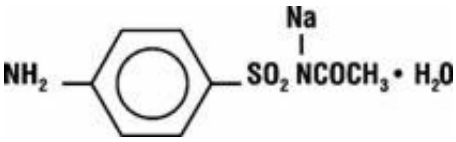
Dosage Form: lotion

Rx only

Sodium Sulfacetamide Description

Each mL of Sodium Sulfacetamide lotion, 10% contains 100 mg of Sodium Sulfacetamide in a vehicle consisting of dimethicone, EDTA, hydroxyethylcellulose, lauramide DEA, methylparaben, PEG-400 laurate, propylene glycol, sodium chloride, sodium metabisulfite, water (aqua) and xanthan gum.

Sodium Sulfacetamide is a sulfonamide with antibacterial activity. Chemically, Sodium Sulfacetamide is N'-[(4-amino phenyl) sulfonyl] - acetamide, monosodium salt, monohydrate. The structural formula is:



Sodium Sulfacetamide - 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%. Sodium Sulfacetamide 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 sulfaniliamide in Sodium Sulfacetamide lotion was evaluated in adult subjects (N=14) with acne vulgaris. The subjects applied Sodium Sulfacetamide lotion to their face, back, chest and shoulders every 12 hours for 28 days. The percentage of the applied dose of Sodium Sulfacetamide lotion excreted in the urine as sulfacetamide plus sulfanilamide, ranged from 0.08 to 0.33%.

INDICATIONS

Sodium Sulfacetamide lotion is indicated in the topical treatment of *acne vulgaris*.

Contraindications

Sodium Sulfacetamide lotion is contraindicated for use by patients having 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).

Sodium Sulfacetamide lotion 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 in 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. Sodium Sulfacetamide 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 the 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 Sodium Sulfacetamide lotion. It is also not known whether Sodium Sulfacetamide lotion can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Sodium Sulfacetamide lotion 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 Sodium Sulfacetamide lotion 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 Sodium Sulfacetamide is excreted in the human milk following topical use of Sodium Sulfacetamide lotion. 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 women.

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 Sodium Sulfacetamide lotion 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 Sodium Sulfacetamide lotion had adverse reactions of erythema, itching and edema. It has been reported that Sodium Sulfacetamide may cause local irritation, stinging and burning. While the irritation may be transient, occasionally, the use of medication has to be discontinued.

Sodium Sulfacetamide Dosage and Administration

Apply a thin film to affected areas twice daily.

How is Sodium Sulfacetamide Supplied

4 FL OZ (118 mL) bottles (NDC 68682-010-04).

Store at 20° to 25°C (68° to 77°F)[See USP Controlled Room Temperature].
Shake well before using. Keep tightly closed.

Distributed by:
Oceanside Pharmaceuticals, a division of

Valeant Pharmaceuticals North America LLC
Bridgewater, NJ 08807 USA

Made in Canada

9473900
Rev. 06/15

PRINCIPAL DISPLAY PANEL - 118 mL Bottle Carton

NDC 68682-010-04

Rx only

Sodium

Sulfacetamide

Lotion, 10%

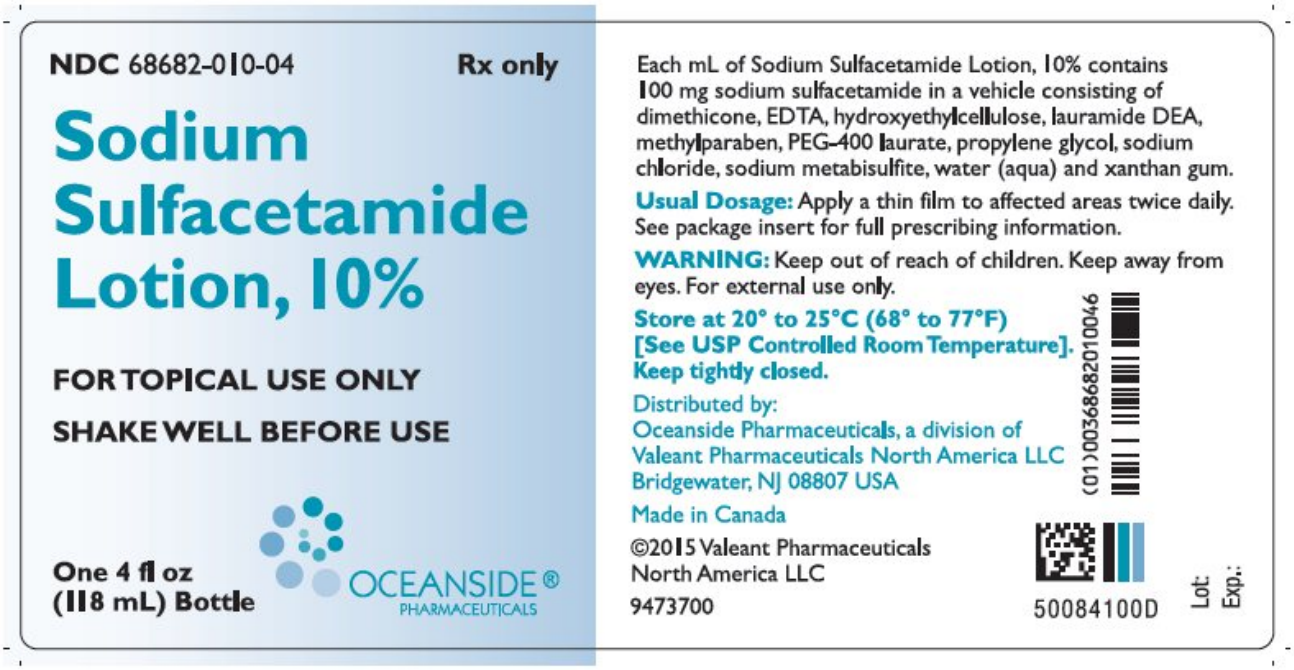
FOR TOPICAL USE ONLY

SHAKE WELL BEFORE USING

One4 fl oz

(118 mL) Bottle

OCEANSIDE®
PHARMACEUTICALS



Sodium Sulfacetamide

Sodium Sulfacetamide lotion

Product Information

Product Type	HUMAN PRESCRIPTION DRUG LABEL	**Item Code (Source)**	NDC:68682-010
Route of Administration	TOPICAL	**DEA Schedule**	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
sulfacetamide sodium (sulfacetamide)	sulfacetamide sodium	100 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
DIMETHICONE	
EDETIC ACID	
HYDROXYETHYL CELLULOSE (2000 MPA.S AT 1%)	
LAURIC DIETHANOLAMIDE	
methylparaben	
PEG-8 LAURATE	
PROPYLENE GLYCOL	

sodium chloride	
sodium metabisulfite	
water	
xanthan gum	

Packaging

#	Item Code	Package Description
1	NDC:68682-010-04	118 mL in 1 BOTTLE, PLASTIC

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA authorized generic	NDA019931	12/18/2015	

Labeler - Oceanside Pharmaceuticals (832011691)

Establishment

Name	Address	ID/FEI	Operations
Valeant Pharmaceuticals International, Inc		245141858	MANUFACTURE(68682-010)

Revised: 06/2015
Oceanside Pharmaceuticals