

OVACE PLUS - sulfacetamide sodium shampoo
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.

OVACE® Plus Shampoo (sodium sulfacetamide 10%)

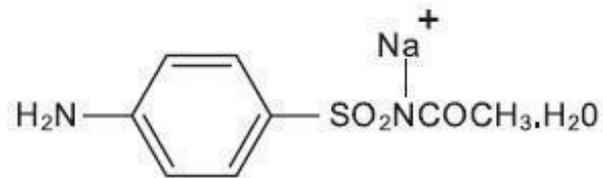
Rx Only

FOR EXTERNAL USE ONLY. NOT FOR OPHTHALMIC USE.

DESCRIPTION:

Each gram of OVACE® Plus Shampoo (sodium sulfacetamide 10% w/w) contains 100 mg of sodium sulfacetamide in a vehicle consisting of cetearyl alcohol (and) PEG-3 distearoylamidoethylmonium methosulfate (and) polysorbate 60, citric acid anhydrous, cocamide MEA, cocamidopropyl betaine, ethylene glycol distearate, Flamenco Super Blue, fragrance, magnesium aluminum silicate, methylparaben, PEG-150 distearate, propylparaben, purified water, sodium chloride and sodium laureth sulfate.

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:



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 OVACE® Plus Shampoo 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 AND USAGE:

OVACE® Plus Shampoo is intended for topical application in the following scaling dermatoses: seborrheic dermatitis and seborrhea sicca (dandruff). Shake well before using.

CONTRAINDICATIONS:

OVACE[®] Plus Shampoo is contraindicated in persons with known or suspected hypersensitivity to sulfonamides or to any of the ingredients of the product.

WARNINGS:

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 THE 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. Hypersensitivity reactions may recur when a sulfonamide is readministered, irrespective of the route of administration, and cross hypersensitivity between different sulfonamides may occur. If OVACE[®] Plus Shampoo produces signs of hypersensitivity or other untoward reactions, discontinue use of the preparation. 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 OVACE[®] Plus Shampoo if the condition becomes worse, or if a rash develops in the area being treated or elsewhere. OVACE[®] Plus Shampoo also should be discontinued promptly and the physician notified if any arthritis, fever or sores in the mouth develop.

Drug Interactions: OVACE[®] Plus Shampoo is incompatible with silver preparations.

Pharmacology: OVACE[®] Plus Shampoo has a bacteriostatic effect against Gram-positive and Gram-negative microorganisms commonly isolated from secondary cutaneous pyogenic infections.

Carcinogenesis, Mutagenesis and Impairment of Fertility: Long-term animal studies for carcinogenic potential have not been performed on OVACE[®] Plus Shampoo 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 OVACE[®] Plus Shampoo. It is also not known whether OVACE[®] Plus Shampoo can affect reproduction capacity or cause fetal harm when administered to a pregnant woman. OVACE[®] Plus Shampoo should be used by a pregnant woman only if clearly needed or when potential benefits outweigh potential hazards to the fetus.

Nursing Mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when OVACE[®] Plus Shampoo is administered to a nursing woman.

Pediatric Use: Safety and effectiveness in children under the age of 12 years has 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 (see WARNINGS). **You should call your doctor for medical advice about side effects. To report a serious adverse event, call 1-800-298-1087.**

OVERDOSAGE:

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

Manifestations: Overdosage may cause nausea and vomiting. Large oral overdose 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:

Apply to wet hair and massage vigorously into scalp. Rinse thoroughly. For best results, use at least twice a week or as directed by a doctor. Avoid contact with eyes or mucous membranes. Do not use on an infant less than 2 months of age.

HOW SUPPLIED:

OVACE[®] Plus Shampoo is available in an 8 fl. oz. (237 mL) bottle, NDC 0178-0485-08 and 5 g sample packets, NDC 0178-0485-05.

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 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.

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 container 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

Patent Pending

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Patent Pending

v1 Rev. 02/2012



R ONLY

NDC 0178-0485-08

OVACE PLUS
SHAMPOO
(SODIUM SULFACETAMIDE 10%)



OVACE PLUS

sulfacetamide sodium shampoo

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0178-0485
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
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
PEG-3 DISTEAROYLAMIDOETHYLMONIUM METHOSULFATE (UNII: 395MHJ5PUR)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
CO CO MONOETHANOLAMIDE (UNII: C80684146D)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3011KX)	

GLYCOL DISTEARATE (UNII: 13W7MDN21W)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
METHYLPARABEN (UNII: A2I8C7H9T)	
PEG-150 DISTEARATE (UNII: 6F36Q0I0AC)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0178-0485-08	237 mL in 1 BOTTLE, PLASTIC		
2	NDC:0178-0485-05	10 in 1 CARTON		
2		5 mL in 1 PACKET		

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: 10/2012

Mission Pharmacal Company