SALICATE- salicylic acid 10% gel
PureTek Coproration

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.

Salicate
Salicylic Acid 10% Serum

Salicate™

Salicylic Acid, 10%

Rx Only

For Topical Dermatological Use Only, not for ophthalmic, oral, or intravaginal use.

Description:

Salicate™ is applied topically and used to remove excessive keratin in hyperkeratotic skin disorders. Each gram of **Salicate™** contains salicylic acid 10% as the active ingredient and the following inactive ingredients: Aqua (Water Purified), Camellia Sinensis (Green Tea) Leaf Extract, Chamomilla Recutita (Matricaria) Flower Extract, Cucumis Sativus (Cucumber) Fruit Extract, Ethylhexylglycerin, Glycerin, Hydroxyethylcellulose, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Phenoxyethanol, Polysorbate 20, Propylene Glycol, Sodium Hydroxide, Symphytum Officinale (Comfrey) Leaf Extract.

Clinical Pharmacology:

Salicylic acid has been shown to produce desquamation of the horny layer of skin while not affecting qualitative or quantitative changes in the structure of the viable epidermis [1,2]. The mechanism of action has been attributed to the dissolution of intercellular cement substances [3]. In a study of the percutaneous absorption of salicylic acid 6% 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 higher serum levels (30 to 40 mg/100 ml). 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 common extracellular space. (See PRECAUTIONS).

The primary 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 competitive mechanisms, other drugs can influence salicylate serum levels. (See PRECAUTIONS).

Contraindications Section:

Salicate™ should not be used in any patient known to be sensitive to salicylic acid or any other listed ingredients.

Indications & Usage:

For dermatologic Use

Salicate™ 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

Salicate™ is a topical aid in removing excessive keratin on dorsal and plantar hyperkeratotic lesions.

Warnings:

Salicate™ is for external use only. It is not for ophthalmic, oral, anal, or intravaginal use. Contact with eyes, lips, broken or inflamed skin, and mucous membranes should be avoided. **Salicate™** should not be used by persons who have a known hypersensitivity to salicylic acid or 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 should be 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, **Salicate™** 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 risk of developing Reye's syndrome, salicylate products should not be administered to children or teenagers with varicella or influenza, unless directed by a physician. When using this product, skin irritation and dryness is more likely to occur if you use another topical acne medication at the same time. If irritation occurs, only use one topical acne medication at a time. Applying the serum more than once per week will increase the risk of skin sensitivity.

Precautions:

Salicate™ 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. **Salicate™** 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 [5] and include reports concerning oral and topical salicylate administration. The relationship of these interactions to the use of SALICYLIC ACID is not known.

A. 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	Decreases tubular reabsorption; clinical toxicity from methotrexate can result
Oral Anticoagulants	Increased bleeding

B. 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

C. 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 probenecid, sulfinpyrazone, and phenylbutazone inhibited

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

Laboratory Tests	Effect of Salicylates
Thyroid Function	Decreased PBI; increased T uptake
Urinary Sugar	False negative with glucose oxidase; false positive with Clinitest with high-dose salicylate therapy (2-5g qd)
5 Hydroxyindole Acetic Acid	False negative with fluorometric test
Acetone, Ketone Bodies	False positive FeCl 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 the dose

Prothrombin	Decreased levels; slightly increased prothrombin time

Pregnancy:

Pregnancy (Category C)

Salicylic acid is 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 four times the Maximum 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. **Salicate™** should be used during pregnancy only if the potential benefit justifies the risk to the fetus.

Nursing Mothers

It is unknown whether topically applied salicylic acid is excreted in human milk. Since many drugs are excreted in human milk, caution should be exercised by physicians when administering **Salicate™** to nursing mothers and nursing mothers should certainly not apply **Salicate™** 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 **Salicate™**, 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 the potential carcinogenic or reproductive effects of **Salicate™**. 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 & Administration:

Clean and dry affected area of skin, then apply **Salicate™** ™ serum over the affected skin once daily, or as directed by healthcare provider. Apply serum using a gauze or cotton pad evenly across treatment area using circular motions. Allow serum to work on the skin for 1 min or less. Use a sunscreen, wear protective clothing, and limit sun exposure while using this product and for a week afterwards. You will experience a stinging or tingling sensation. If excessive stinging or discomfort occurs, neutralize the serum by flushing the skin with cool water. Redness may occur for a short period of time, especially for those with sensitive skin types. If redness persists longer than 20-30 minutes, decrease the contact time of the serum or discontinue use.

Stop Use and Ask a Doctor If

• Excessive facial irritation or redness occurs 48-72 hours after application

• Chest pain, faintness, or dizziness occurs
• You experience pain, swelling, or severe burns
• You experience an allergic reaction
• Your skin becomes infected
• If swallowed, seek medical help or contact a Poison Control Center Immediately
*These statements have not been evaluated by the Food and Drug Administration. This product is not intended to treat, cure, prevent, mitigate or diagnose any disease or effect the structure or function of the human body.

How Supplied:

Salicate™ is a serum supplied in a 1 fl oz Bottle. NDC 59088-214-03

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.

Storage And Handling:

KEEP THIS AND ALL MEDICATIONS OUT OF REACH OF CHILDREN.
Store at 20°-25°C (68°-77°F) [see USP Controlled Room Temperature]. Protect from freezing.

Manufactured in the USA by:
PureTek Corporation
Panorama City, CA 91402
For questions or information
call toll-free: 877-921-787

Salicate™

NDC 59088-214-03 **Rx Only**

Salicate™

Salicylic Acid 10% Serum

1 fl oz / 30 mL

ACTIVE INGREDIENT: Salicylic Acid 10%

INACTIVE INGREDIENTS: Aqua (Water Purified), Camellia Sinensis (Green Tea) Leaf Extract, Chamomilla Recutita (Matricaria) Flower Extract, Cucumis Sativus (Cucumber) Fruit Extract, Ethylhexylglycerin, Glycerin, Hydroxyethylcellulose, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Phenoxyethanol, Polysorbate 20, Propylene Glycol, Sodium Hydroxide, Symphytum Officinale (Comfrey) Leaf Extract.

INDICATIONS:

For dermatologic Use - Salicate 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 - Salicate is a topical aid in removing excessive keratin on dorsal and plantar hyperkeratotic lesions.

DIRECTIONS:

- Clean and dry affected area of skin
- Apply serum using a gauze or cotton pad evenly across treatment area using circular motions.
- Allow serum to work on the skin for 1 min or less.
- Contact time and/or number of layers on subsequent treatments may be increased with tolerance.
- Begin to stop activity and remove serum by flushing with cool water.

KEEP THIS AND ALL MEDICATIONS OUT OF REACH OF CHILDREN.

Store at 20°-25°C (68°-77°F) [see USP Controlled Room Temperature]. Protect from freezing.

WARNING: For external use only. Not for ophthalmic use. do not get into eyes. If swallowed, get medical help or contact a Poison Control Center right away.

ADDITIONAL PRODUCT INFORMATION ENCLOSED.

Manufactured in the USA by:
PureTek Corporation
Panorama City, CA 91402
For questions or information
call toll-free: **877-921-7873**

Please Recycle

List No. 21403IAA Rev.38656

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SALICATE

salicylic acid 10% gel

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:59088-214
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)	SALICYLIC ACID	10 mg in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
CUCUMBER (UNII: YY7C30VXJT)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROXYETHYL CELLULOSE, UNSPECIFIED (UNII: T4V6TWG28D)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
CHAMOMILE (UNII: FGL3685T2X)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
MELALEUCA ALTERNIFOLIA (TEA TREE) LEAF OIL (UNII: VIF565UC2G)	
WATER (UNII: 059QF0KO0R)	
COMFREY LEAF (UNII: DG4F8T839X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59088-214-03	30 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	10/13/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		10/13/2023	

Labeler - PureTek Coproration (785961046)

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