NEOSALUS® FOAM

Hydrating Topical Foam

For Topical Dermatological Use Only

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

NEOSALUS FOAM 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

dimethicone, ethylparaben, glycerin, methylparaben, phenoxyethanol, polysorbate 20, povidone, propylene glycol, propylparaben, purified water, stearic acid, trolamine, and as propellants isobutane and propane.

NEOSALUS FOAM 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 FOAM ingredients.

NEOSALUS FOAM 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 FOAM may result in reactions such as stinging and ocular

If a reaction to NEOSALUS FOAM 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

Apply to affected area three times a day unless otherwise directed by a prescribing healthcare practitioner. NEOSALUS FOAM should be rubbed gently into the skin until it is completely absorbed: Follow these important directions to ensure proper foaming and maximum delivery of product:

- Shake canister vigorously before each use.
 Turn upside down (nozzle down) to dispense.
- Depress ridged portion of dispenser, as illustrated at right.

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

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

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

U.S. Patent 5.993.830.

Manufactured for Exeltis USA Dermatology, LLC. Florham Park, NJ 07932 / (877) 324-9349

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www.ExeltisUSA.com

NEOSALUS® CREAM

Hydrating Topical Cream

For Topical Dermatological Use Only

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 CREAM is a fragrance-free, water soluble dressing formulated for the management of 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 CREAM is indicated for management of various types of dermatoses, including atopic dermatitis and allergic contact dermatitis.

CONTRAINDICATIONS

Known hypersensitivity to any of the NEOSALUS CREAM ingredients.

PRECAUTIONS

NEOSALUS CREAM 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 CREAM may result in reactions such as stinging and ocular irritation.

If a reaction to NEOSALUS CREAM 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 CREAM should be applied to affected area three times a day (or as needed). NEOSALUS CREAM should be rubbed into the skin until it is completely absorbed.

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

HOW SUPPLIED

NEOSALUS CREAM is supplied in a 100 gram plastic tube bearing the item number 23710-001-10, a 180 gram plastic tube bearing the item number 23710-001-18, a 400 gram (two tubes of 200 grams each) bearing the item number 23710-001-40, a 0.1 ounce (3 gram) professional sample tube bearing the item number 23710-001-03 and 100 gram plastic tube bearing item number 23710-001-11 as a professional sample.

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

U.S. Patent 5.993.830.

Manufactured for Exeltis USA Dermatology, LLC., Florham Park, NJ 07932 / (877) 324-9349

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NEOSALUS® LOTION

Hydrating Topical Lotion

For Topical Dermatological Use Only

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).

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Manufactured for Exeltis USA Dermatology, LLC Florham Park, NJ 07932, (877) 324-9349

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