



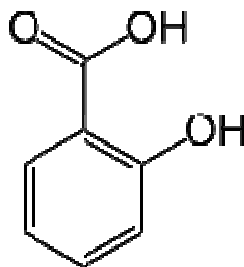
FOR EXTERNAL USE ONLY.

Rx Only

DESCRIPTION

SALKERA™ Emollient Foam is a keratolytic emollient foam for dermatological use. SALKERA Emollient Foam contains 6% salicylic acid USP in an aqueous based emollient foam vehicle. Each gram of SALKERA Emollient Foam contains 6% w/w salicylic acid USP, aloe, ammonium lactate, ceteth-10 phosphate, ceteth-20 phosphate, cetostearyl alcohol NF, dicetyl phosphate, dl-alpha tocopherol acetate USP, edetate disodium dihydrate USP, glycerin USP, methylparaben NF, propylene glycol USP, propylparaben NF, purified water USP, sodium hydroxide NF, white petrolatum USP. Also contains: Propellant HFA-134a (1,1,1,2-tetrafluoroethane).

Salicylic Acid USP is the 2-hydroxy derivative of benzoic acid having the following structure:



CLINICAL PHARMACOLOGY

Salicylic acid has been shown to produce desquamation of the horny layer of skin while not effecting qualitative or quantitative changes in the structure of the viable epidermis. The mechanism of action has been attributed to a dissolution of intercellular cement substance. In a study of the percutaneous absorption of salicylic acid in a 6% salicylic acid gel in four patients with extensive active psoriasis, Taylor and Halprin showed that the peak serum salicylate levels never exceeded 5 mg/100 ml even though more than 60% of the applied salicylic acid was absorbed. Systemic toxic reactions are usually associated with much higher serum levels (30 to 40 mg/100 ml). Peak serum levels occurred within five hours of the topical application under occlusion. The sites were occluded for 10 hours over the entire body surface below the neck. Since salicylates are distributed in the extracellular space, patients with a contracted extracellular space due to dehydration or diuretics have higher salicylate levels than those with a normal extracellular space. (See PRECAUTIONS.)

The major metabolites identified in the urine after topical administration are salicyluric acid (52%), salicylate glucuronides (42%) and free salicylic acid (6%). The urinary metabolites after percutaneous absorption differ from those after oral salicylate

administration; those derived from percutaneous absorption contain more salicylate glucuronides and less salicyluric and salicylic acid. Almost 95% of a single dose of salicylate is excreted within 24 hours of its entrance into the extracellular space.

Fifty to eighty percent of salicylate is protein bound to albumin. Salicylates compete with the binding of several drugs and can modify the action of these drugs; by similar competitive mechanisms other drugs can influence the serum levels of salicylate. (See PRECAUTIONS.)

INDICATIONS AND USAGE

For Dermatologic Use: SALKERA Emollient Foam is a topical aid in the removal of excessive keratin in hyperkeratotic skin disorders, including verrucae, and the various ichthyoses (vulgaris, sex-linked and lamellar), keratosis palmaris and plantaris, keratosis pilaris, pityriasis rubra pilaris, and psoriasis (including body, scalp, palms and soles).

For Podiatric Use: SALKERA Emollient Foam is a topical aid in the removal of excessive keratin on dorsal and plantar hyperkeratotic lesions. Topical preparations of 6% salicylic acid have been reported to be useful adjunctive therapy for verrucae plantares.

CONTRAINDICATIONS

SALKERA Emollient Foam should not be used in any patient known to be sensitive to salicylic acid or any other listed ingredients. SALKERA Emollient Foam should not be used in children under 2 years of age.

WARNINGS

Prolonged and repeated daily use over large areas, especially in children and those patients with significant renal or hepatic impairment, could result in salicylism. Excessive application of the product other than is needed to cover the affected area will not result in a more rapid therapeutic benefit. Concomitant use of other drugs which may contribute to elevated serum salicylate levels should be avoided where the potential for toxicity is present. In children under 12 years of age and those patients with renal or hepatic impairment, the area to be treated should be limited and the patient monitored closely for signs of salicylate toxicity: nausea, vomiting, dizziness, loss of hearing, tinnitus, lethargy, hyperpnea, diarrhea, and psychic disturbances. In the event of salicylic acid toxicity, the use of SALKERA Emollient Foam should be discontinued. Fluids should be administered to promote urinary excretion. Treatment with sodium bicarbonate (oral or intravenous) should be instituted as appropriate. Patients should be cautioned against the use of oral aspirin and other salicylate containing medications, such as sports injury creams, to avoid additional excessive exposure to salicylic acid. Where needed, aspirin should be replaced by an alternative non-steroidal anti-inflammatory agent that is not salicylate based. Due to potential risk of developing Reye's syndrome,

salicylate products should not be used in children and teenagers with varicella or influenza, unless directed by a physician.

Keep out of the reach of children. Contents under pressure. Do not puncture or incinerate container. Do not expose to heat or store at temperatures above 120°F (49°C).

PRECAUTIONS

For EXTERNAL USE ONLY. Avoid contact with eyes and other mucous membranes. Mild burning or stinging may occur. Peeling of the skin may increase as the salicylic acid works to loosen excess keratin. If excessive burning, stinging or peeling occurs, discontinue use and consult your physician. Keep this and all medications out of reach of children.

DRUG INTERACTIONS

I. Due to the competition of salicylate with other drugs for binding to serum albumin the following drug interactions may occur:

<u>DRUG</u>	<u>DESCRIPTION OF INTERACTION</u>
Tolbutamide; Sulfonylureas	Hypoglycemia potentiated.
Methotrexate	Decreases tubular reabsorption; clinical toxicity from methotrexate can result.
Oral Anticoagulants	Increased bleeding.

II. Drugs changing salicylate levels by altering renal tubular reabsorption:

<u>DRUG</u>	<u>DESCRIPTION OF INTERACTION</u>
Corticosteroids	Decreases plasma salicylate level; tapering doses of steroids may promote salicylism.
Acidifying Agents	Increases plasma salicylate level.
Alkanizing Agents	Decreased plasma salicylate levels.

III. Drugs with complicated interactions with salicylates:

DRUG**DESCRIPTION OF INTERACTION**

Heparin	Salicylate decreases platelet adhesiveness and interferes with hemostasis in heparin treated patients.
Pyrazinamide	Inhibits pyrazinamide induced hyperuricemia.
Uricosuric Agents	Effect of probenemide, sulfinpyrazone and phenylbutazone inhibited.

The following alterations of laboratory tests have been reported during salicylate therapy:

LABORATORY TESTS**EFFECT OF SALICYLATES**

Thyroid Function	Decreased PBI; increased T3 uptake.
Urinary Sugar	False negative with glucose oxidase; False positive with Clinitest with high-dose salicylate therapy (2-5g q.d.).
5-Hydroxyindole acetic acid	False negative with fluorometric test.
Acetone ketone bodies	False positive FeCl ₃ in Gerhardt reaction; red color persists with boiling.
17-OH corticosteroids	False reduced values with >4.8g q.d. salicylate.
Vanilmandelic acid	False reduced values.
Uric acid	May increase or decrease depending on dose.
Prothrombin	Decreased levels; slightly increased prothrombin time.

PREGNANCY (Category C)

Salicylic acid has been shown to be teratogenic in rats and monkeys. It is difficult to extrapolate from oral doses of acetylsalicylic acid used in these studies to topical administration as the oral dose to monkeys may represent six times the maximal daily human dose of salicylic acid when applied topically over a large body surface. There are no adequate and well-controlled studies in pregnant women. SALKERA

Emollient Foam should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers: Because of the potential for serious adverse reactions in nursing infants from the mother's use of SALKERA Emollient Foam, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother. If used by nursing mothers, it should not be used on the chest area to avoid the accidental contamination of the child.

Carcinogenesis, Mutagenesis, Impairment of Fertility: No data are available concerning potential carcinogenic or reproductive effects of SALKERA Emollient Foam. Salicylic acid has been shown to lack mutagenic potential in the Ames Salmonella test.

ADVERSE REACTIONS

Excessive erythema and scaling conceivably could result from use on open skin lesions.

DOSAGE AND ADMINISTRATION

Shake Vigorously, Tap Bottom of Can and Prime Before Initial Use. Shake Vigorously and Tap Before Each Use.

To Prime: After shaking, gently tap bottom of can onto palm of other hand or a solid surface at least 3 times. Hold the can upright, direct away from patient, and firmly depress the actuator for 1 to 3 seconds or until foam begins to dispense. (If foam does not dispense within 3 seconds: re-shake can, gently tap bottom of can onto a solid surface at least 3 times, and depress the actuator again until foam begins to dispense.)

Before Each Use: Cleanse affected skin thoroughly and pat dry before each application. Shake vigorously and gently tap bottom of can onto palm of other hand or a solid surface at least 3 times.

During Use: The preferable method of use is to apply SALKERA directly to the affected area and to cover the treated area at night after washing and before retiring. Holding can upright, dispense SALKERA into palm of hand and apply to affected area twice per day, or as directed by a physician. Rub in until completely absorbed. Wipe off any excess foam from actuator after use. Preferably, the skin should be hydrated for at least five minutes prior to application. The medication is washed off in the morning and if excessive drying and/or irritation is observed a bland cream or lotion may be applied. Once clearing is apparent, the occasional use of SALKERA Emollient Foam will usually maintain the remission. In those areas where the placement of a protective covering is difficult or impossible, application of SALKERA Emollient Foam may be made more frequently; hydration by wet packs or baths prior to application apparently enhances the effect. (See WARNINGS.) Unless hands are being treated, hands should be rinsed thoroughly after application. Excessive repeated application of SALKERA Emollient Foam will not necessarily increase its therapeutic benefit, but could result in increased local intolerance and systemic adverse effects such as salicylism.

HOW SUPPLIED:

SALKERA Emollient Foam is supplied in a 60g aluminum can (NDC# 16781-167-60).

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

Manufactured For:



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Patent Pending

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