

Rx ONLY

Ovace® (Sodium Sulfacetamide 10%) Cream

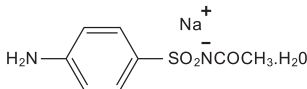
Ovace® (Sodium Sulfacetamide 10%) Gel

FOR DERMATOLOGIC USE ONLY — NOT FOR OPHTHALMIC USE

DESCRIPTION: Each gram of Ovace® Cream contains 100mg of sodium sulfacetamide USP in a vehicle consisting of purified water, glycerin, mineral oil, cetearyl alcohol/ceteareth 20, cetyl alcohol, glyceryl stearate, PEG-100 stearate, phenoxyethanol, dimethicone, methylparaben, disodium EDTA, sodium thiosulfate, quaternium-26 and propylene glycol, propylparaben and lactic acid.

Each gram of Ovace® Gel contains 100 mg of sodium sulfacetamide USP in a vehicle consisting of purified water, glycerin, xanthan gum, methylparaben, disodium EDTA, sodium thiosulfate, quaternium-26 and propylene glycol, and lactic acid.

Sulfacetamide sodium is $C_8H_9NNaO_5S_2 \cdot H_2O$ with 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® 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® is intended for topical application in the following scaling dermatoses: seborrheic dermatitis and seborrhea sicca (dandruff). It is also indicated for the treatment of secondary bacterial infections of the skin due to organisms susceptible to sulfonamides.

CONTRAINDICATIONS: Ovace® 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. Keep out of the reach of children.

PRECAUTIONS:

For external use only

General: Nonsusceptible organisms, including fungi, may proliferate with the use of this preparation. Hypersensitivity reactions may occur when a sulfonamide is readministered, irrespective of the route of administration, and cross hypersensitivity between different sulfonamides may occur. If Ovace® 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® if the condition becomes worse, or if a rash develops in the area being treated or elsewhere. Ovace® also should be discontinued promptly and the physician notified if any arthritis, fever, or sores in the mouth develop.

Drug Interactions: Ovace® is incompatible with silver preparations.

Pharmacology: Ovace® 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® 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®. It is also not known whether Ovace® can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Ovace® 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® 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 for of sulfacetamide in mice is 16.5 g/kg. The LD₅₀ for topical administration of sulfacetamide has not been determined. Oral overdose 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 local Poison Control Center.

DOSAGE AND ADMINISTRATION:

Seborrheic dermatitis including seborrhea sicca — Ovace®: Apply to affected areas twice daily (morning and evening), or as directed by your physician. Avoid contact with eyes or mucous membranes. Repeat application as described for eight to ten 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® should be reinitiated as at the beginning of treatment.

Secondary Cutaneous Bacterial Infections — Apply to affected areas twice daily for eight to ten days.

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.

HOW SUPPLIED:

Ovace® Cream is available in 30 gram (NDC 13548-043-30) and 60 gram (NDC 13548-043-60) tubes.

Ovace® Gel is available in 30 gram (NDC 13548-042-30) and 60 gram (NDC 13548-042-60) tubes.

Store at controlled room temperature 68°-77°F (20°-25°C). Do not freeze.



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

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

REORDER NO.

Ovace® Cream
13548-043-30 (30g tube)
13548-043-60 (60g tube)

Ovace® Gel
13548-042-30 (30g tube)
13548-042-60 (60g tube)

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