

KERALYT- salicylic acid
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 KIT (11086-047)

Keralyt[®] Gel

(salicylic acid) 6%

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

DESCRIPTION:KERALYT[®] is a gel for topical administration containing salicylic acid 6%, in a vehicle composed of propylene glycol, SD-40 alcohol (21%), hydroxypropylcellulose and purified water. Salicylic acid is the 2 hydroxy derivative of benzoic acid having the following 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. ^{1,2}The mechanism of action has been attributed to a dissolution of intercellular cement substance. ³In a study of the percutaneous absorption of salicylic acid from KERALYT GEL in four patients with extensive active psoriasis, Taylor and Halprin ⁴showed 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%). ⁴The 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. ⁵Fifty 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 GEL should not be used in any patient known to be sensitive to salicylic acid or any other listed ingredient. KERALYT 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 GEL 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. **Flammable. Keep away from heat and open flame. Keep this and all medications out of reach of children.**

Drug Interactions.(The following interactions are from a published review ⁵and include reports concerning both oral and topical salicylate administration. The relationship of these interactions to the use of KERALYT GEL 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, sulfapyrazone and phenylbutazone inhibited

The following alterations of laboratory tests have been reported during salicylate therapy⁶:

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 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 tube, 40 g of KERALYT GEL) when applied topically over a large body surface. There are no adequate and well-controlled studies in pregnant women. KERALYT GEL 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 GEL, 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 KERALYT GEL. 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- The preferable method of use is to apply KERALYT GEL thoroughly to the affected area and occlude the area at night. 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 KERALYT GEL 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. Unless hands are being treated, hands should be rinsed thoroughly after application. **For use as a scalp treatment:**KERALYT GEL should be applied directly to the affected areas of the scalp on a frequency directed by your physician. The applicator tip will provide accurate application, avoiding contact with normal hair or skin. The gel should be washed off after 10 to 20 minutes initially, but it can be left on for up to an hour as treatment progresses. The gel can be washed off using KERALYT SHAMPOO or warm water in a bath or shower.

HOW SUPPLIED:60 g Plastic bottle NDC 11086-030-60
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

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The image shows three boxes of Keralyt Complete Kit. Each box contains a 160 mL bottle of Keralyt Shampoo (6% salicylic acid) and a 60 g bottle of Keralyt Gel (6% salicylic acid). The boxes are labeled 'COMPLETE KIT' and 'DO NOT BREAK UP'. The central box provides detailed instructions and ingredients for both products. The shampoo is for topical use only, not for ophthalmic, oral, or intravaginal use. The gel is also for topical use only, not for ophthalmic, oral, or intravaginal use. Both products are used to treat hyperkeratotic disorders, including scaling associated with scalp psoriasis or thickened skin of palms and soles. The shampoo is used as a medicated shampoo, and the gel is used as a medicated gel. The instructions include warnings, directions, and storage information.

KERALYT				
salicylic acid kit				
Product Information				
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:11086-047	
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11086-047-01	1 in 1 BOX; Type 1: Convenience Kit of Co-Package	11/01/2009	

Quantity of Parts		
Part #	Package Quantity	Total Product Quantity
Part 1	0 BOTTLE, WTH APPLICATOR	1 mL
Part 2	0 BOTTLE, WTH APPLICATOR	1 g

Part 1 of 2

KERALYT

salicylic acid shampoo

Product Information

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, WTH APPLICATOR; Type 1: Convenience Kit of Co-Package		

Marketing Information

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

Part 2 of 2

KERALYT

salicylic acid gel

Product Information

Item Code (Source)	NDC:11086-030
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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11086-030-60	60 g in 1 BOTTLE, WTH APPLICATOR; Type 1: Convenience Kit of Co-Package		

Marketing Information

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

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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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