SALICYLIC ACID- salicylic acid gel
SOLUTECH PHARMACEUTICALS LLC

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% Gel

Rx only

For external use only.

Not for ophthalmic use.

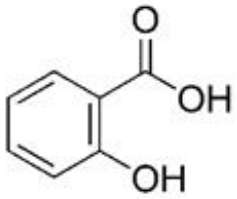
Each gram of Salicylic Acid 6% Gel contains:

ACTIVE: 6% Salicylic Acid in a gel base of:

INACTIVES: SD-40 Alcohol, Propylene Glycol, Water and Hydroxyethyl Cellulose

DESCRIPTION

Salicylic acid 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 **Drug Interactions**.)

INDICATIONS AND USAGE

For Dermatologic Use

Salicylic Acid 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

Salicylic Acid 6% is a topical aid in the removal of excessive keratin on dorsal and plantar hyperkeratotic lesions. Topical preparations of salicylic acid have been reported to be useful adjunctive therapy for verrucae plantares.

CONTRAINDICATIONS

Salicylic Acid 6% should not be used in any patient known to be sensitive to salicylic acid or any other listed ingredients. Salicylic Acid 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 Salicylic Acid 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, lips, broken or inflamed skin and all 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. If swallowed, get medical help or contact Poison Control Center right away. KEEP THIS AND ALL MEDICATION OUT OF THE REACH OF CHILDREN.

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 Salicylic Acid 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 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 FeCl3 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. Salicylic Acid 6% should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Category D in 3rd trimester

It is especially important not to use salicylic acid during the last 3 months of pregnancy unless definitely

directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

NURSING MOTHERS

Because of the potential for serious adverse reactions in nursing infants from the mother's use of Salicylic Acid 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 Salicylic Acid 6%. It has been shown to lack mutagenic potential in the Ames test.

ADVERSE REACTIONS

Some adverse effects are: singing, burning and desquamation.

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.

Excessive erythema and scaling conceivably could result from use on open skin lesions. Call your physician for medical advice about side effects.

DOSAGE AND ADMINISTRATION

Apply Salicylic Acid 6% Gel to the affected area at night or as directed by your doctor. Preferably, 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 blend cream or lotion may be applied. Unless hands are being treated, hands should be rinsed thoroughly after application. Once desired result is achieved, the occasional use of Salicylic Acid 6% will usually maintain the remission. Hydration by wet packs or baths prior to application can enhance the effect. Excessive repeated application of Salicylic Acid 6% will not necessarily increase its therapeutic benefit, but could result in increased local intolerance and systemic adverse effects such as salicylism (See **WARNINGS**.).

How is Salicylic Acid 6% Gel Supplied

Salicylic Acid 6% Gel is supplied in:

240 gm Jar	70350-2610-2
40 gm Jar	70350-2610-1

Store at 25°C (77°F); excursion permitted to 15°C - 30°C (59° - 86°F).

Protect from freezing. [See USP Controlled Room Temperature.]Flammable. Keep away from heat and open flame.

Manufactured for:
Solutech Pharmaceuticals LLC
Peoria, AZ 85345

Rx only

PRINCIPAL DISPLAY PANEL - 40 gm Jar Label

NDC 70350-2610-1

SALICYLIC ACID 6% GEL

FOR TOPICAL USE ONLY

Net WT. 40 gm

Solutech
PHARMACEUTICALS

SALICYLIC ACID

salicylic acid gel

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70350-2610
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**
ALCOHOL (UNII: 3K9958V90M)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
HYDROXYETHYL CELLULOSE (3000 MPA.S AT 1%) (UNII: 7Q6P4JN1QT)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:70350-2610-2	240 g in 1 JAR; Type 0: Not a Combination Product	06/15/2017	
2	NDC:70350-2610-1	40 g in 1 JAR; Type 0: Not a Combination Product	06/15/2017	

Marketing Information			
Marketing Category	**Application Number or Monograph Citation**	**Marketing Start Date**	**Marketing End Date**
Unapproved drug other		06/15/2017	

Labeler - SOLUTECH PHARMACEUTICALS LLC (080040396)

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