

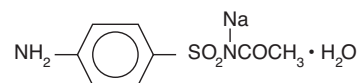
ROSAC[®] Cream

WITH  SUNSCREENS
(sodium sulfacetamide 10% and sulfur 5%)

Rx only

DESCRIPTION: Each gram of Rosac[®] Cream With Sunscreens contains 100 mg of sodium sulfacetamide and 50 mg of sulfur in a cream containing avobenzone, benzyl alcohol, C12-15 alkyl benzoate, cetostearyl alcohol, dimethicone, edetate disodium, emulsifying wax, monobasic sodium phosphate, octinoxate, propylene glycol, purified water, sodium thiosulfate, steareth-2, steareth-21.

Sodium sulfacetamide is a sulfonamide with antibacterial activity while sulfur acts as a keratolytic agent. Chemically, sodium sulfacetamide is N-[(4-aminophenyl) sulfonyl]-acetamide, monosodium salt, monohydrate. The structural formula is:



CLINICAL PHARMACOLOGY: The most widely accepted mechanism of action of sulfonamides is the Woods-Fildes theory which is based on the fact that sulfonamides act as competitive antagonists to para-aminobenzoic acid (PABA), an essential component for bacterial growth. While absorption through intact skin has not been determined, sodium sulfacetamide is readily absorbed from the gastrointestinal tract when taken orally and excreted in the urine, largely unchanged. The biological half-life has variously been reported as 7 to 12.8 hours.

The exact mode of action of sulfur in the treatment of acne is unknown, but it has been reported that it inhibits the growth of *Propionibacterium acnes* and the formation of free fatty acids.

INDICATIONS AND USAGE: Rosac Cream With Sunscreens is indicated in the topical control of acne vulgaris, acne rosacea and seborrheic dermatitis.

CONTRAINDICATIONS: Rosac Cream With Sunscreens is contraindicated for use by patients having known hypersensitivity to sulfonamides, sulfur or any other component of this preparation. This drug is not to be used by patients with kidney disease.

WARNINGS: Although rare, sensitivity to sodium sulfacetamide may occur. Therefore, caution and careful supervision should be observed when prescribing this drug for patients who may be prone to hypersensitivity to topical sulfonamides. Systemic toxic reactions such as agranulocytosis, acute hemolytic anemia, purpura hemorrhagica, drug fever, jaundice, and contact dermatitis indicate hypersensitivity to sulfonamides. Particular caution should be employed if areas of denuded or abraded skin are involved.

PRECAUTIONS: General — If irritation develops, use of the product should be discontinued and appropriate therapy instituted. For external use only. Keep away from eyes. Patients should be carefully observed for possible local irritation or sensitization during long-term therapy. The object of this therapy is to achieve desquamation without irritation, but sodium sulfacetamide and sulfur can cause reddening and scaling of epidermis. These side effects are not unusual in the treatment of acne vulgaris, but patients should be cautioned about the possibility. Keep out of reach of children.

Carcinogenesis, Mutagenesis and Impairment of Fertility — Long-term studies in animals have not been performed to evaluate carcinogenic potential.

Pregnancy — Category C. Animal reproduction studies have not been conducted with Rosac Cream with Sunscreens. It is also not known whether this drug can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. It should be given to a pregnant woman only if clearly needed.

Nursing Mothers — It is not known whether sodium sulfacetamide is excreted in human milk following topical use of Rosac Cream With Sunscreens. However, small amounts of orally administered sulfonamides have been reported to be eliminated in human milk. In view of this and because many drugs are excreted in human milk, caution should be exercised when this drug is administered to a nursing woman.

Pediatric Use — Safety and effectiveness in children under the age of 12 have not been established.

ADVERSE REACTIONS: Although rare, sodium sulfacetamide may cause local irritation.

DOSAGE AND ADMINISTRATION: Apply a thin film of Rosac[®] Cream With Sunscreens to affected areas 1 to 3 times daily.

HOW SUPPLIED: 45 g tubes (NDC 0145-2617-05)

Store at controlled room temperature 15°-30°C (59°-86°F).



Stiefel Laboratories, Inc.
Coral Gables, FL 33134

Patent Pending
813400 Rev. 0804

KTP Equals Pulsed Light for Photodamage

BY KERRI WACHTER
Senior Writer

LAKE BUENA VISTA, FLA. — Potassium titanyl phosphate laser treatment can provide results comparable to and perhaps even better than intense pulsed light that is now considered the preferred method for treatment of photoaging, according to data presented at the annual meeting of the American Society for Laser Medicine and Surgery.

In a study designed to compare the two treatments, a 532-nm potassium titanyl phosphate (KTP) "green" laser (Gemini, made by Laserscope) with a 10-mm spot size was used to treat one side of the face, and intense pulsed light (Quantum SR, made by Lumenis) was used to treat the other side, said Girish Munavalli, M.D., a dermatologic surgeon at Johns Hopkins University in Baltimore. A total of 16 patients with diffuse redness and photoaging pigmentation (Fitzpatrick skin types I-IV) were treated.

The emission profile of the 532-nm KTP laser predicts very good absorption by hemoglobin and melanin. "In addition to the absorption spectrum, as you increase the spot size to 10 mm you get deeper penetration of this wavelength," Dr. Munavalli explained.

Treatment with the KTP laser lasted for 90-120 seconds at 7-9 J/cm² (20-millisecond pulses). Contact cooling is used with this device. Intense pulsed-light (IPL) treatment lasted 3-5 minutes at 26 J/cm² using a 560-nm filter (2.5-millisecond pulses,



Skin shows diffuse erythema and pigmentation from photoaging.

6-millisecond double pulses with a 10-millisecond delay). A thin ice-cold gel layer technique was used with both devices.

Dr. Munavalli has no financial interest in either of the devices used in this study.

Patients were evaluated at 1 week and at 1 month using a standardized scale (1-10) by the treating physician. Canfield stereotactic imaging was performed, and a physician blinded to the study evaluated these images.

At 1 week, physician evaluation rated the KTP treatment as producing an overall improvement in vascularity and pigmentation of 64%, compared with a 50% improvement for IPL. Patients rated the two treatments as producing overall improvements of 56% and 40%, respectively.

At 1 month, both sides were rated as producing an improvement of 50%. However,



After Gemini laser treatment, vascularity and pigmentation are improved.

14 of 16 patients opted for the KTP laser for subsequent treatments, preferring its efficacy, treatment times, and comfort. KTP induced slightly more erythema and edema at 10 and 24 hours posttreatment.

Stereotactic imaging resulted in equivalent if not slightly better reduction of the components of photoaging (lentigines, telangiectasias) with KTP, compared with IPL alone.

The Gemini laser can also be set for spot sizes between 1 and 5 mm, in 0.1-mm increments. In addition the KTP laser can be switched out with a 1,064-nm Nd:YAG laser.

The system has received Food and Drug Administration clearance for the treatment of acne, wrinkles, vascular and pigmented lesions, and hair removal. ■

Radiesse Efficacious as Soft Tissue Filler

BY DAMIAN McNAMARA
Miami Bureau

MIAMI BEACH — Calcium hydroxylapatite can effectively fill wrinkles, correct acne and other scars, and augment lips, although there is a learning curve with lips, David J. Goldberg, M.D., said at a symposium sponsored by the Florida Society of Dermatology and Dermatologic Surgery.

Calcium hydroxylapatite (Radiesse, BioForm Medical Inc.) is identical to a natural compound in human bone and teeth. Oncologists, orthopedists, dentists, and other health care professionals have used the material for years in implants and drug delivery systems. The Food and Drug Administration approved the biomaterial for vocal cord injections, as a tissue marker, and for periodontal use for onlay of bone. Nasolabial folds and HIV facial lipoatrophy studies are currently pending.

Soft tissue filler uses are off label, but it is a legal use of the product, according to Dr. Goldberg, who is in private practice in Westwood, N.J.

There is no need for sensitization testing because calcium hydroxylapatite is nonallergic. Other advantages from a patient's perspective include the product's long-term effectiveness, its lack of migration, and minimal downtime (soft tissue

swelling for about 24-48 hours and some bruising are possible).

Dr. Goldberg surveyed 155 of his patients 6 months after soft tissue augmentation with the filler, and 90% indicated they would use it again.

Calcium hydroxylapatite is packaged as cellulose-based gel with a glycerin-water base. No reconstitution is required. Its consistent viscosity makes it easy to inject.

Other potential advantages for physicians include its stability, a shelf life of 2 years without refrigeration, and its compatibility with other cosmetic procedures, said Dr. Goldberg, who is also director of laser research and Mohs surgery at Mount Sinai School of Medicine, New York.

The filler stays soft in tissue. It is long lasting but not permanent, and eventually resorbs. A disadvantage is predicting exactly how long the correction will last. For example, 12-22 months after injection, 30%-100% of initial results remain, according to Dr. Goldberg. Another potential disadvantage is formation of lip nodules. Use of the filler in lips is best left to experienced operators, he emphasized at the meeting.

A small volume is needed for correction. For example, only 1-2 cc is required for nasolabial folds or the corners of the mouth. A total of about 1 cc is required for upper and lower lip augmentation, unless a very large increase in volume is desired.

Dr. Goldberg recommended a threading technique. Inject a thin thread of the material as the needle is withdrawn. The typ-

ical injection is 0.05 cc. A 25- to 27-gauge, 1.25-inch needle is recommended for nasolabial folds. A smaller 0.5-inch, 25- to 27-gauge needle is recommended for injecting the corners of the mouth.

Local anesthesia with epinephrine is recommended. Also consider

doing a nerve block prior to lip augmentation. A small amount of local anesthetic in the lips promotes vasoconstriction, Dr. Goldberg said.

The calcium hydroxylapatite implant does not calcify or ossify. The particles act as scaffold for tissue infiltration, he explained. There is a self-limited fibroblastic response. The particles are not osteoinductive: They do not cause fibroblasts to differentiate to become osteoblasts. ■

Advantages include stability, a shelf life of 2 years without refrigeration, and compatibility with other cosmetic procedures.