

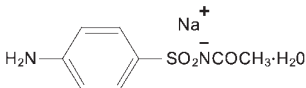
Rx ONLY

OVACE® **(SODIUM SULFACETAMIDE 10%)** **WASH**

FOR DERMATOLOGIC USE ONLY - NOT FOR OPHTHALMIC USE

DESCRIPTION: Each gram of **Ovace® (sodium sulfacetamide 10%) Wash** contains 100 mg of sulfacetamide sodium USP in a vehicle consisting of cocamidopropyl betaine, edetate disodium, methylparaben, PEG-60 almond triglycerides, PEG-150 pentaerythrityl tetrastearate, PEG-6 caprylic/capric glycolides, purified water, sodium laureth sulfate, and sodium thiosulfate.

Sulfacetamide sodium is $C_8H_{11}NaO_5 \cdot H_2O$ 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® Wash** 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® 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® 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 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® 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, 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® Wash** if the condition becomes worse, or if a rash develops in the area being treated or elsewhere. **Ovace® Wash** also should be discontinued promptly and the physician notified if any arthritis, fever, or sores in the mouth develop.

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

Pharmacology: **Ovace® Wash** 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® Wash** to date. Studies on reproduction and fertility also have not been performed. One author 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® Wash**. It is not known whether **Ovace® Wash** can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. **Ovace® 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® Wash** 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 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 doses may cause hematuria, crystalluria, and renal shutdown due to precipitation of sulfa crystals in the renal tubules and urinary tract.

Treatment: The patient should be induced to vomit, even if emesis has occurred spontaneously. Pharmacologic vomiting by the administration of ipecac syrup is a preferred method. However, vomiting should not be induced in patients with impaired consciousness. The action of ipecac is facilitated by physical activity and by the administration of eight to twelve fluid ounces of water. If emesis does not occur within 15 minutes, the dose of ipecac should be repeated. Precautions against aspiration must be taken, especially in infants and children. Following emesis, any drug remaining in the stomach may be absorbed by activated charcoal administered as a slurry with water. If vomiting is unsuccessful or contraindicated, gastric lavage should be performed. Isotonic and one-half isotonic saline are the lavage solutions of choice. Saline cathartics, such as milk of magnesia, draw water into the bowel by osmosis and, therefore, may be valuable for their action in rapid dilution of bowel content. After emergency treatment, the patient should continue to be medically monitored.

Observe kidney function for up to one week and have the patient ingest copious amounts of fluid during this period. Mannitol infusions may be helpful at the first sign of oliguria. Alkalinization of the urine by ingestion of bicarbonate is very helpful in preventing crystallization of sulfa drug in the kidney.

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DOSAGE AND ADMINISTRATION: Seborrheic dermatitis including seborrhea sicca - **Ovace® Wash**: 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 cleaned, massage gently into skin working into a full length, rinse thoroughly and pat dry. Rinsing with plain water will remove any excess medication. Repeat application as described for eight to ten days. If skin dryness occurs it may be controlled by rinsing cleanser off sooner or using less frequently.

Regular shampooing following **Ovace® 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® Wash** should be reinstituted as at the beginning of treatment.

Secondary Cutaneous Bacterial Infections - Wet skin and liberally apply to areas to be cleaned, massage gently into skin working into a full length, rinse thoroughly and pat dry. Rinsing with plain water will remove any excess medication. Repeat application as described for eight to ten days. If skin dryness occurs it may be controlled by rinsing cleanser off sooner or using less often.

HOW SUPPLIED: **Ovace® Wash** is available in a 6 fl. oz. NDC 13548-040-06 bottle and a 12 fl. oz. NDC 13548-040-12 bottle.

Note: Store upright at controlled room temperature. Protect from freezing and excessive heat. The wash may tend to darken slightly on storage. Slight discoloration does not impair the efficacy or safety of the product.

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



Marketed by:
CORIA Laboratories, Ltd.
Fort Worth, TX 76107

Manufactured by:
DPT Laboratories, Ltd.
San Antonio, TX 78215

PATENT PENDING

REORDER NO. 13548-040-06 (6 fl. oz. bottle) and
13548-040-12 (12 fl. oz. bottle)