SALICYLIC ACID- salicylic acid
Exact-Rx, Inc.

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.

Salicylic Acid 6% Cream Kit
Salicylic Acid 6% Lotion Kit

Rx Only

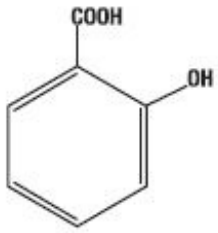
FOR DERMATOLOGICAL USE ONLY. NOT FOR OPHTHALMIC, ORAL OR INTRAVAGINAL USE.

DESCRIPTION

SA 6% Cream contains 6% salicylic acid USP incorporated into a specially formulated oil and water emulsion (0IW)™™ vehicle consisting of trolamine, purified water, methyl paraben, propyl paraben, phenoxyethanol, PEG 100 stearate, mineral oil, glyceryl stearate SE, dimethicone 350, ammonium lactate, disodium EDTA, glycerine, cetearyl alcohol (and) PEG-3, distearoylamidoethylmonium methosulfate (and) polysorbate 60, cetyl alcohol and cetearyl alcohol.

SA 6% Lotion contains 6% w/w salicylic acid USP incorporated into a specially formulated oil and water emulsion (0IW)™ vehicle consisting of trolamine, purified water, methyl paraben, propyl paraben, PEG 100 stearate, cetyl alcohol, mineral oil, glyceryl stearate SE, dimethicone 350, ammonium lactate, disodium EDTA, glycerine, cetearyl alcohol (and) PEG-3 distearoylamidoethylmonium methosulfate (and) polysorbate 60.

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



This (0IW)™ formulation has been shown to provide gradual and prolonged 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 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: SA 6% 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: SA 6% 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

SA 6% should not be used in any patient known to be sensitive to salicylic acid or any other listed ingredients.

SA 6% should not be used in children under 2 years of age.

WARNINGS

Prolonged use over large areas, especially in children and those patients with significant renal or hepatic impairment, could result in salicylism. 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 **SA 6%** 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.

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 what is needed to cover the affected area will not result in a more rapid therapeutic benefit.

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 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 **SA 6%** 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 levels.
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 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 $FeCI_3$ 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. Decreased levels; slightly increased

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.

SA 6% 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 **SA 6%**, 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 accidental contamination of the child.

Carcinogenesis, Mutagenesis, Impairment of Fertility: No data are available concerning potential carcinogenic or reproductive effects of **SA 6%**. It has been shown to lack mutagenic potential in the Ames test.

ADVERSE REACTIONS

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

Call your physician for medical advice about side effects.

OVERDOSAGE See Warnings.

DOSAGE AND ADMINISTRATION

The preferable method of use is to apply **SA 6%** 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 a 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 **SA 6%** 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 **SA 6%** will not necessarily increase its therapeutic benefit, but could result in increased local intolerance and systemic adverse effects such as salicylism*.

HOW SUPPLIED:

Salicyclic Acid 6% Cream Kit, NDC 42808-0399-16, contains a 16 oz. (454 g) jar of Salicylic Acid Cream and a 12 fl. oz. (355 mL) bottle of Hydrating Cleanser.

Salicyclic Acid 6% Lotion Kit, NDC 42808-0399-08, contains an 8 oz. (277 g) bottle of Salicylic Acid Lotion and a 12 fl. oz. and a 12 fl. oz. (355 mL) Hydrating Cleanser..

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

Manufactured in the U.S.A. for Exact-Rx, Inc., Melville, NY 11747

00-0399-16-205-00/00-399-08-205-00 Iss:8/11

PRINCIPAL DISPLAY PANEL - Cream Kit

For External Use Only

NDC 42808-0399-16 Rx Only

Salicylic Acid Kit

6%

CREAM

Kit includes:

• 1 Jar of Salicylic Acid 6% Cream 16 oz. (454 g)

• 1 Bottle of Hydrating Cleanser 12 fl. oz. (355 mL)

• Package Insert

Exact-Rx. INCORPORATED

Dispense as a complete kit

SALICYLIC ACID

salicylic acid kit

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:42808-399

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:42808-399-16	1 in 1 CARTON		

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1	1 JAR	454 g
Part 2	1 BOTTLE	355 mL

Part 1 of 2

SALICYLIC ACID

salicylic acid cream

Product Information	
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**
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
PEG-100 STEARATE (UNII: YD01N1999R)	
MINERAL OIL (UNII: T5L8T28FGP)	
GLYCERYL 1-STEARATE (UNII: 258491E1RZ)	
DIMETHICONE 350 (UNII: 2Y53S6ATLU)	
AMMONIUM LACTATE (UNII: 67M901L9NQ)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	

CETYL ALCOHOL (UNII: 936JST6JCN)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		454 g in 1 JAR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved drug other		08/01/2011	

Part 2 of 2

CLEANSER

cleanser solution

Product Information	
Route of Administration	TOPICAL

Inactive Ingredients	
Ingredient Name	Strength
CARBOMER HOMOPOLYMER TYPE C (UNII: 4Q93RCW27E)	
CERAMIDE 3 (UNII: 4370DF050B)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CHOLESTEROL (UNII: 97C5T2UQ7J)	
POTASSIUM PHOSPHATE (UNII: B7862WZ632)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
HYALURONIC ACID (UNII: S270N0TRQY)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYOXYL 40 STEARATE (UNII: 13A4J4NH9I)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
POTASSIUM PHOSPHATE (UNII: B7862WZ632)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SODIUM LAUROYL LACTYLATE (UNII: 7243K85WFO)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		355 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved drug other		08/01/2011	

Labeler - Exact-Rx, Inc. (137953498)

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