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Salicylic Acid

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Drug Nomenclature

Generic Name: Salicylic Acid

CAS Number: 69-72-7

Synonyms: Acnopur; Adasept; Aknoderm; Almay; Artistry; Aveda; Beauticontrol; Biocure; Bior+; Biore; Canthacur-PS; Cantharone; Carnation; Cerate; Clearasil; Clinique; Cuticura; Denorex; Dermarest; Diprosalic; Duofilm; Duoforte; Duoplant; Effaclar; Freezone; Herbal; Kerasal; Kertyol-S; Mazon; Melaleuca; Neostrata; Nerisalic; Neutrogena; Neutrogena; Noxzema; Occlusal; Occlusal-HP; Off-ezy; Oxipor; Oxy; Panoxyl; Pernox; Phisoderm; Polytar; Psoriasis; Salicylicum; Scalpicin; Sebcur; Sebcur-T; Sebulex; Sebutone; Sensitive; Soluver; Sterex; Tardan; Target; Trans-plantar; Trans-ver-sal; Viron; Virtual; Witfield; X-seb; X-tar; Zap-it!

Introduction

Salicylic acid is a keratolytic agent.

Uses

Salicylic acid is used topically for its keratolytic effect in controlling seborrheic dermatitis of the body and scalp, psoriasis of the body and scalp, dandruff, and other scaling dermatoses. The drug also is used topically for its keratolytic and caustic effect in the removal of common and plantar warts, corns, and calluses. Salicylic acid also has been used in the treatment of localized hyperkeratosis, such as occurs on the palms and soles.

Salicylic acid is used topically alone or in combination with other drugs (e.g., resorcinol, sulfur) for the symptomatic treatment of acne. The exact mechanism(s) of action of salicylic acid in the treatment of acne is not known but may involve the drug's local keratolytic and anti-inflammatory actions; the drug also may promote the penetration of other active ingredients and may have a comedolytic effect. In one 12-week study, 2% salicylic acid was more effective than 5% benzoyl peroxide in reducing the total number of lesions, inflammatory lesions, and open comedones; salicylic acid was particularly effective in reducing inflammatory lesions (i.e., papules and pustules) but was no more effective than benzoyl peroxide or vehicle placebo on closed comedones.

Salicylic acid is not used systemically because of its severe irritating effect on GI mucosa and other tissues; therefore, better tolerated chemical derivatives have been prepared for systemic use. (See the Salicylates General Statement 28:08.04.24.)

Pharmacology

Salicylic acid has a potent keratolytic action and a slight antiseptic action when applied topically to the skin. In low concentrations, the drug has keratoplastic activity (correction of abnormal keratinization) and in higher concentrations

(i.e., 1% or higher, depending on the vehicle), the drug has keratolytic activity (causes peeling of skin). Salicylic acid softens and destroys the stratum corneum by increasing endogenous hydration (water concentration), probably because of decreased pH, which causes the cornified epithelium (horny layer) of the skin to swell, soften, and then desquamate. Necrosis of normal skin has been associated with overuse of the drug. At high concentrations (e.g., 20%), salicylic acid has a caustic effect. Moisture is essential for salicylic acid to exert its action on the skin and for maceration and desquamation of epidermal tissue to occur. The drug has weak antifungal and antibacterial activity. When combined, salicylic acid and sulfur may produce a synergistic keratolytic effect.

Chemistry and Stability

Chemistry

Salicylic acid is a keratolytic agent. Salicylic acid occurs as white crystals, usually in fine needles, or as a fluffy, white, crystalline powder. The drug has a sweetish taste and an acrid aftertaste and is slightly soluble in water and freely soluble in alcohol. Salicylic acid has pK_a s of 2.97 and 13.4. The drug is found principally in wintergreen leaves and in the bark of sweet birch, but can be prepared synthetically.

Salicylic acid collodion contains 9.5–11.5% salicylic acid in flexible collodion. Salicylic acid plaster is a uniform mixture of the drug in a suitable base, spread on paper, cotton cloth, or other suitable backing material (e.g., felt, moleskin, velvet). The Trans-Ver-Sal[®] plaster contains the drug in a controlled-release system consisting of karaya (sterculia) gum, polyethylene glycol 300, propylene glycol, and quaternium-15. In vitro, the system reportedly has released about 16, 48, 65, 79, 89, and 100% of the salicylic acid dose by 0.5, 1, 2, 4, 8, and 24 hours, respectively.

Stability

Salicylic acid should be stored in well-closed containers. Salicylic acid collodion should be stored in tight containers at 15–30°C; because the collodion is flammable, it should not be stored near heat or an open flame. Salicylic acid plaster or gel should be stored in well-closed or tight containers, respectively, preferably at 15–30°C. The Trans-Ver-Sal[®] plaster should be stored at a temperature less than 37.8°C.

Preparations

Salicylic Acid

Routes	Dosage Forms	Strengths	Brand Names	Manufacturer
Bulk	Powder*			
Topical	Cake	2%	Fostex [®] Medicated Cleansing Bar	Bristol-Myers
			Salicylic Acid Cleansing Bar	Stiefel
	Cream	2%	Fostex [®] Medicated Cleansing Cream	Bristol-Myers
			Deep Cleansing [®] Shower Gel	GlaxoSmithKline
	Gel	2%	Neutrogena [®] Clear Pore Treatment	Neutrogena
Propa pH [®] Peel-Off Acne Mask			Del	

		Stri-Dex® Clear Gel Maximum Strength (with SD alcohol 9.3%)	Blistex
	5%	Hydrisalic® (with SD alcohol 40B and propylene glycol)	Pedinol
		Clear Away® Gel (with alcohol 57.6% w/w, ether 16.4% w/w in flexible collodion)	Schering-Plough
	17%	Compound W® Gel (with alcohol 57.6% and ether 16.42% in flexible collodion)	MedTech
		DuoPlant® Gel (with alcohol 67.5% in flexible collodion)	Schering-Plough
Lotion	2%	SalAc® Acne Medication-Cleanser (with benzyl alcohol)	Bioglan
		Sebasorb® (with attapulgate activated 10%)	Summers
Ointment	3%	MG 217® Sal-Acid	Triton
Plaster	15%	Trans-Ver-Sal® (with propylene glycol)	Doak
	40%	Clear Away®	Schering-Plough
		Clear Away® Plantar System	Schering-Plough
		Compound W® One Step Pads	MedTech
		Freezone® Pads	MedTech
		Mediplast®	Beiersdorf
		Sal-Acid®	Pedinol
Pledgets (saturated with solution)	0.5%	Oxy Balance® Daily Cleansing Pads (with SD alcohol 40B 40% and propylene glycol)	GlaxoSmithKline
		Stri-Dex® Regular Strength Pads (with SD alcohol 28%)	Blistex
		Stri-Dex® Sensitive Skin Pads (with SD alcohol 28% and aloe)	Blistex
	2%	Noxzema® 2-in-1 Pads Extra Strength	Procter & Gamble
		Oxy Balance® Maximum Daily Cleansing Pads (with SD alcohol 40B 50% and propylene glycol)	GlaxoSmithKline

		StayClear® Deep Cleaning Pads	Boots
		Stri-Dex® Pads Maximum Strength (with SD alcohol 40 44%)	Blistex
		Stri-Dex® Super Scrub Pads (with SD alcohol 54%)	Blistex
Shampoo	2%	Ionil® Plus (with SD alcohol 40 12%)	Healthpoint
		P&S®	Teva
	3%	DHS® Sal Shampoo	Person & Covey
		Neutrogena® T/Sal Maximum Strength	Neutrogena
Solution	0.5%	Propa pH® Cleanser (with SD alcohol 40 25% and aloe)	Del
		Propa pH® Normal/Sensitive Astringent Cleanser	Del
	1.8%	Sebucare® Lotion (with alcohol 61%)	Bristol-Myers Squibb
	2%	Multi-Action® Astringent (with alcohol 38.8%)	GlaxoSmithKline
		Noxzema® 2-in-1 Astringent	Procter & Gamble
		Propa pH® Foaming Face Wash	Del
		Propa pH® Maximum Strength Astringent Cleanser	Del
		StayClear® Zone-Controlled ClearStick®	Boots
	16.7%	Gordofilm® (in flexible collodian)	Gordon
	17%	Clear Away® Liquid (with 17% SD alcohol 32, ether 52% in flexible collodion)	Schering-Plough
		Compound W® Solution (with alcohol 21.2% and ether 63.5% in flexible collodion)	MedTech
		DuoFilm® (with alcohol SD 32 17% and ether 52% in flexible collodion)	Schering-Plough
		Occlusal®-HP (with isopropyl alcohol 63% in a polyacrylic vehicle)	Bioglan
		Off-Ezy® Wart Remover (with alcohol 21% and ether 65% in flexible collodion)	Del

	Salactic® Film (with isopropyl alcohol 2.7% in a flexible collodion)	Pedinol
	Sal-Plant® Gel (with isopropyl alcohol 2.5% in flexible collodion)	Pedinol
	Wart-Off® (with alcohol 26.35% in flexible collodion)	Pfizer
17.6%	Freezone® (with alcohol 20.5% and ether 65.5% in flexible collodion)	MedTech

* Available generically.

Salicylic Acid Combinations

Routes	Dosage Forms	Strengths	Brand Names	Manufacturer
Topical	Cake	3% with Precipitated Sulfur 5%	Salicylic Acid and Sulfur Soap	Stiefel
	Cleansing Suspension	1.5% and Sublimed Sulfur 2%	Pernox® Scrub Cleanser (lemon and regular)	Bristol-Myers Squibb
	Lotion	1% with Sodium Thiosulfate 25%	Versiclear®	Hope
	Shampoo	2% with Coal Tar 0.5% and Sublimed Sulfur 2%	Sebutone® (cream or lotion)	Bristol-Myers Squibb
		2% with Coal Tar Solution 5% (equivalent to 2.5% coal tar)	Ionil T® (with SD alcohol 40 12% and isopropyl alcohol 4%)	Healthpoint
		2% with Coal Tar Solution 10% (equivalent to 2% coal tar)	Tarsum®	Summers
		2% with Sublimed Sulfur 2%	Sebulex®	Bristol-Myers Squibb
			Sebulex® with Conditioners (with propylene glycol)	Bristol-Myers Squibb
		3% with Colloidal Sulfur 5%	Meted® Improved	Sirius
			MG 217® Medicated Tar-Free Shampoo	Triton

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