SALEX- salicylic acid cream
SALEX- salicylic acid lotion
Coria Laboratories

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Salex® (6% Salicylic Acid) Cream
Salex® (6% Salicylic Acid) Lotion

Rx only

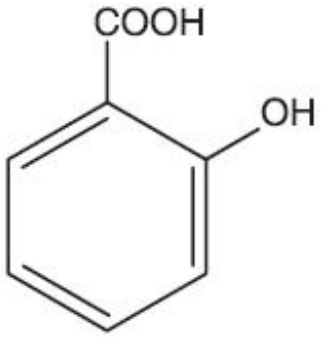
FOR DERMATOLOGIC USE ONLY. NOT FOR OPHTHALMIC, ORAL OR INTRAVAGINAL USE.

DESCRIPTION

Salex® Cream contains 6% salicylic acid USP incorporated into a patented Multivesicular Emulsion (MVE) vehicle consisting of ammonium lactate, behentrimonium methosulfate, cetearyl alcohol, cetyl alcohol, dimethicone 360, disodium EDTA, glycerin, glyceryl stearate SE, methylparaben, mineral oil, PEG-100 stearate, phenoxyethanol, propylparaben, purified water and trolamine.

Salex® Lotion contains 6% w/w salicylic acid USP incorporated into a patented Multivesicular Emulsion (MVE) vehicle consisting of ammonium lactate, behentrimonium methosulfate, cetearyl alcohol, cetyl alcohol, dimethicone 360, disodium EDTA, glycerin, glyceryl stearate SE, methylparaben, mineral oil, PEG-100 stearate, propylparaben, purified water and trolamine.

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



This MVE formulation has been shown to provide gradual and prolonged release of the active ingredient into the skin.[1]

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: Salex® 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: Salex® 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

Salex® should not be used in any patient known to be sensitive to salicylic acid or any other listed ingredients. Salex® 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. 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. 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 Salex® 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.

PRECAUTIONS

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

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 Salex® 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.
Alkalizing 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 T_3 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. Salex® 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 Salex®, 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 Salex®. 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.

OVERDOSAGE

See Warnings.

DOSAGE AND ADMINISTRATION

The preferable method of use is to apply Salex® thoroughly to the affected area and to cover the treated 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 Salex® 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 Salex® will not necessarily increase its therapeutic benefit, but could result in increased local intolerance and systemic adverse effects such as salicylism.

HOW SUPPLIED

Salex® Cream is available in a 454 g (16 oz.) jar - **NDC** 13548-010-16

Salex® Lotion is available in a 8 fl. oz. (237 mL) bottle - **NDC** 13548-011-08

Store at controlled room temperature

20° to 25°C (68° to 77°F). Do not freeze.

(1) Data on file.

Manufactured for:

Valeant Pharmaceuticals North America LLC
Bridgewater, NJ 08807 USA
by:
Denison Pharmaceuticals, LLC
Lincoln, RI 02865 USA

PATENT NO. 6,709,663

REORDER NO.
Salex® Cream: 13548-010-17
Salex® Lotion: 13548-011-09

9497700

70011485

PRINCIPAL DISPLAY PANEL - 454 g Carton

NDC 13548-010-17

Rx only

Salex®
(6% Salicylic Acid)
Cream

For Topical Use Only

- 1 jar of **Salex**® **Cream**
  – Net Wt. 454 g (16 oz.)

Bonus: 1 bottle ofCeraVe® Hydrating Cleanser
– 12 fl. oz.

PATENTED MULTIVESICULAR EMULSION™

VALEANT

PRINCIPAL DISPLAY PANEL - 237 mL Carton

NDC 13548-011-09

Rx only

Salex®
(6% w/w **Salicylic Acid**)
Lotion

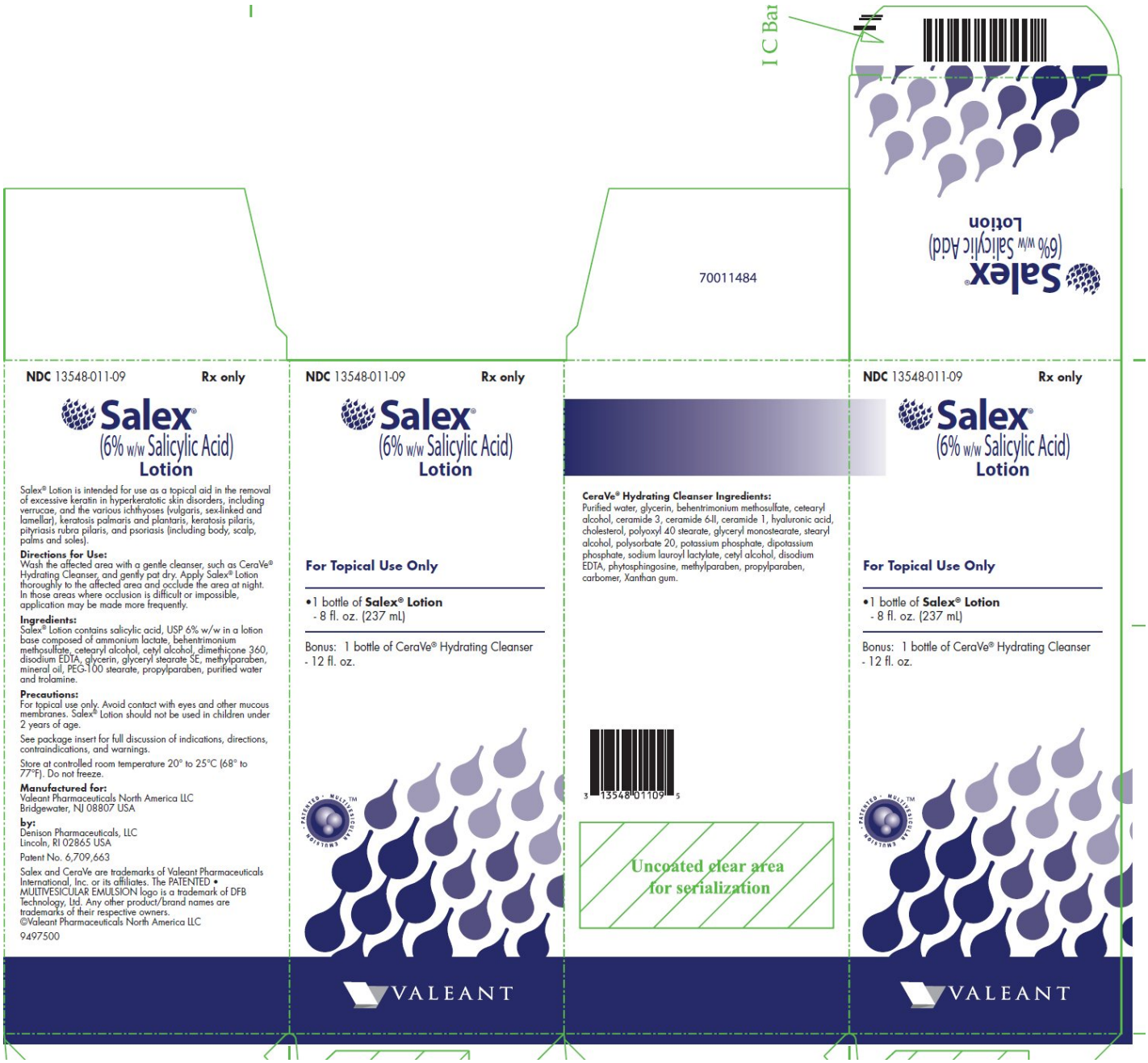
For Topical Use Only

- 1 bottle of **Salex**® **Lotion**
  – 8 fl. oz. (237 mL)

Bonus: 1 bottle ofCeraVe® Hydrating Cleanser
– 12 fl. oz.

PATENTED MULTIVESICULAR EMULSION®

VALEANT



SALEX

salicylic acid cream

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:13548-010
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Salicylic acid (UNII: O414PZ4LPZ) (Salicylic acid - UNII:O414PZ4LPZ)	Salicylic acid	60 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
ammonium lactate (UNII: 67M901L9NQ)	
behentrimonium methosulfate (UNII: 5SHP745C61)	
cetostearyl alcohol (UNII: 2DMT128M1S)	
cetyl alcohol (UNII: 936JST6JCN)	
dimethicone 350 (UNII: 2Y53S6ATLU)	
edetate disodium (UNII: 7FLD91C86K)	
glycerin (UNII: PDC6A3C0OX)	
Glyceryl Monostearate (UNII: 230OU9XXE4)	
methylparaben (UNII: A2I8C7HI9T)	
mineral oil (UNII: T5L8T28FGP)	
PEG-100 STEARATE (UNII: YD01N1999R)	
Phenoxyethanol (UNII: HIE492ZZ3T)	
propylparaben (UNII: Z8IX2SC1OH)	
water (UNII: 059QF0KO0R)	
Trolamine (UNII: 9O3K93S3TK)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:13548-010-17	1 in 1 KIT	06/01/2004	
1	NDC:13548-010-16	454 g in 1 JAR; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved drug other		06/01/2004	

SALEX

salicylic acid lotion

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:13548-011
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Salicylic acid (UNII: O414PZ4LPZ) (Salicylic acid - UNII:O414PZ4LPZ)	Salicylic acid	60 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
ammonium lactate (UNII: 67M901L9NQ)	

behentrimonium methosulfate (UNII: 5SHP745C61)	
cetostearyl alcohol (UNII: 2DMT128M1S)	
dimethicone 350 (UNII: 2Y53S6ATLU)	
edetate disodium (UNII: 7FLD91C86K)	
glycerin (UNII: PDC6A3C0OX)	
Glyceryl Monostearate (UNII: 230OU9XXE4)	
methylparaben (UNII: A2I8C7HI9T)	
mineral oil (UNII: T5L8T28FGP)	
PEG-100 STEARATE (UNII: YD01N1999R)	
Phenoxyethanol (UNII: HIE492ZZ3T)	
propylparaben (UNII: Z8IX2SC1OH)	
water (UNII: 059QF0KO0R)	
Trolamine (UNII: 9O3K93S3TK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13548-011-09	1 in 1 KIT	10/01/2004	
1	NDC:13548-011-08	237 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved drug other		10/01/2004	

Labeler - Coria Laboratories (010977972)

Establishment

Name	Address	ID/FEI	Business Operations
Denison Pharmaceuticals, LLC		001207208	MANUFACTURE(13548-010, 13548-011)

Revised: 4/2016 Coria Laboratories