SODIUM SULFACETAMIDE 10% AND SULFUR 5% CLEANSER- sodium sulfacetamide 10% and sulfur 5% rinse
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.

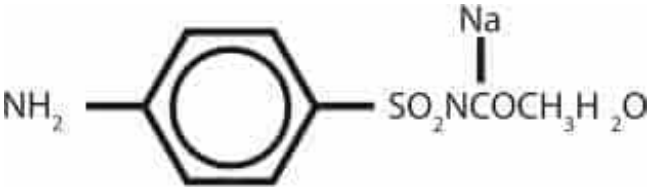
Sodium Sulfacetamide 10% and Sulfur 5% Cleanser

Rx Only

DESCRIPTION

Each gram of sodium sulfacetamide 10% and sulfur 5% cleanser contains 100 mg of sodium sulfacetamide and 50 mg of sulfur in a cleanser containing ammonium Aloe vera leaf extract, Butylated hydroxytoluene, Cetyl alcohol, Citric acid, 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 while sulfur acts as a keratolytic agent. Chemically sodium sulfacetamide is N-[(4-aminophenyl)sulfonyl]-acetamide, monosodium salt, monohydrate. The structural formula is:



INDICATIONS

Sodium Sulfacetamide 10% & Sulfur 5% Cleanser is indicated in the topical control of acne vulgaris, acne rosacea and seborrheic dermatitis.

DOSAGE AND ADMINISTRATION

Wash affected areas once or twice daily, or as directed by your physician. Avoid contact with eyes or mucous membranes. Wet skin and libera ly apply to areas to be cleansed, massage gently into skin for 10-20 seconds working into a full lather, rinse thoroughly and pat dry. If drying occurs, it may be contro led by rinsing cleanser off sooner or using less often.

CAUTION

If redness or irritaiton occurs, discontinue use.
Call your doctor for medical advice about side effects.

FOR EXTERNAL USE ONLY. NOT FOR INTRA VAGINAL OR OPHTHALMIC USE.

(KEEP AWAY FROM EYES).

KEEP OUT OF REACH OF CHILDREN.
Shake well before use

STORAGE

Store at 20°C to 25°C (68°F to 77°F). See USP controlled room temperature.

Protect from freezing.

CLINICAL PHARMACOLOGY

The most widely accepted mechanism of action of sulfonamides is the woods-fields 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.

CONTRAINDICATIONS

Sodium Sulfacetamide 10% & Sulfur 5% Cleanser is contraindicated for use by patients having known hypersensitivity to sulfonamides, sulfur or any other component of this preparation. Sodium Sulfacetamide 10% & Sulfur 5% Cleanser is not to be used by patients with kidney disease.

WARNINGS

Although it is 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.

PRECAUTIONS
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.

INFORMATION FOR PATIENTS

Avoid contact with eyes, eyelids, lips and mucous membranes. If accidental contact occurs, rinse with water. If excessive irritation develops, discontinue use and consult your physician.

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 10% & Sulfur 5% Cleanser. It is also not known whether Sodium Sulfacetamide 10% & Sulfur 5% Cleanser can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Sodium Sulfacetamide 10% & Sulfur 5% Cleanser should be given to a pregnant woman only if clearly needed.

NURSING MOTHERS

It is not known whether sodium sulfacetamide is excreted in the human milk following topical use of Sodium Sulfacetamide 10% & Sulfur 5% Cleanser. However, small amounts of orally administered sulfonamides have milk. In view of this and because many drugs are excreted in human milk, caution should be exercised when Sodium Sulfacetamide 10% & Sulfur 5% Cleanser is administered to a nursing woman.

PEDIATRIC USE

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

undefined

Although rare, sodium sulfacetamide may cause local irritation.

HOW SUPPLIED

Sodium Sulfacetamide 10% & Sulfur 5% Cleanser is available in
6 oz (170 g) bottle NDC 83720-547-06
12 oz (340 g) bottle NDC 83720-547-12

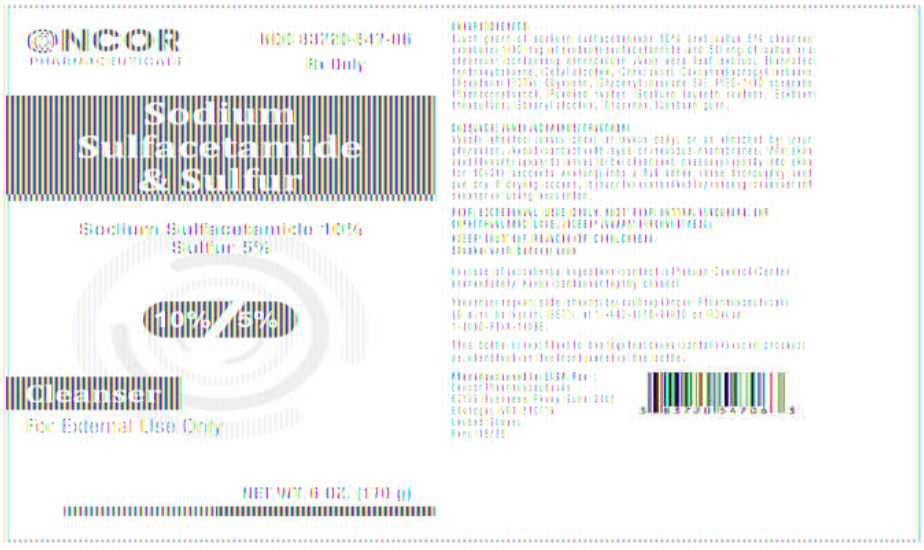
In case of accidental ingestion contact a Poison Control Center immediately. Keep container tightly closed.

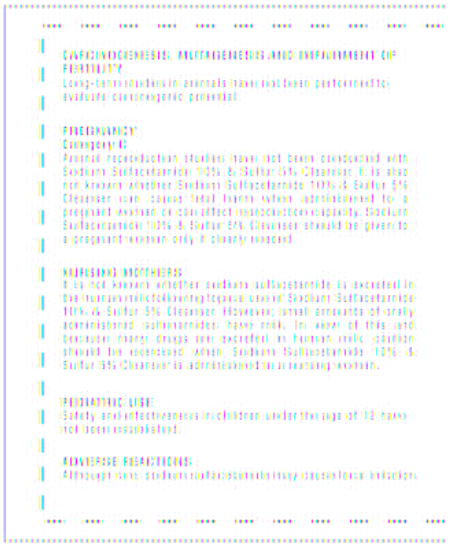
You may report side effects by ca ling Oncor Pharmaceuticals (9 a.m. to 5 p.m. EST), at

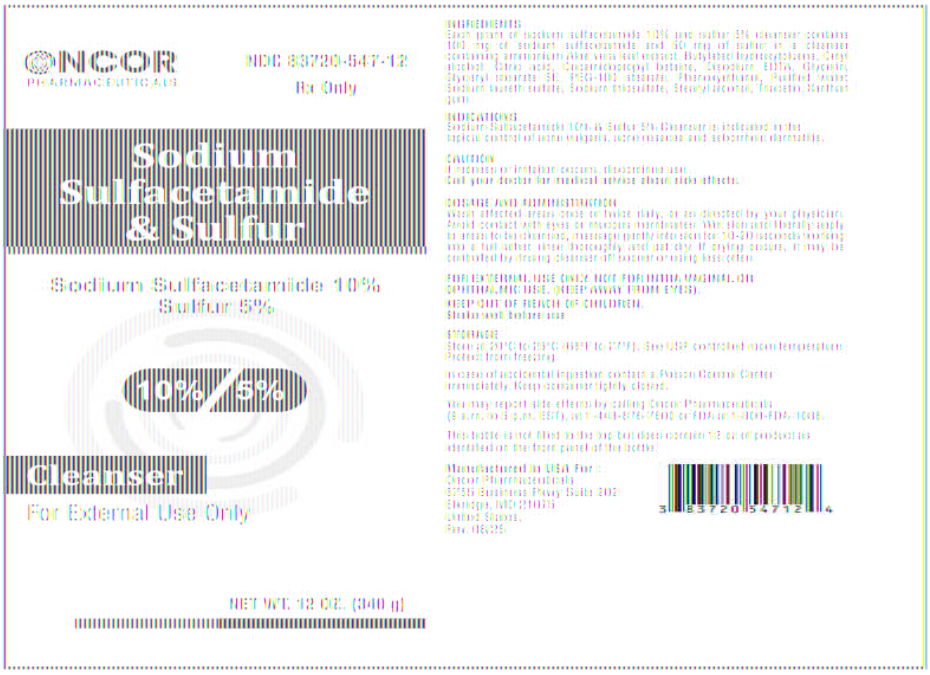
1-443-876-7600 or FDA at 1-800-FDA-1088.

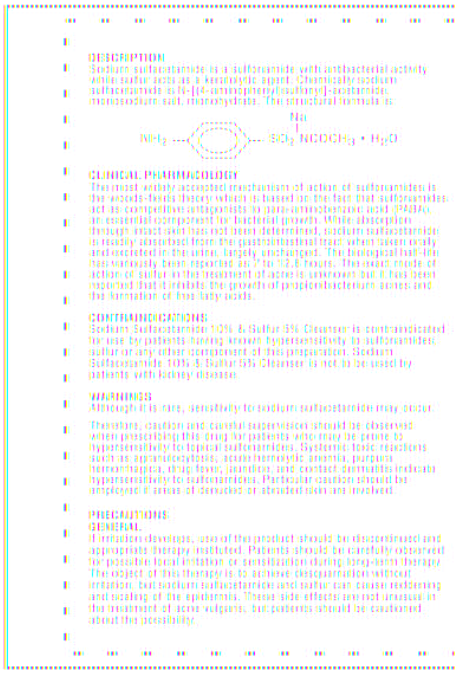
Manufactured In USA For :

Oncor Pharmaceuticals
6755 Business Pkwy Suite 202
Elkridge, MD 21075
United States.
Rev. 08/25









SODIUM SULFACETAMIDE 10% AND SULFUR 5% CLEANSER

sodium sulfacetamide 10% and sulfur 5% rinse

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:83720-547
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 g
SULFUR (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70)	SULFUR	50 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CITRIC ACID (UNII: 2968PHW8QP)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
PEG-100 STEARATE (UNII: YD01N1999R)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
WATER (UNII: 059QF0KO0R)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
SODIUM THIOSULFATE (UNII: HX1032V43M)	

STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
TRIACETIN (UNII: XHX3C3X673)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83720-547-06	170 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/14/2027	
2	NDC:83720-547-12	340 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/14/2027	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		08/14/2025	

Labeler - Oncor Pharmaceuticals (119032580)

Registrant - Oncor Pharmaceuticals (119032580)

Revised: 8/2025 Oncor Pharmaceuticals