

NATURAL PRESCRIPTION CHOICES



ACNE THERAPY

Unique 7% Benzoyl Peroxide Cleanser

- 7% BPO appropriate for all patient-types
- Elegant, smooth-textured formula

Unique vehicle containing Aloe & Green Tea natural ingredients

- Aloe - Natural moisturizing and hydrating properties
- Green tea - Natural, potent antioxidants
- Dye-free

Largest Pump Dispenser

- Ideal for large-area acne
- Better patient value - More therapy with one co-pay



ROSACEA THERAPY

The only 10% Sodium Sulfacetamide and 4% Sulfur Cleansing Pads

- Antibacterial
- Offers a reduced sulfur smell
- Elegant, light-lathering formula for gentle cleansing

Unique vehicle containing natural Green Tea & Aloe ingredients

- Green Tea - Natural, potent antioxidants
- Aloe - Natural moisturizing & soothing properties
- Dye-free

More Therapy with One Co-pay

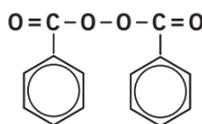
- 60 pads per prescription
- Convenient, single-use pads
- Great for use at home, at work or on-the-go

For more information, visit www.medimetriks.com

Pacnex™ Wash is for external use only. Avoid contact with eyes, lips or mucous membranes. If severe irritation develops, discontinue use of Pacnex™ Wash. While using Pacnex™ Wash, patients should be advised to avoid unnecessary sun exposure. Please see enclosed full Prescribing Information.

Sumaxin™ Cleansing Pads are contraindicated in persons with known or suspected hypersensitivity to sulfonamides or sulfur. Sumaxin™ Cleansing Pads are not to be used by patients with kidney disease. Although rare, topical sodium sulfacetamide may cause local irritation. Please see enclosed full Prescribing Information.

DESCRIPTION: Pacnex™ (7% Benzoyl Peroxide) Wash is intended for topical administration and contains Benzoyl Peroxide for use in the treatment of acne vulgaris. Benzoyl Peroxide is an oxidizing agent that possesses antibacterial properties and is classified as a keratolytic. Benzoyl Peroxide (C₁₄H₁₀O₄) is represented by the following chemical structure:



Each mL of Pacnex™ (7% Benzoyl Peroxide) Wash contains 70 mg of Benzoyl Peroxide in an emulsion based formulation consisting of: aloe, carbomer interpolymers type A, cetyl alcohol, disodium oleamido MEA-sulfosuccinate, edetate disodium, glyceryl stearate/PEG-100 stearate, glycerin, green tea, laureth-12, magnesium aluminum silicate, propylene glycol, purified water, sodium coco-sulfate, sodium lauroamphoacetate, xanthan gum.

CLINICAL PHARMACOLOGY: The mechanism of action of Benzoyl Peroxide is not totally understood but its antibacterial activity against *Propionibacterium acnes* is thought to be a major mode of action. In addition, patients treated with Benzoyl Peroxide show a reduction in lipids and free fatty acids, and mild desquamation (drying and peeling activity) with simultaneous reduction in comedones and acne lesions. Little is known about the percutaneous penetration, metabolism, and excretion of Benzoyl Peroxide, although it has been shown that Benzoyl Peroxide absorbed by the skin is metabolized to benzoic acid and then excreted as benzoate in the urine. There is no evidence of systemic toxicity caused by Benzoyl Peroxide in humans.

INDICATIONS AND USAGE: Pacnex™ (7% Benzoyl Peroxide) Wash is indicated for the topical treatment of acne vulgaris.

CONTRAINDICATIONS: These preparations are contraindicated in patients with a history of hypersensitivity to any of their components.

WARNINGS: When using this product, avoid unnecessary sun exposure and use a sunscreen.

PRECAUTIONS: General: For external use only. If severe irritation develops, discontinue use and institute appropriate therapy. After reaction clears, treatment may often be resumed with less frequent application. These preparations should not be used in or near the eyes or on mucous membranes.

Information for Patients: Avoid contact with eyes, eyelids, lips and mucous membranes. If accidental contact occurs, rinse with water. Contact with any colored material (including hair and fabric) may result in bleaching or discoloration. If excessive irritation develops, discontinue use and consult your physician.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Data from several studies employing a strain of mice that is highly susceptible to developing cancer suggest that Benzoyl Peroxide acts as a tumor promoter. The clinical significance of these findings to humans is unknown. Benzoyl Peroxide has not been found to be mutagenic (Ames Test) and there are no published data indicating it impairs fertility.

Pregnancy: Teratogenic Effects: *Pregnancy Category C:* Animal reproduction studies have not been conducted with Benzoyl Peroxide. It is not known whether Benzoyl Peroxide can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Benzoyl Peroxide should be used by a pregnant woman only if clearly needed. There are no available data on the effect of Benzoyl Peroxide on the later growth, development and functional maturation of the unborn child.

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 Benzoyl Peroxide is administered to a nursing woman.

Pediatric Use: Safety and effectiveness in children have not been established.

ADVERSE REACTIONS: Allergic contact dermatitis and dryness have been reported with topical Benzoyl Peroxide therapy.

OVERDOSAGE: If excessive scaling, erythema or edema occurs, the use of this preparation should be discontinued. To hasten resolution of the adverse effects, cool compresses may be used. After symptoms and signs subside, a reduced dosage schedule may be cautiously tried if the reaction is judged to be due to excessive use and not allergenicity.

DOSAGE AND ADMINISTRATION: Pacnex™ (7% Benzoyl Peroxide) Wash: Apply to affected areas once or twice a day, 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 excessive drying occurs, control by rinsing off cleanser sooner or using less often.

HOW SUPPLIED: Pacnex™ (7% Benzoyl Peroxide) Wash is supplied in a 16 oz bottle, NDC 43538-110-16.

Store at controlled room temperature 15°-25° C (59°-77° F). Protect from freezing.

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

Manufactured for:

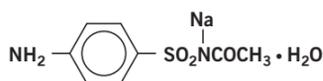


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www.medimetriks.com

Manufactured by: Groupe PARIMA, Inc., Montreal, QC H4S 1X6 CANADA

PP-004 R1

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 pad of Sumaxin™ (sodium sulfacetamide 10% & sulfur 4%) Cleansing Pads is coated with a cleanser-based formulation. Each gram of this cleanser-based formulation contains 100 mg of Sodium Sulfacetamide and 40 mg of Sulfur. The cleanser base consists of: aloe, butylated hydroxytoluene, cetyl alcohol, disodium oleamido MEA sulfosuccinate, edetate disodium, fragrance, glycerin, glyceryl stearate/PEG-100 stearate, green tea, methylparaben, propylparaben, purified water, sodium cocoyl isethionate, sodium lauryl sulfoacetate, sodium thiosulfate, stearyl alcohol.

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 unknown, but it has been reported that it inhibits the growth of *Propionibacterium acnes* and the formation of free fatty acids.

INDICATIONS: Sumaxin™ (sodium sulfacetamide 10% & sulfur 4%) Cleansing Pads are indicated in the topical control of acne vulgaris, acne rosacea and seborrheic dermatitis.

CONTRAINDICATIONS: Sumaxin™ (sodium sulfacetamide 10% & sulfur 4%) Cleansing Pads are contraindicated for use by patients having known hypersensitivity to sulfonamides, sulfur or any other component of this preparation. Sumaxin™ (sodium sulfacetamide 10% & sulfur 4%) Cleansing Pads are not to be used by patients 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.

FOR EXTERNAL USE ONLY. Keep away from eyes. Keep out of reach of children. Keep container tightly closed.

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 long-term 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 Sumaxin™ (sodium sulfacetamide 10% & sulfur 4%) Cleansing Pads. It is also not known whether Sumaxin™ (sodium sulfacetamide 10% & sulfur 4%) Cleansing Pads can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Sumaxin™ (sodium sulfacetamide 10% & sulfur 4%) Cleansing Pads 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 Sumaxin™ (sodium sulfacetamide 10% & sulfur 4%) Cleansing Pads. 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 Sumaxin™ (sodium sulfacetamide 10% & sulfur 4%) Cleansing Pads are 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: Wash affected area(s) with cleansing pad once or twice daily, or as directed by your physician. Wet area(s) with water. Wet pad with a little water and work into a full lather. Cleanse area(s) with pad for 10-20 seconds, avoiding eyes. Rinse thoroughly and pat dry. Discard pad. Do not flush.

HOW SUPPLIED: Sumaxin™ (sodium sulfacetamide 10% & sulfur 4%) Cleansing Pads are available in boxes of 60 cloths (3.7 g), NDC 43538-100-60.

Store at 15°-25° C (59°-77° F).

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IP-007 R1