

SalitopTM Cream & Lotion



SalitopTM Cream & Lotion contains 6% w/w Salicylic Acid, USP in a formulation designed to provide sustained release of the active ingredient into the skin.

For more information on our products, or to learn more about our Clinical Study on SalitopTM, please visit www.bpirx.com.



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Salitop™ Cream (6% Salicylic Acid) Salitop™ Lotion (6% Salicylic Acid)

– RX Only –

FOR TOPICAL USE ONLY. NOT FOR OPHTHALMIC, ORAL OR INTRAVAGINAL USE.

DESCRIPTION:

Salitop™ Cream contains 6% w/w salicylic acid USP finely dispersed in an emulsion consisting of ammonium lactate, behentrimonium chloride, cetyl alcohol, dimethicone 360, disodium EDTA, glycerin, glyceryl stearate SE, methylparaben, mineral oil, PEG-100 stearate, phenoxyethanol, propylparaben, purified water and trolamine. Salitop™ Lotion contains 6% w/w salicylic acid USP finely dispersed in an emulsion consisting of ammonium lactate, behentrimonium chloride, cetyl alcohol, dimethicone 360, disodium EDTA, glycerin, glyceryl stearate SE, methylparaben, mineral oil, PEG-100 stearate, propylparaben, purified water, trolamine.

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

This formulation is designed to provide sustained release of the active ingredient into the skin.

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 5mg/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: Salitop™ 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: Salitop™ 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:

Salitop™ should not be used on any patient known to be sensitive to salicylic acid or any other listed ingredients. Salitop™ should not be used on children under 2 years of age.

WARNINGS:

Prolonged and repeated use over large areas, especially in children and those patients with significant renal or hepatic impairment, could result in salicylism. Patients should be advised not to apply occlusive dressings, clothing or other occlusive topical products such as petrolatum-based ointments to prevent excessive systemic exposure to salicylic acid. 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. On 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 Salitop™ 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 the potential risk of developing Reye's syndrome, salicylate products should not be used on children and teenagers with varicella or influenza, unless directed by a physician.

PRECAUTIONS:

For external use only. Avoid contact with eyes and other mucous membranes.

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. Salitop™ 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 Salitop™, 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 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 Salitop™. It has been shown to lack mutagenic potential in the Ames Salmonella test.

DRUG INTERACTIONS

The following interactions are from a published review and include reports concerning both oral and topical salicylate administration. The relationship of these interactions to the use of Salitop™ is not known.

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

DRUG	DESCRIPTION OF INTERACTION
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.

DRUG	DESCRIPTION OF INTERACTION
Corticosteroids	Decreases plasma salicylate level; tapering doses of steroids may promote salicylism.
Acidifying Agents	Increases plasma salicylate level.
Alkalinizing Agents	Decreases 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, sulfipyrazone 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 (2-5 g 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 >4.8 g q.d. salicylate.
Vanilmandelic acid	False reduced values.
Uric acid	May increase or decrease depending on dose.
Prothrombin	Decreased levels; slightly increased prothrombin time.

ADVERSE REACTIONS:

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

OVERDOSAGE:

See **WARNINGS**.

DOSAGE AND ADMINISTRATION:

The preferable method of use is to apply Salitop™ thoroughly to the affected area and occlude the area at night, after washing and before retiring.

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 Salitop™ will usually maintain the remission. In those areas where occlusion is difficult or impossible, application 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 Salitop™ will not necessarily increase its therapeutic benefit, but could result in increased local intolerance and systemic adverse effects such as salicylism.

HOW SUPPLIED:

Salitop™ Cream is available in 400 gram, (NDC 51991-476-46) tubes.

Salitop™ Lotion is available in 14 fl oz (414 mL), (NDC 51991-477-47) bottles.

Store at 25°C (77°F); excursions permitted to 15°-30°C (59°-86°F). See USP Controlled Room Temperature. Protect from freezing.

WARNING:

Keep This and all medications out of the reach of children. In case of accidental overdose seek professional assistance or contact a Poison Control Center immediately.

All prescription substitutions using this product shall be pursuant to state statutes as applicable. This is not an Orange Book product.

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