

Clarifoam™ EF

EMOLLIENT FOAM

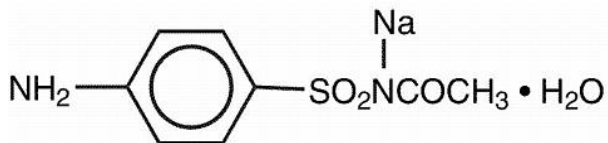
SODIUM SULFACETAMIDE (10%), SULFUR (5%)

Rx Only

DESCRIPTION

Sodium sulfacetamide is a sulfonamide with antibacterial activity while sulfur acts as a keratolytic agent. Chemically, sodium sulfacetamide is N-[(4-aminophenyl) sulfonyl]-acetamide, monosodium salt, monohydrate.

The structural formula is:



Each gram of CLARIFOAM® EF (sodium sulfacetamide 10% and sulfur 5%) Emollient Foam contains 100 mg of sodium sulfacetamide and 50 mg of sulfur in an aqueous based emollient foam vehicle containing cetyl alcohol NF, emulsifying wax NF, lactic acid USP, methylparaben NF, propylene glycol USP, propylparaben NF, steareth-10, water USP. Also contains: Propellant HFA-134A (1,1,1,2-tetrafluoroethane).

CLINICAL PHARMACOLOGY

Sodium sulfacetamide exhibits antibacterial activity. The most widely accepted mechanism of action of sulfonamides is the Woods-Fildes theory which is based on the fact that sulfonamides act as competitive antagonists to para-aminobenzoic acid (PABA), an essential component for bacterial growth. While absorption through intact skin has not been determined, sodium sulfacetamide is readily absorbed from the gastrointestinal tract when taken orally and excreted in the urine, largely unchanged. The biological half-life has variously been reported as 7 to 12.8 hours.

It is estimated that 1% of topically applied sulfur is absorbed. Although the exact mode of keratolytic activity of sulfur is unknown, it is reported to result from the interaction of sulfur with the cysteine content of keratinocytes. In combination with sulfacetamide, sulfur has been reported to inhibit the growth of *Propionibacterium acnes* thereby reducing the associated inflammation.

INDICATIONS

CLARIFOAM EF Emollient Foam is indicated in the topical control of acne vulgaris, acne rosacea and seborrheic dermatitis.

CONTRAINDICATIONS

CLARIFOAM EF Emollient Foam is contraindicated for use by patients having known hypersensitivity to sulfonamides, sulfur or any other component of this preparation. CLARIFOAM EF Emollient Foam is not to be used by patients with kidney disease.

WARNINGS

Although rare, hypersensitivity reactions to products containing sodium sulfacetamide may occur, including Stevens-Johnson syndrome and exfoliative dermatitis. Systemic toxic reactions such as agranulocytosis, acute hemolytic anemia, purpura hemorrhagica, drug fever, jaundice, and contact dermatitis indicate hypersensitivity to sulfonamides. Particular caution should be employed if areas of denuded or abraded skin are involved. **FOR EXTERNAL USE ONLY.** Keep away from eyes. **Keep out of the reach of children.** Contents under pressure. Do not puncture or incinerate container. Do not expose to temperatures above 120°F (49°C).

PRECAUTIONS

General

The object of this therapy is to achieve desquamation without irritation, but sodium sulfacetamide and sulfur can cause reddening and scaling of epidermis. These side effects are not unusual in the treatment of acne vulgaris, but patients should be cautioned about the possibility. If irritation develops, use of the product should be discontinued and appropriate therapy instituted. Patients should be carefully observed for possible local irritation or sensitization during long-term therapy.

Information for Patients

Avoid contact with eyes, eyelids, lips, and mucous membranes. If accidental contact occurs, rinse with water. If excessive irritation develops discontinue use and consult your physician.

Carcinogenesis, Mutagenesis and Impairment of Fertility

Long-term studies in animals have not been performed to evaluate carcinogenic potential.

Pregnancy

Category C. Animal reproduction studies have not been conducted with CLARIFOAM EF Emollient Foam. It is also not known whether CLARIFOAM EF Emollient Foam can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. CLARIFOAM EF Emollient Foam should be given to a pregnant woman only if clearly needed.

Nursing Mothers

It is not known whether sodium sulfacetamide is excreted in the human milk following topical use of CLARIFOAM EF Emollient Foam. However, small amounts of orally administered sulfonamides have been reported to be eliminated in human milk. In view of this and because many drugs are excreted in human milk, caution should be exercised when CLARIFOAM EF Emollient Foam is administered to a nursing woman.

Pediatric Use

Safety and effectiveness in children under the age of 12 have not been established.

ADVERSE REACTIONS

Although rare, sodium sulfacetamide may cause local irritation.

DOSAGE AND ADMINISTRATION**Shake Vigorously and Prime Before Initial Use. Shake Vigorously Before Each Use.**

To Prime: shake vigorously, then hold CLARIFOAM EF Emollient Foam can upright, direct away from patient, and depress the actuator for 3 to 5 seconds or until foam begins to dispense.

WASH-OFF APPLICATION: Cleanse affected skin thoroughly and pat dry before each application. Shake well before each use. Holding can upright, dispense a small amount of CLARIFOAM EF Emollient Foam onto the fingertips. Massage the dispensed foam into the affected area and wait 10 minutes. Rinse thoroughly with water and pat dry. Treat the affected area 1 to 3 times daily, or as directed by a physician.

LEAVE-ON APPLICATION: Cleanse affected skin thoroughly and pat dry before each application. Shake well before each use. Holding can upright, dispense a small amount of CLARIFOAM EF Emollient Foam onto the fingertips. Massage the foam into the affected area 1 to 3 times daily, or as directed by a physician. Wipe off any excess.

HOW SUPPLIED

CLARIFOAM EF Emollient Foam is supplied in a 60 g (NDC 16781-154-60) aluminum can.

Store between 15° and 30°C (59° and 86°F).

Protect from freezing

Store upright

Manufactured For:



Onset Therapeutics
Cumberland, RI 02864

www.onsettx.com

PATENT PENDING

P/N 2603-pf Rev. 3