SALICYLIC ACID- salicylic acid gel
Acella 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

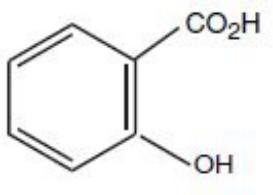
FOR TOPICAL USE ONLY. NOT FOR OPHTHALMIC, ORAL OR INTRAVAGINAL USE.

DESCRIPTION

Salicylic Acid 6% Gel is applied topically and used in the removal of excessive keratin in hyperkeratotic skin disorders. Each gram of Salicylic Acid 6% Gel contains salicylic acid 6% as the active ingredient, and the following inactive ingredients: hydroxypropylcellulose and propylene glycol.

CHEMICAL STRUCTURE

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



CLINICAL PHARMACOLOGY

Salicylic acid has been shown to produce desquamation of the horny layer of skin while not affecting qualitative or quantitative changes in structure of the viable epidermis. [1,2] The mechanism of action has been attributed to dissolution of intercellular cement substance. [3] In a study of the percutaneous absorption of salicylic acid from Salicylic Acid 6% Gel in four patients with extensive active psoriasis, Taylor and Halprin [4] showed that 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/100mL). Peak serum levels occurred within 5 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. [5] (See **PRECAUTIONS**).

The major metabolites identified in the urine after topical administration are salicyluric acid (52%), salicylate glucuronides (42%), and free salicylic acid (6%). [4] The urinary metabolites after percutaneous absorption differ from those after oral salicylate administration; those derived from percutaneous absorption contain more 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. [5]

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 competetive mechanisms other drugs can influence the serum levels of salicylate. (See **PRECAUTIONS**).

INDICATIONS AND USAGE

For the removal of excess keratin in hyperkeratotic disorders, including scaling associated with psoriasis or thickened skin of palms and soles, corns and calluses.

CONTRAINDICATIONS

Salicylic Acid 6% Gel should not be used in any patient known to be sensitive to salicylic acid or any other listed ingredients. Salicylic Acid 6% Gel should not be used in children under 2 years of age.

WARNINGS

Contact with eyes, lips, broken or inflamed skin, and all mucous membranes should be avoided.

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, hyperpnoea, diarrhea, psychic disturbances. In the event of salicylic acid toxicity, the use of Salicylic Acid 6% Gel should be discontinued. Fluids should be administered to promote urinary excretion. Treatment with sodium bicarbonate (oral or intravenous) should be instituted as appropriate.

Considering the potential of developing Reye’s syndrome, salicylate products should not be administered to children or teenagers with varicella or influenza, unless directed by a physician.

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. **Flammable. Keep away from heat and open flame. Keep this and all medications out of the reach of children**.

Drug Interactions. (The following interactions are from a published review [5] and include reports concerning both oral and topical salicylate administration. The relationship of these interactions to the use of Salicylic Acid 6% Gel 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**
Tolbutamide;	Hypoglycemia potentiated

Sulfonylureas	Hypoglycemia potentiated
Methotrexate	Decrease 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
Ammonium Sulfate	Increases plasma salicylate level

III. Drugs with complicated interactions with salicylates:

Drug	**Description of Interaction**
Heparin	Salicylate decreases platelet adhesivesness and interferes with hemostasis in heparin-treated patients
Pyrazinamide	Inhibits pyrazinamide-induced hyperuricemia
Uricosuric Agents	Effect of probenecid, sulfinpyrazone and phenylbutazone inhibited

The following alterations of laboratory tests have been reported during salicylate therapy [6]:

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 - 5 g qd)
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 qd 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 4 times the maximum daily human dose of salicylic acid (as supplied in one tube, 40 g of Salicylic Acid 6% Gel) when applied topically over a large body surface. There are no adequate and well-controlled studies in pregnant women. Salicylic Acid 6% Gel should be used during pregnancy only if the potential benefit justifies the risk to the fetus.

Nursing Mothers - It is not known whether topically applied salicylic acid is excreted in human milk. Due to the fact that many drugs are excreted in human milk, caution should be exercised by physicians when administering Salicylic Acid 6% Gel to nursing mothers

and nursing mothers should certainly not apply Salicylic Acid 6% Gel to the chest area or any other part of the body with which the nursing child's mouth is likely to come in contact.

Because of the potential for serious advers reactions in nursing infants from the mother's use of Salicylic Acid 6% Gel, 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.

Carcinogenesis, Mutagenesis, Impairment of Fertility - No data are available concerning potential carcinogenic or reproductive effects of Salicylic Acid 6% Gel. It has been shown to lack mutagenic potential in the Ames Salmonella test.

KEEP THIS AND ALL OTHER MEDICATIONS OUT OF THE REACH OF CHILDREN.

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 Salicylic Acid 6% Gel thoroughly to the affected area and occlude the area at night. 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 Salicylic Acid 6% Gel 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. Unless hands are being treated, hands should be rinsed thoroughly after application.

HOW SUPPLIED

Salicylic Acid 6% Gel is supplied in a 40 gram plastic tube bearing the NDC Number 42192-134-40.

Store at controlled room temperature 15° - 30°C (59° - 86°F). [See USP "Controlled Room Temperature"]

REFERENCES:

1. Davies M, Marks R: Br J Dermatol 95: 187-192, 1976.
2. Mars R, Davies M, Cattel A: J Invest Dermatol 64: 283, 1975.
3. Huber C, Christophers E: Arch Derm Res 257: 293-297, 1977.
4. Taylor JR, Halprin KM: Arch Dermatol 111: 740-743, 1975.
5. Goldsmith LA: Int J Dermatol 18: 32-36.
6. Wilson JG, Ritter EJ, Scott WJ, Fradlein R: Tox Appl Pharmacol 41: 67-78, 1977.

All prescription substitutions using this product shall be made subject to state and federal statutes as applicable. **NOTE: this is not an Orange Book product and has not been subjected to FDA therapeutic equivalency or other equivalency testing. No representation is made as to generic status or bioequivalency.** Each person recommending a prescription substitution using this product shall make

such recommendations based on each such person’s professional opinion and knowledge, upon evaluating the active ingredients, excipients, inactive ingredients and chemical formulation information provided herein.

MANUFACTURED FOR

Acella Pharmaceuticals, LLC

Alpharetta, GA 30009

1-800-541-4802

L-0079 Rev 1020-02

PRINCIPAL DISPLAY PANEL - 40 g container label

NDC 42192-134-40

Salicylic
Acid 6%
GEL

Rx only

Net Wt. 40 g

Acella
PHARMACEUTICALS, LLC

NDC 42192-134-40

Salicylic Acid 6% Gel

Rx only

Net Wt 40 g

Acella PHARMACEUTICALS, LLC

Manufactured for:
Acella Pharmaceuticals, LLC
Alpharetta, GA 30005
1-800-541-4802
L-0078 Rev 1020-02

Ingredients: Salicylic Acid 6% as the active ingredient in a vehicle containing hydroxypropyl cellulose and propylene glycol.

Indication: For the removal of excess keratin in hyperkeratotic disorders, including scaling associated with psoriasis or thickened skin of palms and soles, corns and calluses.

Directions: Apply Salicylic Acid 6% Gel thoroughly to the affected area and occlude the area at night. Preferably, the skin should be hydrated (soaked in water) for at least five minutes prior to application. The medication is washed off in the morning. In those areas where occlusion is difficult or impossible, application may be made more frequently. Once clearing is apparent, the occasional use of Salicylic Acid 6% Gel will usually maintain the remission. Unless hands are being treated, hands should be rinsed thoroughly afer application.

Warnings: For external use only. Avoid contact with eyes and other mucous membranes. May cause mild irritation. If excessive irritation or sensitivity occurs, discontinue use and consult your physician. Do not use on children under 2 years of age. Read package insert carefully. **Flammable. Keep away from heat and open flame. Keep this and all medications out of the reach of children.**

Store at 20°-25°C (68°-77°F); excursions permitted to 15°-30°C (59°-86°F).
[See USP "Controlled Room Temperature".]

All prescription substitutions and/or recommendations using this product shall be made subject to state and federal statutes as applicable. **NOTE: This is not an Orange Book product. No representation is made as to generic status or bioequivalency.** See package insert for more details.

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SALICYLIC ACID

salicylic acid gel

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:42192-134
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
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
HYDROXYPROPYL CELLULOSE (1600000 WAMW) (UNII: RFW2ET671P)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42192-134-40	1 in 1 CARTON	05/19/2011	
1		40 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		05/19/2011	

Labeler - Acella Pharmaceuticals, LLC (825380939)

Establishment

Name	Address	ID/FEI	Business Operations
Acella Pharmaceuticals, LLC		825380939	manufacture(42192-134)

Revised: 1/2024 Acella Pharmaceuticals, LLC