™ Cleanser (sodium sulfacetamide 10% w/w and sulfur 5% w/w) contains 100 mg of sodium sulfacetamide and 50 mg of colloidal sulfur in a mild aqueous based cleansing vehicle containing benzyl alcohol, cetyl alcohol, gum arabic, fragrance, phenoxyethanol, propylene glycol, purified water, sodium lauryl sulfate, sodium magnesium silicate, sodium thiosulfate and stearyl alcohol.

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:**

AVAR™ Cleanser is indicated for use in the topical control of acne vulgaris, acne rosacea and seborrheic dermatitis.

**CONTRAINDICATIONS:**

AVAR™ Cleanser is contraindicated for use by patients having known hypersensitivity to sulfonamides,

sulfur or any other component of this preparation. AVAR™ Cleanser 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:**

**FOR EXTERNAL USE ONLY. NOT FOR OPHTHALMIC USE.**

**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 AVAR™ Cleanser. It is also not known whether AVAR™ Cleanser can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. AVAR™ Cleanser 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 AVAR™ Cleanser. 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 AVAR™ Cleanser 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. Call your doctor for medical advice about side effects. **To report SUSPECTED ADVERSE REACTIONS, contact the FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).**

#### **DOSAGE AND ADMINISTRATION:**

Wash affected areas with AVAR™ Cleanser 1 to 2 times daily or as directed by a physician. Avoid contact with eyes or mucous membranes. Wet skin and liberally apply to areas to be cleansed, massage gently into skin for 10 to 20 seconds working into a full lather, rinse thoroughly and pat dry. If drying occurs, it may be controlled by rinsing cleanser off sooner or using cleanser less often.

**HOW SUPPLIED:**

AVAR™ Cleanser is supplied in an 8 oz. (227 g) bottle, NDC 0178-0480-08, and in 5 g sample packets, NDC 0178-0480-05.

Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F).  
See USP Controlled Room Temperature.

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 container 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:  
Mission Pharmacal Company  
San Antonio, TX 78230-1355

Patent Pending

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

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NDC 0178-0480-08

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**CLEANSER**  
sodium sulfacetamide 10%, sulfur 5%

R ONLY

8 oz. (227 g)

Distributed by:  
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Patent Pending

3 01780 48008 3

**AVAR**

sulfacetamide sodium, sulfur emulsion

**Product Information**

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:0178-0480
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
SULFACETAMIDE SODIUM (UNII: 4NRT660KJQ) (SULFACETAMIDE - UNII:4965G3J0F5)	SULFACETAMIDE SODIUM	100 mg in 1 g
SULFUR (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70)	SULFUR	50 mg in 1 g

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
ACACIA (UNII: 5C5403N26O)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0K00R)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
HECTORITE (UNII: 08X4KI73EZ)	
SODIUM THIOSULFATE (UNII: HX1032V43M)	
STEARYL ALCOHOL (UNII: 2KR89I4HIY)	

**Product Characteristics**

<b>Color</b>	yellow (light yellow)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

#	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:0178-0480-08	227 g in 1 BOTTLE, PLASTIC		

**Marketing Information**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
unapproved drug other		09/15/2011	

**Labeler** - Mission Pharmacal Company (008117095)