

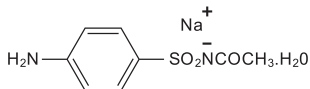
Rx ONLY

## OVACE® (SODIUM SULFACETAMIDE 10%) FOAM

FOR DERMATOLOGIC USE ONLY — NOT FOR OPHTHALMIC USE

**DESCRIPTION:** Each gm (0.95ml) of Ovace® (sodium sulfacetamide 10%) Foam contains 100 mg of sodium sulfacetamide USP in a vehicle consisting of purified water, PVP/DMAPE acrylates copolymer, povidone, cocamidopropyl betaine, methylparaben, disodium EDTA, sodium thiosulfate, glycerin, aluminum 26, propylene glycol and lactic acid and is dispersed from an aluminum can pressurized with a hydrocarbon propellant (propane/butane).

Sulfacetamide sodium is  $C_8H_9N_3NaO_5 \cdot H_2O$  with a molecular weight of 254.24. Chemically, it is Acetamide N-[4-(aminophenyl)sulfonyl]-, monosodium salt, monohydrate, with the following structural formula:



Sulfacetamide sodium 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:** Sulfacetamide sodium 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 are no clinical data available on the degree and rate of systemic absorption of Ovace® Foam when applied to the skin or scalp. However, significant absorption of sulfacetamide sodium through the skin has been reported.

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

**INDICATIONS AND USAGE:** Ovace® Foam 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® Foam 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 sulfacetamide sodium 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.

### PRECAUTIONS:

For external use only

**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® Foam 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, potentially any of the adverse effects produced by the systemic administration of these agents could occur and appropriate observations and laboratory determinations should be performed.

**Information For Patients:** Patients should discontinue Ovace® Foam if the condition becomes worse, or if a rash develops in the area being treated or elsewhere. Ovace® Foam also should be discontinued promptly and the physician notified if any arthritis, fever, or sores in the mouth develop.

**Drug Interactions:** Ovace® Foam is incompatible with silver preparations.

**Pharmacology:** Ovace® Foam has 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® Foam to date. Studies on reproduction and fertility also have not been performed. One other detected chromosomal nondisjunction in the yeast, *Saccharomyces cerevisiae*, following application of sulfacetamide sodium. The significance of this finding to the topical use of sulfacetamide sodium in the human is unknown.

**Pregnancy Category C:** Animal reproduction studies have not been conducted with Ovace® Foam. It also is not known whether Ovace® Foam can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Ovace® Foam 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® Foam is administered to a nursing woman.

**Pediatric Use:** Safety and effectiveness in children under the age of 12 years have not been established.

**ADVERSE REACTIONS:** Reports of irritation and hypersensitivity to sulfacetamide sodium are uncommon. The following adverse reactions, reported after administration of sterile ophthalmic sulfacetamide sodium, 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 has been reported. (See WARNINGS)

**OVERDOSAGE:** The oral LD<sub>50</sub> of sulfacetamide in mice is 16.5 g/kg. The LD<sub>50</sub> for topical administration of sulfacetamide has not been determined. Oral overdosage may cause nausea and vomiting. Large oral overdosage may cause hematuria, crystalluria, and renal shutdown due to precipitation of sulfa crystals in the renal tubules and the urinary tract. For treatment, contact local Poison Control Center.

### DOSAGE AND ADMINISTRATION:

**NOTE:** For proper dispensing of foam, the can must be inverted.

**Seborrheic dermatitis including seborrhea sicca-Ovace® Foam:** Shake well before use. Remove clear cap. Gently break the thin plastic piece where the back of the nozzle connects to the top. Invert can and dispense small amount of Ovace® Foam onto hand. The exact amount needed will vary

according to the size of the affected area. Hair should be towel-dried or dry before applying to scalp. With fingers, gently massage Ovace® Foam into affected areas of the scalp until foam disappears. Use twice daily or as directed by your physician. Wash your hands after applying the foam. Allow the treated area to air dry. Do not wash the treated area immediately after applying the foam. Hair styling products can be used as usual after the foam has been applied. Repeat application as described for 8-10 days.

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® Foam should be reinitiated as at the beginning of treatment.

**Secondary Cutaneous Bacterial Infections—** Shake well before use. Remove clear cap. Gently break the thin plastic piece where the back of the nozzle connects to the top. Invert can and dispense small amount of Ovace® Foam onto hand. The exact amount needed will vary according to the size of the affected area. With fingers, gently massage Ovace® Foam into affected areas until foam disappears. Repeat application as described for eight to ten days.

**HOW SUPPLIED:** Ovace® Foam is available in 100 gram (NDC 13548-041-10) and 50 gram (NDC 13548-041-50) aluminum cans.

**NOTE:** Store at controlled room temperature 68°-77°F (20°-25°C).

Store Upright.

Occasionally, a slight yellowish discoloration may occur when an excessive amount of the foam 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.

**WARNING: FLAMMABLE. AVOID FIRE, FLAME OR SMOKING DURING USE.** Contents under pressure. Do not puncture or incinerate container. Do not expose to heat or store at temperatures about 104°F (40°C).

Keep out of reach of children.



Marketed by:  
**CORIA LABORATORIES, LTD.**  
Fort Worth, TX 76107

Manufactured by:  
**DPT LABORATORIES, LTD.**  
San Antonio, TX 78215

### REORDER NO.

13548-041-10 (100gm can)  
13548-041-50 (50gm can)