SALICYLIC ACID- salicylic acid aerosol, foam
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% Foam

(salicylic acid in a water and lipid based foam, 6%)

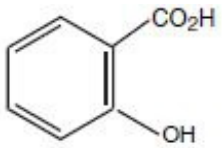
Rx Only

DESCRIPTION

Salicylic Acid 6% Foam is applied topically and used in the removal of excessive keratin in hyperkeratotic skin disorders. Each gram of Salicylic Acid 6% Foam contains salicylic acid 6% as the active ingredient, and the following inactive ingredients: dimethicone, ethylparaben, glycerin, methylcellulose, methylparaben, phenoxyethanol, polyoxyl 40 stearate, polysorbate 20, polysorbate 80, povidone, propylene glycol, propylparaben, purified water, sodium citrate, sodium hydroxide, stearic acid and trolamine and in propellants butane and propane.

CHEMICAL STRUCTURE

Salicylic acid is a 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. The mechanism of action has been attributed to dissolution of intercellular cement substance. In a study of the percutaneous absorption of salicylic acid from Salicylic Acid 6% Foam in four patients with extensive active psoriasis, Taylor and Halprin showed that peak serum 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. (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 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 competetive mechanisms other drugs can influence the serum levels of salicylate. (See **PRECAUTIONS**).

PHARMACOKINETICS

The mechanism of action of topically applied salicylic acid has been attributed to the dissolution of intercellular cement substance.

INDICATIONS AND USAGE

For Dermatologic Use: Salicylic Acid 6% Foam is a topical aid in the removal of excessive keratin in hyperkeratotic skin disorders, including verrucae and the various ichthyoses, keratosis palmaris and plantaris, keratosis pilaris, pityriasis rubra pilaris and psoriasis.

For Podiatric Use: Salicylic Acid 6% Foam is a topical aid in the removal of excessive keratin on dorsal and plantar hyperkeratotic lesions.

CONTRAINDICATIONS

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

WARNINGS

Salicylic Acid 6% Foam is for external use only. It is not for ophthalmic, oral, anal or intravaginal use. Contact with eyes, lips, broken or inflamed skin, and all mucous membranes should be avoided. Salicylic Acid 6% Foam should not be used by persons who have a known hypersensitivity to salicylic acid or any of the other listed ingredients.

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% Foam 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

Salicylic Acid 6% Foam should be used only as directed by a physician and should not be used to treat any condition other than that for which it is prescribed. Salicylic Acid 6% Foam should not be used on any skin area where inflammation or exudation is present as increased absorption may occur. If redness or irritation occurs, discontinue use and consult with prescribing physician.

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% Foam 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; 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
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
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:

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 in the human. There are no adequate and well-controlled studies in pregnant women. Salicylic Acid 6% Foam should be used during pregnancy only if the potential benefit justifies the potential 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% Foam to nursing mothers and nursing mothers should certainly not apply Salicylic Acid 6% Foam 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 adverse reactions in nursing infants from the mother's use of Salicylic Acid 6% Foam, 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% Foam. 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

Transient stinging, burning, itching or irritation is possible. 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.

DOSAGE - See WARNINGS

DOSAGE AND ADMINISTRATION

Unless otherwise directed by a prescribing physician, Salicylic Acid 6% Foam should be applied to the affected area twice a day. Salicylic Acid 6% Foam should be rubbed into the skin until it is completely absorbed.

Salicylic Acid 6% Foam should be shaken vigorously before each application and inverted to administer.

HOW SUPPLIED

Salicylic Acid 6% Foam is supplied in a 70 gram or 2.5 ounce aerosolized canister bearing the NDC Number 42192-112-70 and a 200 gram or 7.1 ounce aerolized canister bearing the NDC Number 42192-130-02 .

Store at controlled room temperature 15° - 25°C (59° - 77°F).

Contains flammable materials. Contents under pressure. Do not puncture and/or incinerate the containers. Do not expose to temperatures over 120°F (48°C) even when empty.

MANUFACTURED FOR
Acella Pharmaceuticals, LLC
Alpharetta, GA 30009
1-800-541-4802
Rev. 0311v5

"PACKAGE LABEL.PRINCIPAL DISPLAY PANEL - 200 g

NDC 42192-130-02

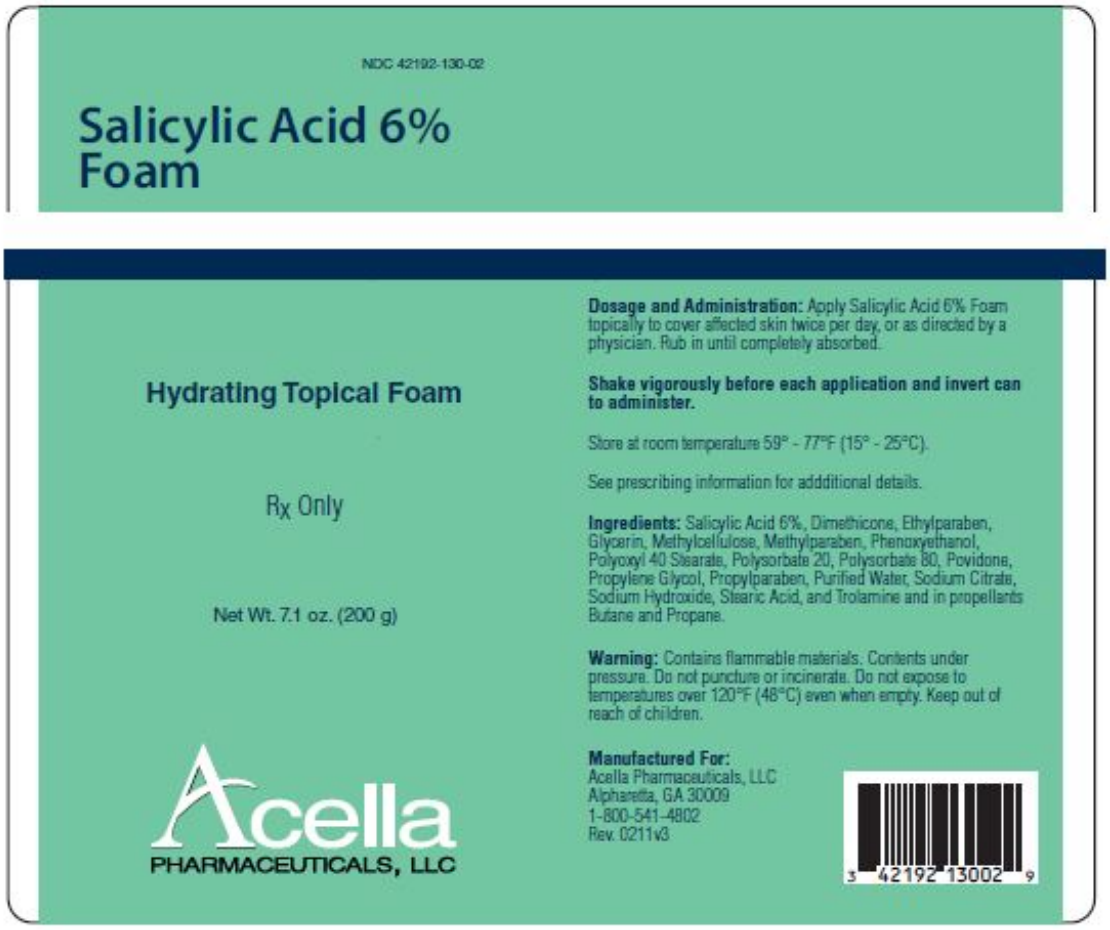
SALICYLIC ACID 6%
FOAM

Hydrating Topical Foam

Rx Only

Net Wt. 7.1 oz. (200 g)

Acella
Pharmaceuticals LLC



SALICYLIC ACID

salicylic acid aerosol, foam

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:42192-130
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)	SALICYLIC ACID	6 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
DIMETHICONE (UNII: 92RU3N3Y1O)	
ETHYLPARABEN (UNII: 14255EXE39)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLCELLULOSE (100 CPS) (UNII: 4GFU244C4J)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYOXYL 40 STEARATE (UNII: 13A4J4NH9I)	

POLYSORBATE 20 (UNII: 7T1F30V5YH)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TROLAMINE (UNII: 9O3K93S3TK)	
BUTANE (UNII: 6LV4FOR43R)	
PROPANE (UNII: T75W9911L6)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42192-130-02	200 g in 1 CANISTER; Type 0: Not a Combination Product	05/17/2011	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		05/17/2011	

Labeler - Acella Pharmaceuticals, LLC (825380939)

Registrant - Acella Pharmaceuticals, LLC (825380939)

Establishment

Name	Address	ID/FEI	Business Operations
Acella Pharmaceuticals, LLC		825380939	manufacture(42192-130)

Revised: 1/2024 Acella Pharmaceuticals, LLC