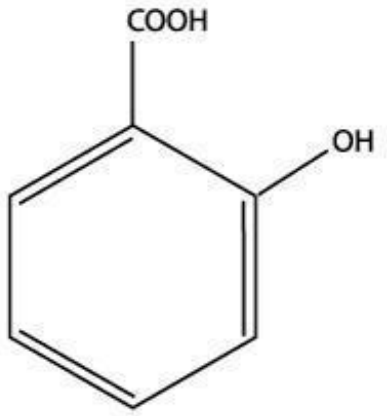
SALICYLIC ACID 6 PERCENT- salicylic acid shampoo
PruGen, Inc.

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 SHAMPOO

Salicylic Acid Shampoo contains 6% w/w salicylic acid USP in a vehicle consisting of purified water, acrylates copolymer, sodium laureth sulfate, trolamine, quaternium 26 and propylene glycol, cocamidopropyl betaine, behentrimonium methosulfate and cetearyl alcohol, propylparaben, methylparaben, glycerin, disodium EDTA and chamomile tea fragrance.
Salicylic acid is the 2-hydroxy derivative of benzoic acid having the following structure:



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/100ml).
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 a 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 a salicylate is protein bound to albumin. Salicylates compete with the binding of several drugs and can modify the actions of these drugs; by similar competitive mechanisms other drugs can influence the serum levels of salicylate. (See PRECAUTIONS)

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

Salicylic Acid 6% (w/w) Shampoo should not be used in any Patient known to be sensitive to salicylic acid or any other listed ingredients. Salicylic Acid 6% (w/w) Shampoo should not be used in children under 2 years of age.

Prolonged use over large areas, especially in children and those patients with significant renal or hepatic impairment could result in salicylism. Excessive application of the product other than is needed to cover the affected area will not result in more 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 the Salicylic Acid 6% (w/w) Shampoo 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 and 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.

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

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% (w/w) Shampoo is not known.

I.Due to the competition of salicylate with other drugs for bindingto 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.
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 hyper-uricemia.
Uricosuric	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	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 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	09-0080 May increase or decrease depending on

dose.
ProthrombinDecreased levels; slightly Increased pro-
thrombin time.

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% (w/w) Shampoo should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Because of the potential for serious adverse reactions in nursing infants from the mother's use of Salicylic Acid 6% (w/w) Shampoo, 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.

No data are available concerning potential carcinogenic or reproductive effects of Salicylic Acid 6% (w/w) Shampoo. Salicylic acid has been shown to lack mutagenic potential in the Ames Salmonella test.

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

See Warnings.

Wet hair and apply Salicylic Acid 6% (w/w) Shampoo to the scalp. Work into a lather then rinse. Repeat the treatment as needed until the condition clears. Once clearing is apparent, the occasionaluse of Salicylic Acid 6% (w/w) Shampoo will usually maintain the remission.

Salicylic Acid 6% (w/w) Shampoo is available in 177mL plastic bottles (NDC 42546-279-06).
Store at controlled room temperature 20°-25°C (68°-77°F). Do not freeze

NDC 42546-279-06

Rx Only

Salicylic Acid Shampoo 6% (w/w)

177mL

PruGen, Inc. Pharmaceuticals

NDC 42546-279-06 Rx Only

SALICYLIC ACID
6% (w/w)
SHAMPOO

177 ml

DESCRIPTION
Shampoo contains 6% w/w salicylic acid USP in a vehicle composed of purified water, ammonium lauryl sulfosuccinate, cocamidopropyl betaine, hexylene glycol, linoleamidpropyl PG-dimonium chloride phosphate, polyquaternium-22, propylene glycol, sodium C14-16 olefin sulfomate, sodium citrate, sodium lauryl sarcosinate, tetrasodium EDTA, tocopherol acetate and fragrance.

DIRECTIONS
Wet hair and apply Salicylic Acid 6% (w/w) Shampoo to the scalp. Work into a lather then rinse. Repeat the treatment as needed until the condition clears. Once clearing is apparent, the occasional use of Salicylic Acid 6% (w/w) Shampoo will usually maintain the remission.

STORAGE
Store at controlled room temperature 20°-25°C (68°-77°F). Do not freeze.

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

Manufactured for:
PruGen, Inc. Pharmaceuticals
8714 E Vista Bonita Dr
Scottsdale, AZ 85255
Rev 2.0

PRUGEN PHARMACEUTICALS

N3 42546 27906 0

SALICYLIC ACID 6 PERCENT
salicylic acid shampoo

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:42546-279
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 mg in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
water (UNII: 059QF0KO0R)	
CARBOMER COPOLYMER TYPE A (UNII: 71DD5V995L)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	

TROLAMINE (UNII: 9O3K93S3TK)	
QUATERNIUM-22 (UNII: MXO138JCBP)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
BEHENTRIMONIUM METHOSULFATE (UNII: 5SHP745C61)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
GLYCERIN (UNII: PDC6A3C0OX)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
CHAMOMILE (UNII: FGL3685T2X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42546-279-06	1 in 1 BOX		
1		177 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		01/01/2009	

Labeler - PruGen, Inc. (929922750)

Revised: 2/2013 PruGen, Inc.