



Rx only

Product Description:

Both CLENIA® (sodium sulfacetamide 10% and sulfur 5%) Foaming Wash and CLENIA® (sodium sulfacetamide 10% and sulfur 5%) Emollient Cream are available by prescription only and contain the following active ingredients: Sodium Sulfacetamide 10% and Sulfur 5%. Other inactive ingredients contained within each product are listed below.

CLENIA® Foaming Wash: Butylated Hydroxytoluene, NF, Disodium EDTA, USP, Disodium Oleamido MEA Sulfosuccinate, Fragrance, Glyceryl Stearate (and) PEG-100 Stearate, Magnesium Aluminum Silicate, NF, Methylparaben, NF, Mica, PEG-55 Propylene Glycol Oleate, Propylene Glycol, USP, Propylparaben, NF, Purified Water, USP, Silicon Dioxide, Sodium Cocoyl Isethionate, Sodium Methyl Oleate, Sodium Thiosulfate, USP, Stearic Acid, NF, Titanium Dioxide, Xanthan Gum, NF.

CLENIA® Emollient Cream: Allantoin, Disodium EDTA, USP, Emulsifying Wax, NF, Fragrance, Glyceryl Monostearate, Isopropyl Myristate, NF, Methylparaben, NF, PEG-8 Stearate, Propylene Glycol, USP, Propylparaben, NF, Purified Water, USP, Sodium Thiosulfate, USP, Stearic Acid, NF, Xanthan Gum, NF.

Medical Action:

Sodium sulfacetamide has bacteria fighting action and helps to block the overgrowth of the bacteria thought to be involved in acne development.

Sulfur has exfoliating properties, helping to promote the removal of dead cells from the top layer of the skin.

Intended Use:

CLENIA® (sodium sulfacetamide 10% and sulfur 5%) Foaming Wash and CLENIA® (sodium sulfacetamide 10% and sulfur 5%) Emollient Cream are indicated for the topical control of acne vulgaris, acne rosacea and seborrheic dermatitis.

Warnings and Precautions:

CLENIA® Foaming Wash and CLENIA® Emollient Cream should not be used by anyone having a known allergy to sulfonamides, sulfur or any other ingredient in these products. In addition, patients with kidney disease should not use CLENIA® Foaming Wash and CLENIA® Emollient Cream.

As with other products containing sodium sulfacetamide and sulfur, serious allergic reactions, although rare, may occur in some individuals. If you notice any unexpected effects while using these products, such as fever, excessive fatigue or serious skin reactions, contact your doctor.

CLENIA® Foaming Wash and CLENIA® Emollient Cream are for external use only. Avoid contact with the eyes, eyelids, lips, other mucous membranes (e.g., inside the nose), and any damaged areas of the skin, such as wounds or open sores. If accidental contact with one of these areas occurs, rinse thoroughly with water.

If you are pregnant or nursing, talk to your doctor about the potential risks before using CLENIA® Foaming Wash or CLENIA® Emollient Cream.

The safety and effectiveness of CLENIA® Foaming Wash and CLENIA® Emollient Cream have not been evaluated in children under the age of 12 years.

Possible Side Effects:

Like any medication, CLENIA® Foaming Wash and CLENIA® Emollient Cream may occasionally cause side effects in some people. Although uncommon, some possible side effects may include skin irritation such as redness, dryness, itching or swelling. If you experience excessive skin irritation, contact your doctor.

Directions for Use:

CLENIA® Foaming Wash:

Wash affected area(s) with CLENIA® Foaming Wash once or twice daily, or as directed by your doctor.

- 1) Wet your skin and apply CLENIA® Foaming Wash liberally, making sure to avoid contact with your eyes, interior of your nose and mouth.
- 2) Massage gently into your skin for 10-20 seconds, working into a lather.
- 3) Rinse thoroughly and pat your skin dry.
- 4) If your skin feels too dry, you may reduce your cleansing time by rinsing the product off sooner or you may use the wash less often.

CLENIA® Emollient Cream:

Apply CLENIA® Emollient Cream to affected area(s) 1-3 times daily, or as directed by your doctor.

- 1) Cleanse your skin thoroughly before application.
- 2) Apply a thin layer of CLENIA® Emollient Cream to the affected area(s) as directed by your doctor.
- 3) Start by using CLENIA® Emollient Cream once daily to minimize dryness. Then, increase application frequency to 2-3 times daily or as directed by your doctor.

Storage Recommendations:

CLENIA® Foaming Wash and CLENIA® Emollient Cream should be stored at controlled room temperature (15–25°C or 59–77°F). Avoid exposing the products to excessive heat. **Keep out of the reach of children.**

How Supplied:

CLENIA® (sodium sulfacetamide 10% and sulfur 5%) Foaming Wash is available in 6 oz bottles (NDC 0245-0168-06) and 12 oz bottles (NDC 0245-0168-12).

CLENIA® (sodium sulfacetamide 10% and sulfur 5%) Emollient Cream is available in 1 oz tubes (NDC 0245-0169-01).

Manufactured for
UPSHER-SMITH LABORATORIES, INC.
Minneapolis, MN 55447

If you have any questions, please call 1-800-654-2299.

US Patent 6,977,081 for CLENIA® (sodium sulfacetamide 10% and sulfur 5%) Emollient Cream

CAPPI02

Revised 0808