OVACE PLUS - sulfacetamide sodium liquid
Mission Pharmacal Company

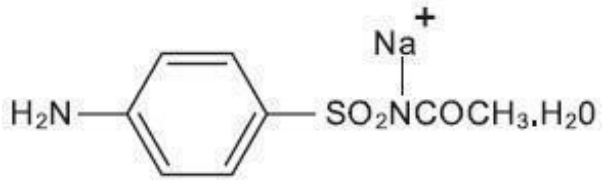
Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

OVACE® Plus Wash Cleansing Gel (sodium sulfacetamide 10%)

Rx Only
FOR EXTERNAL USE ONLY. NOT FOR OPHTHALMIC USE.

DESCRIPTION:
Each gram of OVACE® Plus Wash (sodium sulfacetamide 10% w/w) contains 100 mg of sodium sulfacetamide incorporated into a specially formulated oil and water emulsion (OIW™), delivered in a gel vehicle consisting of cocamidopropyl betaine, sodium thiosulfate, emulsifying wax, glyceryl stearate SE, cetearyl alcohol (and) PEG-3 distearoylamidoethylmonium methosulfate (and) polysorbate 60, PEG-150 pentaerythrityl tetrastearate (and) aqua (and) PEG-6 caprylic/capric glycerides, methylparaben, purified water, sodium laureth ether sulfate, disodium EDTA dihydrate, xanthan gum and fragrance.

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. This OIW™ formulation has been shown to provide gradual and prolonged release of the active ingredient into the skin.

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 Wash 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 Wash 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.

CONTRAINDICATIONS:
OVACE® Plus Wash 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 Wash 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 Wash if the condition becomes worse, or if a rash develops in the area being treated or elsewhere. OVACE® Plus Wash also should be discontinued promptly and the physician notified if any arthritis, fever or sores in the mouth develop.

Drug Interactions: OVACE® Plus Wash is incompatible with silver preparations.

Pharmacology: OVACE® Plus Wash 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 Wash 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 Wash. It is also not known whether OVACE® Plus Wash can affect reproduction capacity or cause fetal harm when administered to a pregnant woman. OVACE® Plus Wash 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 Wash 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). Call your doctor for medical advice about side effects. **To report SUSPECTED ADVERSE REACTIONS, contact the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.**

OVERDOSAGE:
The oral LD_{50} 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 medication. Repeat application as described for 8 to 10 days. lf skin dryness occurs it may be controlled by rinsing cleanser off sooner or using less frequently. Regular shampooing following OVACE® Plus Wash 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 OVACE® Plus Wash should be reinitiated as at the beginning of treatment.

Secondary cutaneous bacterial infections - 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 for 8 to 10 days. If skin dryness occurs it may be controlled by rinsing cleanser off sooner or using less often.

HOW SUPPLIED:
OVACE® Plus Wash is available in a 12 fl. oz. (355 mL) bottle, NDC 0178-0490-12, and 5 g sample packets, NDC 0178-0490-05.

Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F). See USP Controlled Room Temperature.

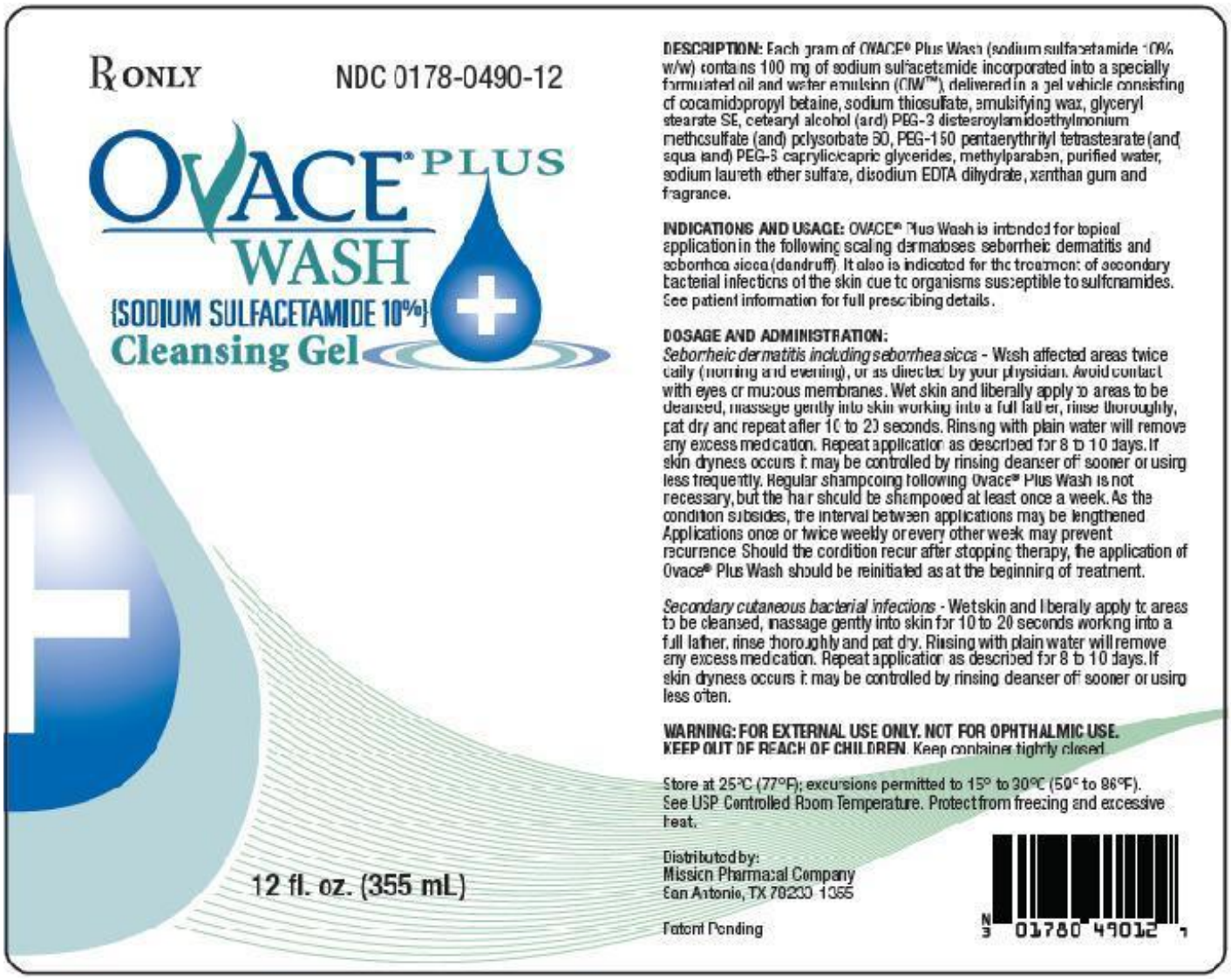
Note: Protect from freezing and excessive heat. The product may tend to darken slightly on storage. Slight discoloration does not impair the efficacy or safety of the product. Keep container or packet tightly closed.

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



OVACE PLUS

sulfacetamide sodium liquid

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG LABEL	**Item Code (Source)**	NDC:0178-0490
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
CETOSTEARYL ALCOHOL	
PEG-3 DISTEAROYLAMIDOETHYLMONIUM METHOSULFATE	
POLYSORBATE 60	
COCAMIDOPROPYL BETAINE	
EDETATE DISODIUM	
GLYCERYL STEARATE SE	
METHYLPARABEN	
PEG-150 PENTAERYTHRITYL TETRASTEARATE	
PEG-6 CAPRYLIC/CAPRIC GLYCERIDES	
WATER	
SODIUM LAURETH SULFATE	
SODIUM THIOSULFATE	
XANTHAN GUM	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0178-0490-12	355 mL in 1 BOTTLE, PLASTIC		
2	NDC:0178-0490-05	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