TRIFLUENT PHARMA®

NDC 73352-750-01
Rx Only

Sodium Sulfacetamide 10% and Sulfur 1% Emulsion

FOR EXTERNAL USE ONLY

177 mL

TRIFLUENT PHARMA™

Emulsion Therapy For Multiple Skin Conditions

- Familiar option in dermatology
- Helps inhibit bacterial growth

Sodium Sulfacetamide 10% and Sulfur 1% Emulsion

NDC: 73352-750-01

INDICATIONS:
Sodium Sulfacetamide 10% - Sulfur 1% Emulsion is indicated in the topical control of acne vulgaris, acne rosacea, and seborrheic dermatitis.

ADVERSE REACTIONS:
Although rare, sodium sulfacetamide may cause local irritation.

WARNINGS:
Although rare, sensitivity to sodium sulfacetamide may occur. Therefore, caution and careful supervision should be observed when prescribing this drug for patients who may be prone to hypersensitivity to topical sulfonamides. 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 reach of children.

In case of accidental ingestion contact a poison control center immediately. Keep container tightly closed.

For full Prescribing Information, see attached Product Insert.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit fda.gov/medwatch or call 1-800-FDA-1088.

Sodium Sulfacetamide 10% and Sulfur 1% Emulsion has not been reviewed by the FDA for safety or efficacy.

Indicated for Once Or Twice-Daily Use

Dual-Action Treatment for Adolescents & Adults

Antibacterial
Reduces or inhibits the growth of bacteria on the skin

Keratolytic
Helps break down excess keratin in the skin

COPAY INFORMATION

UP TO $50 OFF*

BIN #: 610600
PCN #: AS
GROUP #: 349
ID #: 34905139472

Help Desk: 877-274-3244
*Terms and conditions may apply.

HOW TO WRITE:

Sodium Sulfacetamide 10% and Sulfur 1% Emulsion
Apply to affected area once or twice daily.
☐ 10% / 1%
Dispense as written

Visit our website at:
TRIFLUENTPHARMA.COM

LB-TRI-01 Rev. 04/2026

SODIUM SULFACETAMIDE AND SULFER EMULSION-
sodium sulfacetamide and
sulfer emulsion
Trifluent Pharma

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Sodium Sulfacetamide 10% - Sulfur 1% Emulsion
NDC 773352-750-01

Sodium Sulfacetamide 10 % and Sulfur 1% Emulsion
Rx Only

FOR EXTERNAL USE ONLY. NOT FOR OPHTHALMIC USE.

Net. Wt. 177 mL
Active ingredients: Sodium Sulfacetamide 10% and Sulfer 1%

Indications: For the topical control of acne vulgaris, acne rosacea and seborrheic dermatitis.

Directions: Wash affected areas once or twice daily or as directed by a physician. Wet skin and liberally apply to areas to be cleansed, message gently into skin for 10-20 seconds, working into a full lather, rinse thoroughly and pat dry. If drying occurs, it may be controlld by rinsing cleanser off sooner or using less often. See attached booklet for full prescribing information.

Warning: for external use only.Avoid Contract with eyes.

KEEP OUT OF REACH OF CHILDREN.

Keep bottle tightly closed.

Store at controlled room temperatures, 15º - 30ºC (59º - 86º F).

Protect from freezing.

All prescription substitutions and or recommendations using this product shall be made subject to the state and federal statutes as applicable.

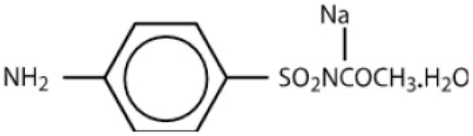
NOTE: This is not an Orange Book product. No representation is made as to generic status or bioequivalency. Please see attached booklet fo more information.

Distributed by:
Trifluent Pharma, LLC
San Antonio, TX 78212

Rev. 07-255
Rx Only

DESCRIPTION
Each gram of Sodium Sulfacetamide 10% and Sulfur 1% Emulsion contains 100 mg of sodium sulfacetamide and 10 mg of sulfur in a formulation containing Butylated Hydroxytoluene, Cetyl Alcohol, Citric Acid, Cocamidopropyl Betaine, Disodium EDTA, Glycerin, Glyceryl Stearate SE, PEG-100 Stearate, Phenoxyethanol, Purified Water, Sodium Laureth Sulfate, Sodium Thiosulfate, Stearyl Alcohol, Triacetin, Xanthan Gum.

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:



CLINICAL PHARMACOLOGY
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. The exact mode of action of sulfur in the treatment of acne is known, but it has been reported that it inhibits the growth of Propionibacterium acnes and the formation of free fatty acids.

INDICATIONS
Sodium Sulfacetamide 10% - Sulfur 1% Emulsion is indicated in the topical control of acne vulgaris, acne rosacea and seborrheic dermatitis.

CONTRAINDICATIONS
Sodium Sulfacetamide 10% and Sulfur 1% Emulsion is contraindicated for use by patients having known hypersensitivity to sulfonamides, sulfur or any other component of this preparation. Sodium Sulfacetamide 10% and Sulfer 1% Emulsion is not to be used by patietns with kidney disease.

WARNINGS
Although rare, sensitivity to sodium sulfacetamide may occur. Therefore, caution and careful supervision should be observed when prescribing this drug for patients who may be prone to hypersensitivity to topical sulfonamides. 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.

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PRECAUTIONS

General

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 longterm therapy. The object of this therapy is to achieve desquamation without irritation, but sodium sulfacetamide and sulfur can cause reddening and scaling of the epidermis. These side effects are not unusual in the treatment of acne vulgaris, but patients should be cautioned about the possibility.

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 Sodium Sulfacetamide 10% and Sulfer 1% Emulsion. It is not known whether Sodium Sulfacetamide 10% and Sulfer 1% Emulsion can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Sodium Silfacetamide 10% and Sulfer 1% Emulsion 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 Sodium Sulfacetamide 10% and Sulfur 1% Emulsion. 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 Sodium Sulfacetamide 10% and Sulfur 1% Emulsion 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.

Call your doctor for medical advice about side effects. To report a serious adverse event, please contact Trifluent Pharma, LLC at 1-888-927-5191.

DOSAGE AND ADMINISTRATION

Apply Sodium Sulfacetamide 10% and Sulfur 1% Emulsion once or twice daily to affected areas, or as directed by your physician.

Wet skin and liberally apply to areas to be cleansed.

Massage gently into skin for 10-20 seconds, working into a full lather, rinse thoroughly and pat dry. If drying occurs, it may be controlled by rinsing off Sodium Sulfacetamide 10% and Sulfur 1% Emulsion sooner or using less often.

HOW SUPPLIED

Sodium Sulfacetamide 10% and Sulfur 1% Emulsion is available in 177 mL bottles, NDC 73352-750-01.

STORAGE AND HANDLING

Store at controlled room temperature, 15° - 30°C (59° - 86°F). Protect from freezing.

KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.

Distributed by:
Trifluent Pharma, LLC.
San Antonio, Tx 78213

All prescription substitutions and or recommendations using this product shall be made subject to state and federal statutes as applicable. Note: This is not an Orange Book product. No representation is made as to the generic satus or bioequivalency. Each person recommending a prescription substitution using this product shall make such recommendationss based on each such person's professonal opinion and knowlege, upon evaluating the active ingredients, excipients, inactive ingredients and chemical formulation provided herein.

PRINCIPAL DISPLAY PANEL - 177 mL Bottle Label

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Net Wt. 177mL

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