

NEOSALUS® LOTION

Hydrating Topical Lotion

For Topical Dermatological Use Only

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INSTRUCTIONS FOR USE

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Rx Only – Prescription Medical Device – Caution: Federal Law restricts this device to sale by, or on the order of, a licensed healthcare practitioner.

DESCRIPTION

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

INGREDIENTS

Carbomer, dimethicone, ethylparaben, glycerin, methylparaben, phenoxyethanol, polysorbate 20, povidone, propylene glycol, propylparaben, purified water, sodium hydroxide, stearic acid, trolamine.

INDICATIONS FOR USE

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

CONTRAINDICATIONS

Known hypersensitivity to any of the NEOSALUS LOTION ingredients.

PRECAUTIONS

NEOSALUS LOTION is to be used only as directed by a healthcare practitioner. It should not be used to treat any condition other than that for which it is prescribed. **For external use only.** Avoid contact with the eyes, lips, and other mucous membranes. Exposure of the eye to NEOSALUS LOTION may result in reactions such as stinging and ocular irritation.

If a reaction to NEOSALUS LOTION suggesting sensitivity or chemical irritation occurs, use of the medication should be discontinued and the prescribing healthcare practitioner consulted. This product provides no sunscreen protection. Use of sunscreen products and protective clothing over treated areas is recommended when exposure cannot be avoided.

Certain temporary symptoms such as erythema, dryness, scaling, burning or pruritus may be experienced. These are most likely to occur during the first two to four weeks and will usually lessen with continued use of the medication. Depending upon the severity of the reaction patients should be instructed to reduce the frequency of application or discontinue use and to contact their prescribing healthcare practitioner.

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

DIRECTIONS FOR USE

Unless otherwise directed by a prescribing healthcare practitioner, NEOSALUS LOTION should be applied to affected area three times a day (or as needed). NEOSALUS LOTION should be rubbed into the skin until it is completely absorbed.

Cleanse affected area with a mild or soap-free cleanser before applying NEOSALUS LOTION. Non-astringent moisturizers may be used if necessary.

HOW SUPPLIED

NEOSALUS LOTION is supplied in an 8 fluid ounce (236 mL) pump bottle bearing the NDC Number 23710-002-08, and a 0.1 fluid ounce (3 mL) professional sample tube bearing the NDC Number 23710-002-01.

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

U.S. Patent 5,993,830.

Manufactured for Quinnova Pharmaceuticals, LLC
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