

SULFACETAMIDE SODIUM- sulfacetamide sodium suspension
E. Fougera & Co. a division of Fougera Pharmaceuticals Inc.

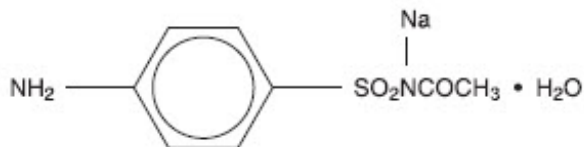
SULFACETAMIDE SODIUM
TOPICAL SUSPENSION USP, 10%

Rx only

FOR TOPICAL USE ONLY.

DESCRIPTION:

Each mL of Sulfacetamide Sodium Topical Suspension USP, 10% contains 100 mg of sulfacetamide sodium in a vehicle consisting of purified water, propylene glycol, lauramide DEA (and) diethanolamine, polyethylene glycol 400 monolaurate, hydroxyethyl cellulose, sodium chloride, sodium metabisulfite, methylparaben, xanthan gum, EDTA and simethicone. Sulfacetamide sodium is a sulfonamide with antibacterial activity. Chemically sulfacetamide sodium 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, based on sulfonamides acting as a competitive inhibitor of para-aminobenzoic acid (PABA) utilization, an essential component for bacterial growth. While absorption through intact skin in humans has not been determined, *in vitro* studies with human cadaver skin indicated a percutaneous absorption of about 4%. Sulfacetamide sodium is readily absorbed from the gastrointestinal tract when taken orally and excreted in the urine largely unchanged. The biological half-life has been reported to be between 7 to 13 hours.

The pharmacokinetics of sulfacetamide and its major metabolite sulfanilamide in Sulfacetamide Sodium Topical Suspension USP, 10% was evaluated in adult subjects (N=14) with *acne vulgaris*. The subjects applied Sulfacetamide Sodium Topical Suspension USP, 10% to their face, back, chest and shoulders every 12 hours for 28 days. The percentage of the applied dose of Sulfacetamide Sodium Topical Suspension USP, 10% excreted in the urine as sulfacetamide plus sulfanilamide, ranged from 0.08 to 0.33%.

INDICATIONS:

Sulfacetamide Sodium Topical Suspension USP, 10% is indicated in the topical treatment of *acne vulgaris*.

CONTRAINDICATIONS:

Sulfacetamide Sodium Topical Suspension USP, 10% is contraindicated for use by patients having a known hypersensitivity to sulfonamides or any other component of this preparation (see **WARNINGS** section).

WARNINGS:

Fatalities have occurred, although rarely, due to severe reactions to sulfonamides including Stevens-Johnson syndrome, toxic epidermal necrolysis, fulminant hepatic necrosis, agranulocytosis, aplastic anemia, and other blood dyscrasias. Hypersensitivity reactions may occur when a sulfonamide is readministered, irrespective of the route of administration. Sensitivity reactions have been reported in individuals with no prior history of sulfonamide hypersensitivity. At the first sign of hypersensitivity, skin rash or other reactions, discontinue use of this preparation (see **ADVERSE REACTIONS** section).

Sulfacetamide Sodium Topical Suspension USP, 10% contains sodium metabisulfite, a sulfite that may cause allergic-type reactions including anaphylactic symptoms and life threatening or less severe asthmatic episodes in certain susceptible people. The overall prevalence of sulfite sensitivity in the general population is unknown and probably low. Sulfite sensitivity is seen more frequently in asthmatic than non-asthmatic people (see **CONTRAINDICATIONS** section).

PRECAUTIONS:

General: For external use only. Keep away from eyes. 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. Hypersensitivity reactions may occur when a sulfonamide is readministered irrespective of the route of administration, and cross-sensitivity between different sulfonamides may occur. Sulfacetamide sodium can cause reddening and scaling of the skin. Particular caution should be employed if areas of involved skin to be treated are denuded or abraded.

Keep out of reach of children.

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 Sulfacetamide Sodium Topical Suspension USP, 10%. It is also not known whether Sulfacetamide Sodium Topical Suspension USP, 10% can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Sulfacetamide Sodium Topical Suspension USP, 10% should be given to a pregnant woman only if clearly needed.

Kernicterus may occur in the newborn as a result of treatment of a pregnant woman at term with orally administered sulfonamide. There are no adequate and well controlled studies of Sulfacetamide Sodium Topical Suspension USP, 10% in pregnant women, and it is not known whether topically applied sulfonamides can cause fetal harm when administered to a pregnant woman.

Nursing Mothers: It is not known whether sulfacetamide sodium is excreted in the human milk following topical use of Sulfacetamide Sodium Topical Suspension USP, 10%. Systemically administered sulfonamides are capable of producing kernicterus in the infants of lactating women. Small amounts of orally administered sulfonamides have been reported to be eliminated in human milk. Because many drugs are excreted in human milk, caution should be exercised in prescribing for nursing mothers.

Pediatric Use: Safety and effectiveness in pediatric patients under the age of 12 have not been established.

ADVERSE REACTIONS:

In controlled clinical trials for the management of *acne vulgaris*, the occurrence of adverse reactions associated with the use of Sulfacetamide Sodium Topical Suspension USP, 10% was infrequent and restricted to local events. The total incidence of adverse reactions reported in these studies was less than 2%. Only one of 105 patients treated with Sulfacetamide Sodium Topical Suspension USP, 10% had local adverse reactions of erythema, itching and edema. It has been reported that sulfacetamide

sodium may cause local irritation, stinging and burning. While the irritation may be transient, occasionally, the use of the medication has to be discontinued.

DOSAGE AND ADMINISTRATION:

Apply a thin film to affected areas twice daily.

HOW SUPPLIED:

Sulfacetamide Sodium Topical Suspension USP, 10%, is supplied in
118 mL bottles (4 fl oz) NDC 0168-0382-04

Store at controlled room temperature 20° to 25°C (68° to 77°F) [see USP].
Shake well before using. Keep tightly closed.

E. FOUGERA & CO.

A division of
Fougera
PHARMACEUTICALS INC.
Melville, New York 11747
I2382C/IF2382C
R07/13
#280

PACKAGE LABEL – PRINCIPAL DISPLAY PANEL – 118 mL (4 fl oz) CONTAINER LABEL

NDC 0168-0382-04

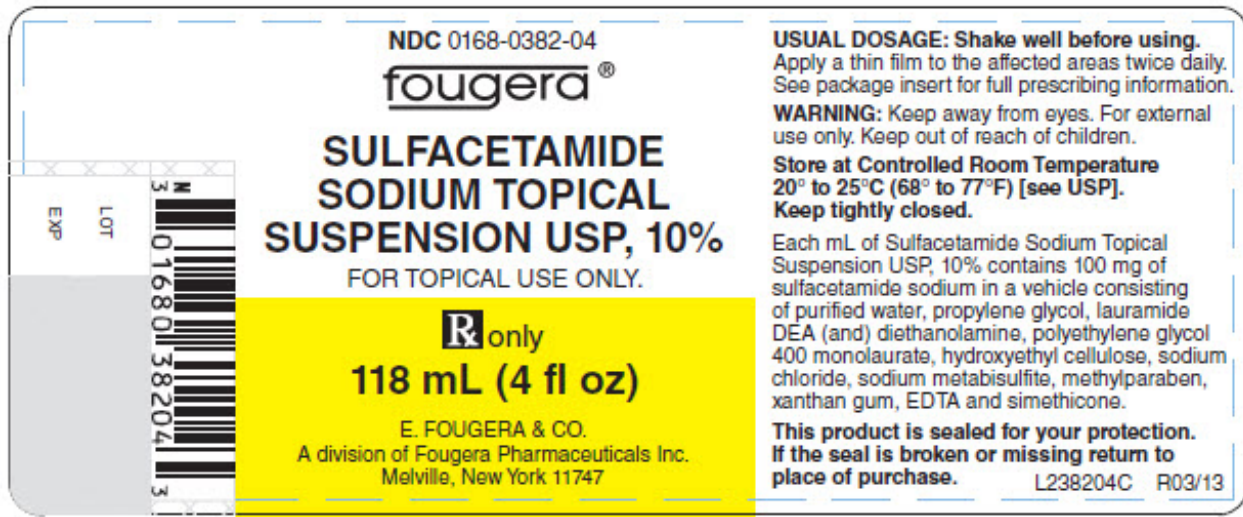
FOUGERA®

**SULFACETAMIDE
SODIUM TOPICAL
SUSPENSION USP, 10%**

FOR TOPICAL USE ONLY.
Rx Only

118 mL (4 floz)

E. FOUGERA & CO.
A division of Fougera Pharmaceuticals Inc.
Melville, New York 11747



PACKAGE LABEL – PRINCIPAL DISPLAY PANEL – 118 mL (4 fl oz) CARTON

NDC 0168-0382-04

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SODIUM TOPICAL
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USP, 10%**

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SULFACETAMIDE SODIUM

sulfacetamide sodium suspension

Product Information

Product Type

HUMAN PRESCRIPTION DRUG

Item Code (Source)

NDC:0168-0382

Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				
	Ingredient Name	Basis of Strength	Strength	
	SULFACETAMIDE SODIUM (UNII: 4NRT660KJQ) (SULFACETAMIDE - UNII:4965G3J0F5)	SULFACETAMIDE SODIUM	100 mg in 1 mL	
Inactive Ingredients				
	Ingredient Name	Strength		
	WATER (UNII: 059QF0KO0R)			
	SODIUM CHLORIDE (UNII: 451W47IQ8X)			
	SODIUM METABISULFITE (UNII: 4VON5FNS3C)			
	XANTHAN GUM (UNII: TTV12P4NEE)			
	PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
	METHYLPARABEN (UNII: A2I8C7HI9T)			
	LAURIC DIETHANOLAMIDE (UNII: I29I2VHG38)			
	DIETHANOLAMINE (UNII: AZE05TDV2V)			
	PEG-8 LAURATE (UNII: 762O8IWA10)			
	EDETIC ACID (UNII: 9G34HU7RV0)			
	SILICON DIOXIDE (UNII: ETJ7Z6XBU4)			
	DIMETHICONE (UNII: 92RU3N3Y1O)			
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0168-0382-04	118 mL in 1 BOTTLE		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA077015	11/17/2006		

Labeler - E. Fougera & Co. a division of Fougera Pharmaceuticals Inc. (043838424)

Revised: 9/2014

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