AVAR-E LS - sulfacetamide sodium and sulfur cream
Mission Pharmacal Company

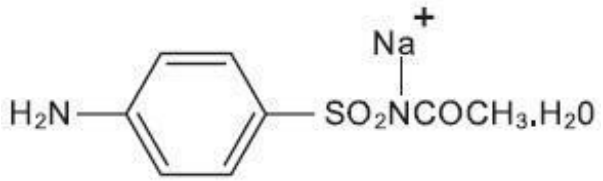
Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

AVAR™-e LS Emollient Cream (sodium sulfacetamide 10% and sulfur 2%)

Rx Only
FOR EXTERNAL USE ONLY.
NOT FOR OPHTHALMIC USE.

DESCRIPTION:
Each gram of AVAR™-e LS Emollient Cream (sodium sulfacetamide 10% w/w and sulfur 2% w/w) contains 100 mg of sodium sulfacetamide and 20 mg of colloidal sulfur in an emollient cream vehicle containing: arabica gum, benzyl alcohol, cetyl alcohol, 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:
AVAR™-e LS Emollient Cream is indicated for use in the topical control of acne vulgaris, acne rosacea and seborrheic dermatitis.

CONTRAINDICATIONS:
AVAR™-e LS Emollient Cream is contraindicated for use by patients having known hypersensitivity to sulfonamides, sulfur or any other component of this preparation. AVAR™-e LS Emollient 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:
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™-e LS Emollient Cream. It is also not known whether AVAR™-e LS Emollient Cream can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. AVAR™-e LS Emollient 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 topicaI use of AVAR™-e LS Emollient 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 AVAR™-e LS Emollient 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. **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:
AVAR™-e LS Emollient Cream is available in the following sizes:
Net wt. 45 g (1.6 oz) tube, NDC 0178-0465-45
Net wt. 2 oz (57 g) bottle, NDC 0178-0465-02
Net wt. 5 g sample packet, NDC 0178-0465-05

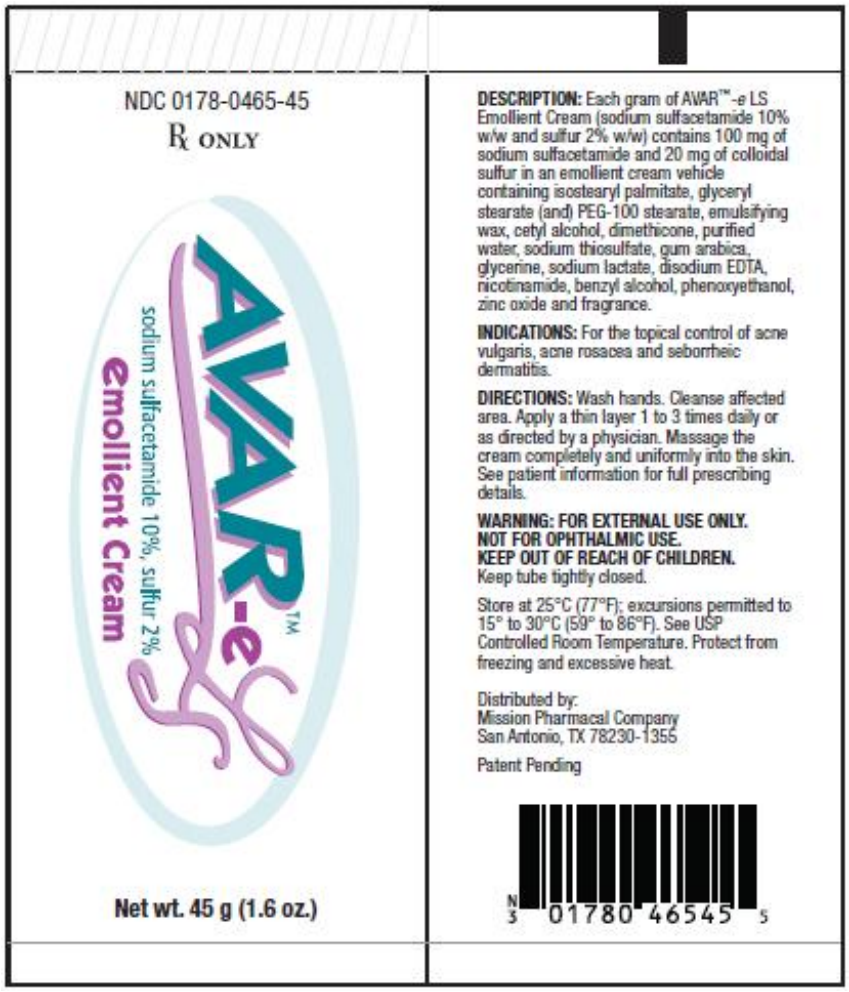
Store at 20°C to 25°C (68°F to 77°F), excursions permitted between 15°C and 30°C (between 59°F and 86°F). Brief exposures to temperatures up to 40°C (104°F) may be tolerated provided the mean kinetic temperature does not exceed 25°C (77°F); however, such exposure should be minimized.

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:
MISSION PHARMACAL COMPANY
San Antonio, TX 78230 1355

v2 Rev. 09/2012
Patent Pending



AVAR-E LS

sulfacetamide sodium, sulfur cream

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0178-0465
Route of Administration	TOPICAL	**DEA Schedule**	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SULFACETAMIDE SODIUM (UNII: 4NRT660KJQ) (SULFACETAMIDE - UNII:4965G3J0F5)	SULFACETAMIDE SODIUM	100 mg in 1 g
SULFUR (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70)	SULFUR	20 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
ACACIA (UNII: 5C5403N26O)	
ISOSTEARYL PALMITATE (UNII: 9EHU0R7ER1)	
NIACINAMIDE (UNII: 25X51I8RD4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
WATER (UNII: 059QF0KO0R)	
SODIUM LACTATE (UNII: TU7HW0W0QT)	

SODIUM THIOSULFATE (UNII: HX1032V43M)	
ZINC OXIDE (UNII: SOI2LOH54Z)	

Product Characteristics

Color	yellow (light yellow)	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0178-0465-45	1 in 1 CARTON		
1		45 g in 1 TUBE		
2	NDC:0178-0465-05	10 in 1 CARTON		
2		5 g in 1 PACKET		
3	NDC:0178-0465-02	57 g in 1 BOTTLE, PLASTIC		

Marketing Information

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

Labeler - Mission Pharmacal Company (008117095)

Revised: 12/2012 Mission Pharmacal Company