CosmeticDermatology



In recent years, manufacturers of laser and light-based technologies

have developed equipment that physicians can adjust to safely and effectively treat darker-skinned patients, an expert says. He predicts such developments will continue.

lex™ (6% Salicylic Acid) Cream Salex™ (6% Salicylic Acid) Lotion

Rx Only
FOR DERMATOLOGICAL USE ONLY, NOT FOR OPHTHALMIC, ORAL OR INTRAVAGINAL USE
DESCRIPTION
Acidiying increases plasma

Siles** Lotton contains 61s will salicytic acid USP incorporated into a patiented Motivesicular Emission (MVE) which consisting of ammoniar lactate, behanfrincoluum methosufalle and cetanyl alcohol, cetyl alcohol dimethicons 300, dispolium ETVD, opporer, opicyry sleatax 85, methyl-paraben, mineral oil, PEG-100 stearate, progriparaben, purified water an

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

This MVE formulation has been shown to provide gradual and prolonged misses of the active ingredient into the skin?

CLINICAL PHARMACOLOGY

Salicylic acid has been shown to produce desquamation of the borry layer of skin while not effecting qualitative or quantitative changes in the structure of the viable epidermis. The machanism of action has been structure of the visible equiternis. The mechanism of action has been attributed to a dissolution of interedistan cement substance. In a study of the percellations absorption of satisfyie and in a first particular or the percellations are substanced in the percellations are substanced in the percellation of the solution and Halpini shower that the peets serum satisfyidate levels never exceeded 5 mg/100 mill even though more than 60% of the applied satisfyits add was absorbed. Systemic busic readitions are usually associated with much higher serum levels (30 to 40 mg/100 mill). Peak serum levels occurred within five hour of the topical application index excellation. The shale serve occusived methods to the entire body surface below the each. Since solvipulars are distributed in the extraordistic space, potents with a contracted consolitation again due to despitable of characters have higher satisfyiate levels than those with a normal satisfacelosise space. (See PRECALTIONS.)

The major metabolites identified in the unite after topical administration are saleyturic acid (52%), saleytete glacuternites (42%) and free saleytic acid (65%). The sensity metabolites after percutaneous absorption differ from those after self-saleytic administration; these derived from percutaneous absorption contain more saleytist glacuternites and less saleytics and saleytic and saleytic and. Almost 95% of a single dose of saleytiste is sucreted within 24 hours of its entracellar in the extracellar space.

It this constraint. Safety the is protein bound to albumin. Safety compets with the binding of oweral drugs and can modify the action of these drugs; by similar competitive mechanisms other drugs can influence the serum levels of safetylate. (See PRECAUTIONS.)

INDICATIONS AND USAGE

For Deminatologic Use: Sales^{ter} is a topical sid in the removal of excessive tensith in hyperventation sin disorders, including venucae, and the various inhibytosis (volgaris, see-linked and lamelar), keratosis palmaris and plantars, keratosis plants, phyriasis notra pilaris, and poortiasis (including body, scale, palms and soles).

The profuses the Conference of the conference of

For Podiabric Use: Sales^{on} is a topical aid in the removal of excessive kind on dorsal and plantar hyperkeranoic lestors. Topical preparations of 6% salicytic and have been reported to be useful adjunctive theirapy for vernicus glaintares.

Salekth should not be used in any patient known to be serisitive to salitylic acid or any other listed ingredients. Salekth should not be used in children under 2 years of age.

WARNINGS

Protonged and repeated daily use over large areas, especially in children and those patients with significant resul or hepatic inspairment, could result in salicytism. Patients should be advised not to apply occusive dessings, cohing or other controller logical products such as periodistrantices of internets to prevent excessive systemic exposure to salicytic acid. Essessive application of the predact other than is needed to cover the affected area will not result in a more capit therapeutic benefit. Concomitant use of other drugs which may contribute to elevated serium salicytate levels should be another large which may contribute to elevated serium salicytate levels should be provided where the potential for tracicity is present. In children under 12 years of age and those patients with result or hepatic impairment, the area to be treated should be inimited and the patient monitored closely for signs of salicytate toxicity, nausea, ventiled activations, loss of hearing, thoritis, lethargy, hepseprea, durintea, and psychic disturbances. In the event of salicytic acid toxicity, the use of Salicytic behavior of the patient with solution bicarbonate (one) or intravenous) should be instituted as appropriate. Patients should be cardinored against the use of arial salprim and other salicytate certaining medications, such as sport injury creams, to avoid additional excessive exposure to salicyte acid. Where needed, aspirin should be replaced by an alternative non-steroidal anti-manimum yargent that is not salicytate based.

[Due to petential risk of developing Roys's syndrome; salicytate groducts

Due to potential risk of developing Reye's syndrome, salicylate products should not be used in children and menagers with varicella or influence, unless directed by a physician

PRECAUTIONS

For external use only, Avoid contact with eyes and other mu

DRUG INTERACTIONS

following interactions are from a published review and include its concerning both end and topical salinytate administration. The ionship of these interactions to the use of Salex^{ia} is not known.

Due to the competition of salicylate with other drugs for binding to serum albumin the following drug interactions may occur:

DRUG DESCRIPTION OF INTERACTION

Hypoglycemia potentiated.

Increased bleeding.

III. Drugs changing salicylate levels by altering renal tubular reabsorption

DESCRIPTION OF INTERACTION

Corticosteroids Decreases plasma salicylate level; tapering doses of steroids may promote salindiem.

Decreased plasma salicytate levels. III. Drugs with o unlicated interactions with extended

DESCRIPTION OF INTERACTION DAUG Salicylate decreases platelet adher interferes with hemostasis in hepo

Inhibits pyrazinamide induced

Effect of probenemide, sulfinpyrazone and phenylbutazone inhibited.

The following alti salicylate therapy rations of laboratory tests have been reported during

LABORATORY EFFECT OF SALICYLATES TESTS

False negative with glucose oxidase, false positive with Climitest with high-dose salicylate therapy (2-5g q.d.).

ole False negative with fluorometric test.

False positive FeCl₃ in Gerhardt reaction rad color persists with boiling. 17-OH False reduced values with >4.8g q.d. salicylate

Unic acid

May increase or decrease depending on dose. Decreased levels; slightly increased prothrombin time.

proteomore time.

Pregnancy (Category C): Satoylic acid his been shown to be teratogenic in rats and monkeys. It is difficult to extrapolate from enal doses of sociytisalicytic acid used in these studies to topical administration as the oral dose to marrively may represent six times the maximal dely human dose of saticytic acid when applied topically over a large body surface. There are to adequate and well-coatrible shodies in pregnant worsen. Sales" should be used change pregnancy only if the potential benefit justifies, the potential risk to the lefus.

pustiess the potentiar risk to the lettus. Nursing Mothers: Because of the potential for serious advisese maction in nursing letterts from the mother's use of Salock*, a decision should be made whether to disconstitue marsing or to disconstrue the drug, salving into account the importance of the drug to the entitler. It used by aurany mothers, it should not be used on the chest area to avoid the accidental contamination or the child.

Certinogenesis, Mutagenesis, Impairment of Fertility: No data are walkbite concerning potential carcinogenic or reproductive effects of Salex^{ast}, Salicylic acid has been shown to lack mutagenic potential in the Arnes Salincrella last.

ADVERSE REACTIONS

Excessive crythems and scaling conceinably could result from use on

OVERDOSAGE

DOSAGE AND ADMINISTRATION

The preferable method of use is to apply Salex^{ex} thoroughly to the affactor area and for cover the treated area at right after washing and before retiring. Preferably, the skin should be hydrated for at least five minutes price to application. The medication is seathed off in the morning and if excessive drying and/or inhabition is observed a basic cream or fellow may be applied. Once clearing is appearent, the occasional use of Salex^{ext} will usually maintain the remission. In those areas where occlusion is difficult or impossible, application upon the made more frequently, hydration by mate packs or battle prior to applications appearedly enhances the effect (See WARNINGS.) Unless hands are bring treated, hands should be need throughly after application. Excessive repealed application of Salex^{ext} will not necessarily increase its therapeatic benefit, but could result in increased local intolerance and systemic adverse effects such as salicytism.

Salex^M Cream is available in 400g (NDC 13548-010-13) bottles.

Saler^{ce} Lotion is available in 14 ff oz (414 ml) (MDC 13548-011-14) bottles.

Store at controlled room temperature 20" - 25"C (68" - 77"F). Do not freezy

(1) Data on flie



Marketed by CORIA LABORATORIES, LTD. Fort Worth, TX 76107 PATENT NO. 6,709,663

REORDER NO. Salex™ Cream: 13548-010-13 (400g bottle)

Salex** Lotion; 13548-011-14 14 fl oz (414 ml bottle)

Salex is a trademark of Healthpoint, Ltd.

Laser treatment of ethnic skin: Seeing the light

Requires adjustment for differences in physiology

BY JOHN JESTUS

SENIOR STAFF CORRESPONDENT

Las Vegas - Safe, effective laser treatments for ethnic patients require lower energy settings, longer pulses and longer wavelengths than one would typically use for Caucasian patients, as well as greater attention to cooling techniques, an expert says.

"At one point a few years ago, laser manufacturers virtually ignored dark-skinned people and believed



these technologies could not be used to treat them," Khalil Khatri, M.D., says.

However, Dr. Khatri, who is medical director of Skin and Laser Surgery Center of New England,

with offices in Chelmsford, Mass., and Nashua, N.H., says the current generation of laser technology is built in a way that allows physicians to change settings so that they can treat darkerskinned patients.

"Not only (in) the United States, but also worldwide there's a huge population whose skin is much darker than Caucasian skin," Dr. Khatri tells Dermatology Times.

And manufacturers' increasing attention to darker-skinned patients has boosted the popularity of laser and light treatments worldwide, he adds.

Idiosyncra:sies of darker skin

Compared to lighter skin, the epidermis of darker-skinned patients possesses increased melanin (but the same number of melanocytes) and larger, more melanized melanosomes, which degrade more slowly than those of fairskinned patients, Dr. Khatri says.

Because of these factors, he says, "Darker skin absorbs and scatters more UW light, which gives darkskinned patients better photoprotection. This results in less photodamage, skin cancers and wrinkles" than Caucasian patients typically experience.

However, Dr. Khatri adds, "The dermis itself is also thicker in darker skin, and the mesenchymal activity within the dermis is higher, which leads to greater risk of developing hypertrophic and keloidal scars."

Accordingly, he says that if one treats dark-skinned patients with the same settings as one would use for Caucasian patients, the increased amount of melanin within the epidermis of the darker-skinned patients means their skin would absorb more energy and suffer more complications - namely, hyperpigmentation, hypopigmentation or depigmentation — as a result.

To avoid these problems, common cooling techniques include use of gel packs, ice packs and cryogenic sprays, all of which physicians typically

A patient with skin type V before (left) and after Er:YAG laser ablation of dermatosis papulosa nigra.



employ before and, if desired, after treatment, Dr. Khatri notes.

"Contact cooling is probably the best way, because it allows one to cool the area being treated before treatment, during treatment and right after treatment," he says.

Contact cooling mechanisms include water-based systems and sapphire crystals.

With such mechanisms, Dr. Khatri says, "One can parallel cool as well while one is delivering the pulse because the pulse is going through the sapphire crystal, which is already making the epidermis cold."

One also can lower energy levels to make treatments safer for darkerskinned patients, although this practice decreases efficacy, he says.

In contrast, he says, "Cooling helps in two ways - it reduces the risk of complications and allows us to use higher energy settings, which can provide better efficacy."

Furthermore, Dr. Khatri says that with most laser devices, "We use a longer pulse when treating darkerskinned patients."

He likens this practice to pouring a pail of water slowly - which allows heat energy to dissipate during treatment as opposed to dumping it all at once.

Regarding wavelengths, he says that for applications such as hair removal, 1,064 nm Nd:YAG lasers and intense pulsed light (IPL) devices (near the higher end of their 500 nm to 1,200 nm range) probably are safest for darkskinned patients.

"With the 1,064 nm laser," Dr. Khatri explains, "the absorption of melanin is very low. That's one of the reasons it's better for darker skin."

As for pulse durations, he says that for hair removal in dark-skinned patients, "One would probably want to use a setting of 40 ms or higher," compared to 10 ms to 20 ms or perhaps lower in Caucasian patients.

Moves to meet the need

By the same token, he says one can use bleaching creams to lower dark skin's melanin content before treatment.

But if one does this, Dr. Khatri recommends making sure that patients use sunblock before and after laser or light treatments.

Along with hair removal, he says that state-of-the-art laser and pulsedlight technologies also can be used for photorejuvenation, skin resurfacing, vascular treatments and tattoo removal in darker skin. DT

Disclosure: Dr. Khatri reports no financial interests relevant to this article.

For more information: www.skinlaseronline.com



A patient with skin type IV before and after hair removal with an IPL device.

GALDERMA

Treating symptoms of moderate to severe scalp psoriasis is made easy1

ITCHY, FLAKY SCALP? JUST ADD WATER.



- Relieves pruritus, scaling, plaque thickening and erythema²
- In a clinical study, approximately 50% remained symptom free 2 weeks post-treatment²
- 86% of patients found it easy to use3*
- Over 90% of patients had a better experience with Clobex® Shampoo than with any other product3*

Clobetasol propionate has been shown to suppress the HPA axis at the

In controlled clinical trials, the following adverse reactions have been reported: burning/stinging, pruritus, edema, folliculitis, acne, dry skin, irritant dermatitis, alopecia, urticaria, skin atrophy and telangiectasia

Clobex® Shampoo is not recommended for use on anyone younger than

Please see next page for brief summary of Important Safety Information. *As reported in a national survey of 273 patients with moderate to severe scalp psoriasis. www.clobex.com



RINSE AND RELIEF