

INSTRUCTIONS FOR USE NEOSALUS™ FOAM

For Topical Dermatological Use Only

Rx Only – Prescription Medical Device – Federal Law prohibits the sale of Device by, or on the order of, anyone other than a physician.

DESCRIPTION

NEOSALUS FOAM is fragrance-free, non-comedogenic water soluble foam dressing formulated for the management and relief of irritation experienced with various types of dermatoses, including atopic dermatitis and allergic contact dermatitis.

INGREDIENTS

Dimethicone, ethylparaben, glycerin, methylparaben, phenoxyethanol, polysorbate 20, povidone, propylene glycol, propylparaben, purified water, stearic acid, tromamine and in propellants butane and propane.

INDICATIONS FOR USE

NEOSALUS FOAM is indicated for management and relief of irritation associated with various types of dermatoses, including atopic dermatitis and allergic contact dermatitis.

CONTRAINDICATIONS

Known hypersensitivity to any of the NEOSALUS FOAM ingredients.

PRECAUTIONS: *General:*

Patients using NEOSALUS FOAM should receive the following information and instructions:

NEOSALUS FOAM is to be used only as directed by the physician. It should not be used to treat any condition other than that for which it is prescribed. It is for external use only. Avoid contact with the eyes, lips, angles of the nose, and mucous membranes. Cleanse affected area with a mild or soapless cleanser before applying NEOSALUS FOAM. Non astringent moisturizers may be used if necessary. Exposure of the eye to NEOSALUS FOAM may result in reactions such as swelling, conjunctivitis, and eye irritation.

If a reaction to NEOSALUS FOAM suggesting sensitivity or chemical irritation occurs, use of NEOSALUS FOAM should be discontinued and the prescribing healthcare professional consulted. Exposure to sunlight, and artificial ultraviolet irradiation, including sunlamps and sunbeds, should be minimized during the use of NEOSALUS FOAM. Patients who normally experience high levels of sun exposure, and those with inherent sensitivity to sun, should be warned to exercise caution. Use of sunscreen products and protective clothing over treated areas is recommended when exposure cannot be avoided.

Certain cutaneous signs and symptoms such as erythema, dryness, scaling, burning or pruritus may be experienced during treatment. These are most likely to occur during the first two to four weeks and will usually lessen with continued use of NEOSALUS FOAM. Depending upon the severity of adverse events, patients should be instructed to reduce the frequency of application or discontinue use and to contact their prescribing physician.

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

DOSAGE AND ADMINISTRATION

Clean and dry affected skin. Then apply NEOSALUS FOAM to affected area three times a day (or as needed). NEOSALUS FOAM should be rubbed into the skin until it is completely absorbed.

HOW SUPPLIED

NEOSALUS FOAM is supplied in a 200 gram aerosolized canister bearing the NDC Number 23710-000-02, a 70 gram aerosolized canister bearing the NDC Number 23710-000-70, and a 10 gram aerosolized canister bearing the NDC Number 23710-000-01.

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

Contains flammable materials. Contents under pressure. Do not puncture or incinerate. Do not expose to temperatures over 120°F (48°C) even when empty.

NEOSALUS FOAM is covered by U.S. Patent 5,993,830.

NEOSALUS FOAM is manufactured for Quinnova Pharmaceuticals, Inc., Newtown, PA 18940, (877) 660-6263, www.QUINNOVA.com.

Prescribing Information as of September 2009.

