KERALYT- salicylic acid shampoo
Summers Laboratories 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.

SUMMERS LABS (as PLD) - Keralyt Shampoo (11086-043)

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

Salicylic acid is the 2 hydroxy derivative of benzoic acid

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 a dissolution of intercellular cement substance. [3]In a study of the percutaneous absorption of salicylic acid 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/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 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 competitive mechanisms other drugs can influence the serum levels of salicylate. [5](See PRECAUTIONS).

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

CONTRAINDICATIONS:KERALYT SHAMPOO should not be used in any patient known to be sensitive to salicylic acid or any other listed ingredient. KERALYT SHAMPOO 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. 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 KERALYT SHAMPOO 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.

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. **Keep this and all medications out of 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 KERALYT SHAMPOO 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	Decreases tubular reabsorption; clinical toxicity from methotrexate can result
Oral Anticoagulant	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 adhesiveness 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_3uptake
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	

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 acetyl salicylic 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 bottle, 8 oz. of KERALYT SHAMPOO) when applied topically over a large body surface. There are no adequate and well-controlled studies in pregnant women. KERALYT SHAMPOO should be used during pregnancy only if the potential benefit justifies the risk to the fetus.

Nursing Mothers: Because of the potential for serious adverse reactions in nursing infants from the mother's use of KERALYT 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 in the chest area in order to avoid accidental exposure to a nursing child.

Carcinogenesis, Mutagenesis, Impairment of Fertility: No data are available concerning potential carcinogenic or reproductive effects of KERALYT SHAMPOO. It 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
For use as a concentrated scalp treatment BEFORE bathing: Do not wet hair. Twist open applicator tip and apply KERALYT SHAMPOO w/applicator evenly, directly to affected areas of the scalp. Leave on for 5 minutes, gradually increasing treatment time up to one hour, or as directed by physician. Wash hands after applying KERALYT SHAMPOO w/applicator. After treatment, rinse thoroughly with water. Although no additional shampoo is needed to cleanse hair, a non-medicated shampoo may be used if desired. **For use as a medicated shampoo:**Wet hair and apply KERALYT SHAMPOO w/applicator to the scalp. Work into a lather, leave on for several minutes, then rinse. Use daily until the condition clears. After clearing is apparent, use KERALYT SHAMPOO w/applicator occasionally to maintain clearing or as directed by your physician.

HOW SUPPLIED:160 mL plastic bottles NDC 11086-043-06
Store at controlled room temperature 59° to 86° F (15° to 30° C)

REFERENCES:
1. Davies M, Marks R: *Br J Dermatol*95: 187-192,1976.
2. Marks 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.

SUMMERS
LABORATORIES INC
Manufactured by:
EMS Contract Packaging, Hatfield, PA 19440
Distributed by:
Summers Laboratories, Inc. Collegeville, PA 19426

1-800-533-SKIN (7546) • www.sumlab.com

Keralyt® Shampoo
(salicylic acid) 6% w/ applicator

NDC 11086-043-06

Rx only

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

160 mL

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LEBG222K

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Keralyt® Shampoo
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Rx only
160 mL

Distributed by:
Summers Laboratories, Inc.
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SUMMERS LABORATORIES INC

L-0043-06B-02

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(6% salicylic acid) w/applicator

Rx only
160 mL

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

INGREDIENTS: 6% w/w salicylic acid USP in a vehicle composed of purified water, disodium laureth sulfosuccinate, cocamidopropyl betaine, hexylene glycol, linoleamidopropyl PG-dimonium chloride phosphate, polyquaternium-22, propylene glycol, sodium C14-16 olefin sulfonate, sodium citrate, sodium lauryl sarcosinate, tetrasodium EDTA, tocopherol acetate and fragrance.

INDICATION: For the removal of excess keratin in hyperkeratotic disorders, including scaling associated with scalp psoriasis.

DIRECTIONS: ***For use as a concentrated scalp treatment BEFORE bathing:*** Do not wet hair. Twist open applicator tip and apply KERALYT SHAMPOO with applicator evenly, directly to affected areas of the scalp. Leave on for 5 minutes, gradually increasing treatment time up to one hour, or as directed by physician. Wash hands after applying KERALYT SHAMPOO. After treatment, rinse thoroughly with water. Although no additional shampoo is needed to cleanse hair, a non-medicated shampoo may be used if desired.

For use as a medicated shampoo: Wet hair and apply KERALYT SHAMPOO to the scalp. Work into a lather, leave on for several minutes, then rinse. Use daily until the condition clears. After clearing is apparent, use KERALYT SHAMPOO occasionally to maintain clearing or as directed by your physician. See prescribing information for additional details.

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.

Keep this and all medications out of reach of children.

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Keralyt® Shampoo
(salicylic acid) 6% w/ applicator

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160 mL

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KERALYT

salicylic acid shampoo

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:11086-043
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 92.6 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11086-043-06	160 mL in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product	11/01/2009	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		11/01/2009	

Labeler - Summers Laboratories Inc (002382612)

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