SALICYLIC ACID- salicylic acid
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 6% Cream

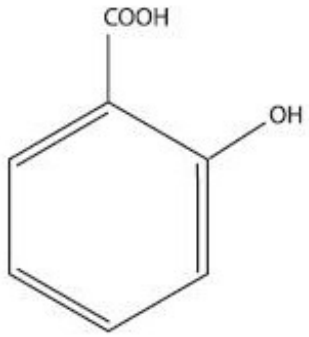
Rx Only

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

DESCRIPTION

Salicylic Acid 6% (w/w) Cream contains salicylic acid, USP 6% in a cream base composed of ammonium lactate, cetearyl alcohol, cetearyl alcohol (and) PEG-3 distearoylamidoethylmonium methosulfate (and) polysorbate 60, cetyl alcohol, dimethicone 350, disodium EDTA, glycerine, glyceryl stearate SE, methylparaben, mineral oil, PEG-100 stearate, phenoxyethanol, propylparaben, purified water and trolamine.

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



This 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 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)

INDICATIONS AND USAGE

For Dermatologic Use

Salicylic Acid 6% (w/w) Cream 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) Cream 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.

CONTRAINDICATIONS

Salicylic Acid 6% (w/w) Cream should not be used in any patient known to be sensitive to salicylic acid or any other listed ingredients. Salicylic Acid 6% (w/w) Cream 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. 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) Cream 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.

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 Salicylic Acid 6% (w/w) Cream 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 level.
Alkanizing Agents	Decreased plasma salicylate levels.

III. Drugs with complicated interactions with salicylates:

DRUG	DESCRIPTION OF INTERACTION
	Salicylate decreases platelet adhesiveness and

Heparin	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 $FeCl_3$ 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.
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% (w/w) Cream 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 Salicylic Acid 6% (w/w) Cream, 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.

Carcinogenesis, Mutagenesis, Impairment of Fertility

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

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 6% Salicylic Acid (w/w) Cream 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 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% (w/w) Cream 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 Salicylic Acid 6% (w/w) Cream will not necessarily increase its therapeutic benefit, but could result in increased local intolerance and systemic adverse effects such as salicylism.

HOW SUPPLIED

Salicylic Acid 6% (w/w) Cream Kit includes a 16 oz. (454 g) jar with Salicylic Acid 6% (w/w) Cream (NDC 42546-270-16) as well as a complimentary 12 fl. oz. PruDrate Hydrating Cleanser.

Store at 20°C to 25°C (68°F to 77°F), excursions permitted between 15°C and 30°C (between 59°F and 86°F). Brief exposure to temperatures up to 40°C (104°F) may be tolerated provided the mean kinetic temperature does not exceed 25°C (77°F); however, such exposure should be minimized.

Do not freeze.

Manufactured for:
PruGen Pharmaceuticals
18899 N Thompson Peak Pkwy
Scottsdale, AZ 85255

Rev 3.0

PRINCIPAL DISPLAY PANEL - Kit Box

NDC 42546-270-01
Rx Only

Salicylic Acid
6% Cream
Kit

Dispense as a complete kit
For Topical Use Only

Kit includes:

- 1 jar of Salicylic Acid 6% Cream
  - Net Wt. 16 oz (454 g)
- 1 bottle PruDrate Hydrating Cleanser
  - 12 fl oz (355 mL)
- Package Insert

PRUGEN®
PHARMACEUTICALS

NDC 42546-270-01

Rx Only

Salicylic Acid 6% Cream Kit

Dispense as a complete kit
For Topical Use Only

Kit includes:

- 1 jar of Salicylic Acid 6% Cream - Net Wt. 16 oz (454 g)
- 1 bottle PruDrate Hydrating Cleanser - 12 fl oz (355 mL)
- Package Insert

PRUGEN PHARMACEUTICALS

Directions for use:
Wash the effected area with the PruDrate Hydrating Cleanser and gently pat dry. Apply Salicylic Acid 6% Cream thoroughly to the affected area and occlude the area at night. In those areas where occlusion is difficult or impossible, application may be made more frequently.

Salicylic Acid 6% Cream Ingredients:
Contains salicylic acid, USP 6% in a cream base composed of ammonium lactate, cetearyl alcohol, cetearyl alcohol (and) PEG-3 distearoylamidoethylmonium methosulfate (and) polysorbate 60, cetyl alcohol, dimethicone 350, disodium EDTA, glycerine, glyceryl stearate SE, methylparaben, mineral oil, PEG-100 stearate, phenoxyethanol, propylparaben, purified water and trolamine.

Precautions:
For topical use only. Avoid contact with eyes and other mucous membranes. Salicylic Acid 6% Cream should not be used in children under 2 years of age.

See package insert for full discussion of indications, directions, contraindications, and warnings.

Store at 20°C to 25°C (68°F to 77°F), excursions permitted between 15°C and 30°C (between 59°F and 86°F).

Do not freeze.

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PruGen Pharmaceuticals
18899 N Thompson Peak Pkwy
Scottsdale, AZ 85255

Rev3.0

NDC 42546-270-01

Rx Only

Salicylic Acid 6% Cream Kit

Dispense as a complete kit

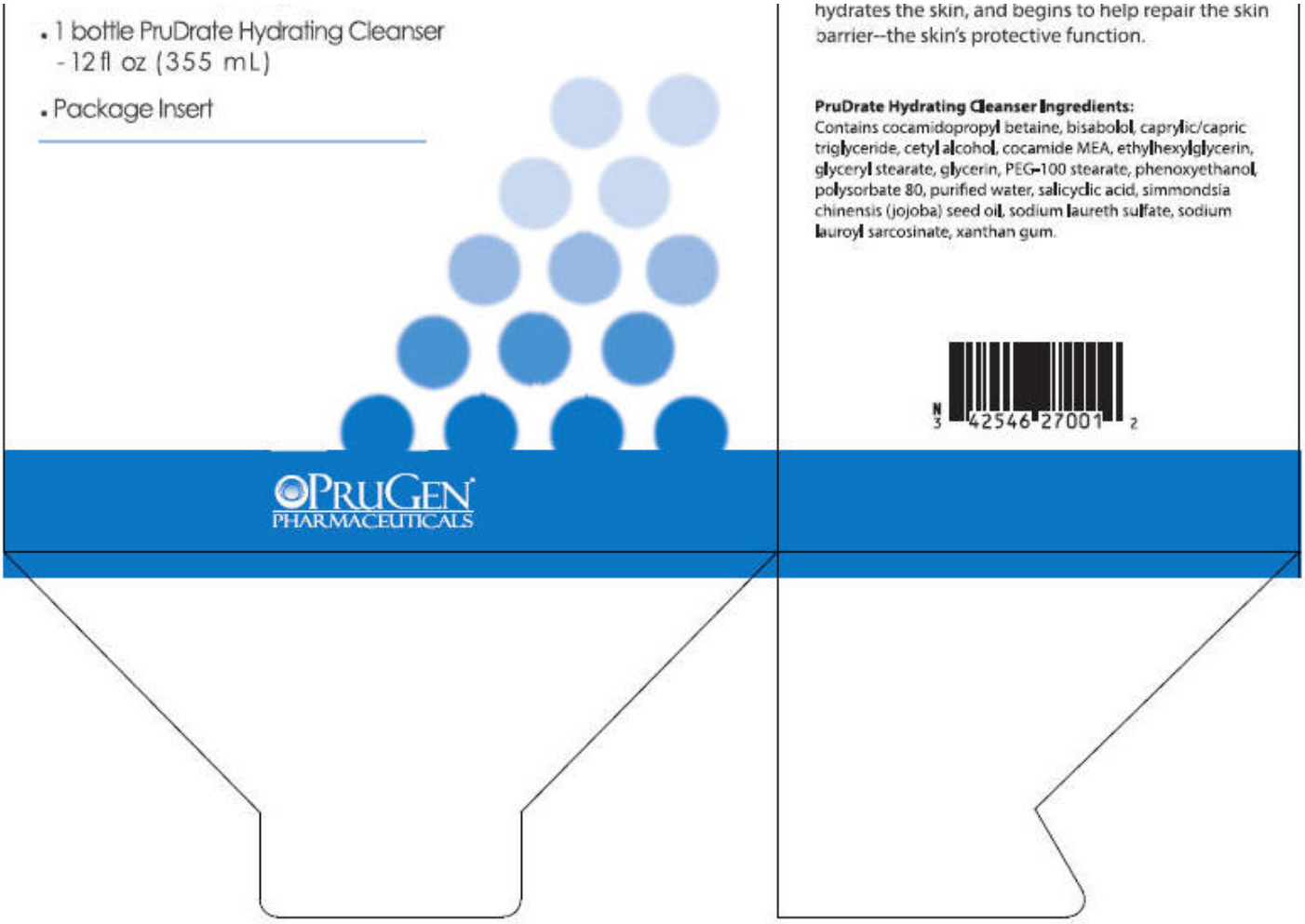
For Topical Use Only

Kit includes:

- 1 jar of Salicylic Acid 6% Cream
  - Net Wt. 16 oz (454 g)

Salicylic Acid 6% Cream is intended for use as 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).

This convenient kit also includes a complimentary 12 oz. bottle of PruDrate Hydrating Cleanser, which when used prior to applying Salicylic Acid 6% Cream, gently prepares the skin for medication,



SALICYLIC ACID

salicylic acid kit

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:42546-270

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42546-270-01	1 in 1 BOX	05/01/2011	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 JAR	454 g
Part 2	1 BOTTLE	355 g

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
AMMONIUM LACTATE (UNII: 67M901L9NQ)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
PEG-3 DISTEAROYLAMIDOETHYLMONIUM METHOSULFATE (UNII: 395MHJ5PUR)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
DIMETHICONE 350 (UNII: 2Y53S6ATLU)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
MINERAL OIL (UNII: T5L8T28FGP)	
PEG-100 STEARATE (UNII: YD01N1999R)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
TROLAMINE (UNII: 9O3K93S3TK)	

Product Characteristics

Color	WHITE	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		454 g in 1 JAR; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		05/01/2011	

Part 2 of 2

PRUDRATE HYDRATING CLEANSER

cleansing (cold creams, cleansing lotions, liquids, and pads) solution

Product Information

Route of Administration	TOPICAL

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	**WATER** (UNII: 059QF0KO0R)	
INGR	**SODIUM LAURETH-3 SULFATE** (UNII: BPV390UAP0)	
INGR	**COCAMIDOPROPYL BETAINE** (UNII: 5OCF3O11KX)	
INGR	**GLYCERIN** (UNII: PDC6A3C0OX)	
INGR	**COCO MONOETHANOLAMIDE** (UNII: C80684146D)	
INGR	**SODIUM LAUROYL SARCOSINATE** (UNII: 632GS99618)	
INGR	**GLYCERYL MONOSTEARATE** (UNII: 230OU9XXE4)	
INGR	**PEG-100 STEARATE** (UNII: YD01N1999R)	
INGR	**CETYL ALCOHOL** (UNII: 936JST6JCN)	
INGR	**JOJOBA OIL** (UNII: 724GKU717M)	
INGR	**POLYSORBATE 80** (UNII: 6OZP39ZG8H)	
INGR	**PHENOXYETHANOL** (UNII: HIE492ZZ3T)	
INGR	**ETHYLHEXYLGLYCERIN** (UNII: 147D247K3P)	
INGR	**LEVOMENOL** (UNII: 24WE03BX2T)	
INGR	**MEDIUM-CHAIN TRIGLYCERIDES** (UNII: C9H2L21V7U)	
INGR	**XANTHAN GUM** (UNII: TTV12P4NEE)	
INGR	**SALICYLIC ACID** (UNII: O414PZ4LPZ)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		355 g in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

COSMETIC		05/01/2011	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		05/01/2011	

Labeler - PruGen, Inc. (929922750)

Establishment

Name	Address	ID/FEI	Business Operations
DERMAZONE SOLUTIONS, INC.		136116865	MANUFACTURE(42546-270)

Revised: 1/2022 PruGen, Inc.