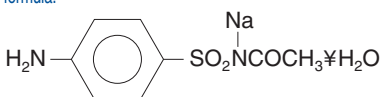


**CARMOL®****Scalp Treatment Lotion****(10% sulfacetamide sodium)****FOR DERMATOLOGIC USE ONLY —  
NOT FOR OPHTHALMIC USE**

**DESCRIPTION:** CARMOL® Scalp Treatment Lotion contains in each gram: 100 mg sulfacetamide sodium in an emulsion base containing 10% urea, polyethylene glycol 400 monostearate, isopropyl myristate, propylene glycol monostearate, propylene glycol, sodium thiosulfate, methylparaben, tetrasodium EDTA, and purified water. This bland lotion, containing surface active agents which allow the medication to come into intimate contact with the skin, is greaseless and disappears when rubbed into the skin or scalp. The hair can be combed and arranged as usual after application. The lotion rinses easily from the scalp with water.

Sulfacetamide sodium is  $C_8H_9N_2NaO_2S \cdot H_2O$ , 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 CARMOL® Scalp Treatment Lotion 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:** CARMOL® Scalp Treatment Lotion 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:** CARMOL® Scalp Treatment Lotion is contraindicated in persons with known or suspected hypersensitivity to sulfonamides or to any of the ingredients of the preparation.

**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:** *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 CARMOL® Scalp Treatment Lotion 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 CARMOL® Scalp Treatment Lotion if the condition becomes worse, or if a rash develops in the area being treated or elsewhere. CARMOL® Scalp Treatment Lotion also should be discontinued promptly and the physician notified if any arthritis, fever, or sores in the mouth develop.

*Drug Interactions:* CARMOL® Scalp Treatment Lotion is incompatible with silver preparations.

*Carcinogenesis, Mutagenesis, and Impairment of Fertility:* Long-term animal studies for carcinogenic potential have not been performed on CARMOL® Scalp Treatment Lotion 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 CARMOL® Scalp Treatment Lotion. It also is not known whether CARMOL® Scalp Treatment Lotion can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. CARMOL® Scalp Treatment Lotion should be used by a pregnant woman only if clearly needed.

**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 CARMOL<sup>®</sup> Scalp Treatment Lotion is administered to a nursing woman.

**Pediatric Use:** Safety and effectiveness in children below 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. In the event of overdosage, 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 1 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.

**DOSAGE AND ADMINISTRATION:** *Seborrheic dermatitis including seborrhea sicca*— In mild cases involving the scalp and adjacent skin areas, including noninflammatory types with scaling (dandruff), the lotion should be applied as directed by a physician with best results occurring when applied at bedtime and allowed to remain overnight. Its application should be preceded by a shampoo if the hair and scalp are oily or greasy or if there is considerable debris. In severe cases with crusting, heavy scaling, and inflammation involving the scalp or the scalp and other skin, the lotion should be applied twice daily. Initially, the hair and scalp should be cleansed with a nonirritating shampoo, such as, CARMOL<sup>®</sup> Deep Cleansing Antibacterial Shampoo (10% Urea base). To ensure intimate contact of the medication with the affected skin, cleansing should be repeated as frequently as necessary thereafter.

The applicator tip of the plastic tube is convenient for applying CARMOL<sup>®</sup> Scalp Treatment Lotion, especially for patients with thick hair. Part hair one section at a time and apply a small amount of lotion along part line. Repeat until scalp is moistened, then massage into scalp thoroughly with fingers. Remove excess lotion or large scales by gently brushing scalp. Leave lotion on overnight or as directed by physician. Shampooing following treatment is not necessary but hair should be washed at least once a week. (A thorough brushing or rinsing with plain water will remove any excess medication.) The application of the lotion, as described, should be repeated 8 to 10 times. As the eruption subsides, the interval between applications may be lengthened. Applications once or twice weekly or every other week may prevent recurrence. Should the eruption recur after stopping therapy, the application of CARMOL<sup>®</sup> Scalp Treatment Lotion should be reinitiated as at the beginning of treatment.

**Secondary Cutaneous Bacterial Infections** — The lotion should be applied to affected areas 2 to 4 times daily until the infection has cleared.

**HOW SUPPLIED:** CARMOL<sup>®</sup> Scalp Treatment Lotion 85 g (3 oz.) NDC 10337-653-19 plastic squeeze tube, box of one or as part of a CARMOL<sup>®</sup> Scalp Treatment Kit NDC 10337-655-01 also containing CARMOL<sup>®</sup> Deep Cleansing Antibacterial Shampoo (10% Urea base) and a CARMOL<sup>®</sup> Scalp Treatment Brush.

**Note:** Store at controlled room temperature 15°-30°C (59°-86°F). Protect from freezing. The lotion may tend to darken slightly on prolonged standing. 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 lotion 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.

Manufactured for:



**DOAK DERMATOLOGICS**

A SUBSIDIARY OF BRADLEY PHARMACEUTICALS, INC.

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PATENT PENDING

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