SODIUM SULFACETAMIDE WASH 10%- sodium sulfacetamide liquid
Oncor Pharmaceuticals

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.

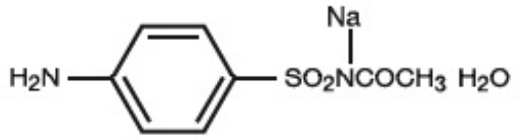
Sodium Sulfacetamide Wash 10%

Rx Only

DESCRIPTION:

Each gram contains 100 mg of sodium sulfacetamide in a vehicle consisting of: Butylated hydroxytoluene, Citric acid, Cetyl alcohol, Cocamidopropyl betaine, Disodium EDTA, Glycerin, Glyceryl stearate SE, PEG-100 stearate, Phenoxyethanol, Purified water, Sodium laureth sulfate, Sodium thiosulfate, Stearyl alcohol, Triacetin, Xanthan gum.

Sodium sulfacetamide is a sulfonamide with antibacterial activity. Sodium sulfacetamide is $C_8H_9N_2NaO_3S.H_2O$ with molecular weight of 254.24. Chemically sodium sulfacetamide is N-[(4-aminophenyl) sulfonyl)acetamide, monosodium salt, monohydrate. The structural formula is:



Sodium sulfacetamide is an odorless, white, crystalline powder with a bitter taste. It is freely soluble in water, sparingly soluble in alcohol, while practically insoluble in benzene, in chloroform and in ether.

CLINICAL PHARMACOLOGY:

Sodium sulfacetamide exerts a bacteriostatic effect against sulfonamide sensitive gram-positive and gram-negative microorganisms commonly isolated from secondary cutaneous pyogenic infections. It acts by restricting the synthesis of folic acid required by bacteria for growth, by its competition with para-aminobenzoic acid. There is no clinical data available on the degree and rate of systemic absorption of this product when applied to the skin or scalp. However, significant absorption of sodium sulfacetamide through the skin has been reported.

The following in vitro data is available but the clinical significance is unknown. Organisms that show susceptibility to sodium sulfacetamide are:
Streptococci, Staphylococci, E. coli, Klebsiella pneumoniae, Pseudomonas pyocyanea, Salmonella species, Proteus vulgaris, Nocardia and Actinomyces.

INDICATIONS:

This product is intended for topical application in the following scaling dermatoses: Seborrheic dermatitis and seborrhea sicca (dandruff). It also is indicated for the treatment of secondary bacterial infections of the skin due to

organisms susceptible to sulfonamides.

DIRECTION OF USE:

Wash affected areas twice daily (morning and evening) or as directed by your 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. Rinsing with plain water will remove any excess medication. Repeat application as described above for 8 to 10 days or as directed by your physician, If skin dryness occurs it may be controlled by rinsing cleanser off sooner or using less frequently. See package insert for full prescribing information.

CONTRAINDICATIONS:

This product is contraindicated in persons with known or suspected hypersensitivity to any of the ingredients of the product. This product is not
to be used by patients with kidney disease.

WARNINGS:

Sulfonamides are known to cause sevens-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: Nonsusceptible organisms, including fungi, may proliferate with the use of this preparation.

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. If the use of this product produces signs of hypersensitivity or other untoward reactions, discontinue use of the preparation. Patients should be carefully observed for possible local irritation or sensitization during long-term therapy. 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. Systemic absorption of topical sulfonamides is greater following application to large, infected, abraded, denuded or severely burned areas. Under these circumstances, any of the adverse effects produced by the systemic administration of these agents could potentially occur, and appropriate observations and laboratory determinations should be performed.

INFORMATION FOR PATIENTS:

Patients should discontinue the use of this product if the condition becomes worse or if a rash develops in the area being treated or elsewhere. The use of this product also should be discontinued promptly and the physician notified if any arthritis, fever or sores

in the mouth develop. Avoid contact with eyes, lips and mucous membranes.

DRUG INTERACTIONS: This product is incompatible with silver preparations.

CARCINOGENESIS, MUTAGENESIS AND IMPAIRMENT OF FERTILITY:

Long-term animal studies for carcinogenic potential have not been performed on this product to date. Studies on reproduction and fertility also
have not been performed. Chromosomal nondisjunction has been reported in the yeast, Saccharomyces cerevisiae, following application of sodium sulfacetamide. The significance of this finding to the topical use of sodium sulfacetamide in the human is unknown.

PREGNANCY: Category C. Animal reproduction studies have not been conducted with this product. It is also not known whether this product can cause fetal harm when administered to a pregnant woman. This product should be given to a pregnant woman only if clearly needed or when potential benefits outweigh potential hazards to the fetus..

NURSING MOTHERS: It is not known whetherthis drug is excreted in the human milk. Because many drugs are excreted in human milk, caution should be exercised when this is administered to a nursing woman.

PEDIATRIC USE:

Safety and effectiveness in children under the age of 12 have not been established.

ADVERSE REACTIONS:

Reports of irritation and hypersensitivity to sodium sulfacetamide are uncommon. The following adverse reactions, reported after administration
of sterile ophthalmic sodium sulfacetamide, are noteworthy: instances of Stevens-Johnson syndrome and instances of local hypersensitivity which
progressed to a syndrome resembling systemic lupus erythematosus; in one case a fatal outcome was reported.

OVERDOSAGE:
The oral LD50 of sulfacetamide in mice is 16.5 g/kg. In the event of overdosage, emergency treatment should be started immediately.

MANIFESTATIONS: Overdosage may cause nausea and vomiting. Large oral overdosage may cause hematuria, crystalluria and renal shutdown due to the precipitation of sulfa crystals in the renal tubules and the urinary tract. For treatment, contact your local Poison Control Center or your doctor.

DOSAGE AND ADMINISTRATION:

Seborrheic dermatitis including seborrhea sicca - Wash affected areas twice daily (morning and evening) or as directed by your physician. Avoid contact with eyes or mucous membranes. Wet skin and liberally apply to areas to be cleansed, massage gently into skin working into a full lather, rinse thoroughly, pat dry and repeat after 10 to 20 seconds. Rinsing with plain water will remove any excess medicatlon. Repeat application as described above for 8 to 10 days or as directed by your physician. If skin dryness occurs it may be controlled by rinsing cleanser off sooner or using less frequently. Regular shampooing following the use of this product is not necessary, but the hair should be shampooed at least once a week. As the condition subsides, the interval between applications may be lengthened. Applications once or twice weekly or

every other week may prevent recurrence. Should the condition recur after stopping therapy, the application of this product should be reinitiated as at the beginning of treatment.

Secondary cutaneous bacterial infecllons - Wash affected areas twice daily (morning and evening) or as directed by your physician. Avoid contact with eyes or mucous membranes. Wet skin and liberally apply to areas to be cleansed, massage gently into skin for 1 o to 20 seconds working into a full lather, rinse thoroughly and pat dry. Rinsing with plain water will remove any excess medication. Repeat application as described above for 8 to 10 days or as directed by your physician. If skin dryness occurs it may be controlled by rinsing cleanser off sooner or using less frequently.

INACTIVE INGREDIENTS:

Butylated hydroxytoluene, Citric acid, Cetyl alcohol, Cocamidopropyl betaine, Disodium EDTA, Glycerin, Glyceryl stearate SE, PEG-100 stearate,
Phenoxyethanol, Purified water, Sodium laureth sulfate, Sodium thiosulfate, Stearyl alcohol, Triacetin, Xanthan gum.

STORAGE:

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 exposure 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.

NOTICE:

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 bottle tightly closed.

Occasionally, a slight discoloration of fabric 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.

HOW SUPPLIED:

This product is supplied in the following size(s):
6 oz. (177 ml) bottles NDC 83720-533-06
12 oz. (355 ml) bottles NDC 83720-533-12
In case of accidental ingestion contact a Poison Control Center immediately.
Keep container lightly closed.

You may report side effects by calling Oncor Pharmaceuticals (9 a.m. to 5 p.m. EST), at 1-443-876-7900 or FDA at 1-800-FDA-1088.

This bottle is not filled to the top but does contain 6 fl oz of product as identified on the front panel of the bottle.

Manufactured In USA For :
ONCOR PHARMACEUTICALS
8815 Center Park Dr Suite 430
Columbia
Maryland 21045

Rev.05/24

ONCOR PHARMACEUTICALS

NDC 83720-533-06

Sodium Sulfacetamide

Sodium Sulfacetamide 10%

10% Wash

For External Use Only
Not For Ophthalmic Use.

Rx Only

NET WT.6 OZ. (177 ml)

SODIUM SULFACETAMIDE WASH 10%

sodium sulfacetamide liquid

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:83720-533
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
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
PEG-100 STEARATE (UNII: YD01N1999R)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
TRIACETIN (UNII: XHX3C3X673)	
SODIUM THIOSULFATE (UNII: HX1032V43M)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
WATER (UNII: 059QF0KO0R)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83720-533-06	177 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/10/2024	
2	NDC:83720-533-12	355 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/10/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		05/10/2024	

Labeler - Oncor Pharmaceuticals (119032580)

Registrant - Oncor Pharmaceuticals (119032580)