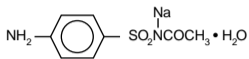


Rosac[®] Cream^{With Sunscreens} (sodium sulfacetamide 10% and sulfur 5%)

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 avobenzene, 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

Rev. 0403

E-Mail Could Replace Some Patient Visits

BY SHARON WORCESTER
Tallahassee Bureau

ORLANDO, FLA. — Don't take this personally, but ... "Patients really don't want to see you," John Bachman, M.D., said at the annual meeting of the American Academy of Family Physicians.

That's one reason why e-mail communication between physicians and patients can be successfully incorporated into a medical practice, he said.

The standard process for an office visit is expensive, inefficient, and inconvenient, but e-mail can change all that, said Dr. Bachman, professor of primary care at the Mayo Clinic, Rochester, Minn.

In a recent survey, 50% of patients said they would like to communicate with their doctor online, and half said they would make the availability of e-mail communication a factor in choosing a doctor. About 25% of doctors said they had communicated with patients via e-mail, and about two-thirds said they would use e-mail if they were paid for the service.

E-mail provides an opportunity to improve patient satisfaction—and it is reimbursable in some instances. Furthermore, most patients are willing to pay out of pocket for the convenience, Dr. Bachman said. At one major practice, about 16,000 patients pay \$60 per year for electronic access to their physician via MyChart (Epic Systems Corp.). More than 90% of the 150 physicians in the practice say they are satisfied with the system, he added.

Additionally, major insurers such as Aetna, BlueCross BlueShield, and UnitedHealthcare provide reimbursement or are testing reimbursement for e-mail communications by doctors. Reimbursement is generally in the \$20-\$25 range, and in some cases patients have a \$5 co-pay for the service, he said, adding that the ICD-9 code for e-mail consultations is 0074T.

E-mail communication works best with established patients with whom you already have a good relationship; those who start practicing medicine via e-mail with patients they don't know could be setting themselves up for malpractice suits, he said.

It could be used prior to patient visits for history taking and for appointment reminders, or after a visit for reporting lab results. Immunization records could easily be supplied to patients enrolling in school.

The approach reduces phone calls and workload for staff. A physician could easily process 12 e-mails in an hour, Dr. Bachman said, noting that in his experience, 85% of e-mails can be handled by staff, and e-mail communication reduces follow-up office visits by 50%, and all visits by 20%.

Establishing effective physician-patient e-mail communications requires a secure server. A platform with a Web site that allows patients to provide medical information, download medical information, schedule visits, and pay bills is ideal. ■

POLICY & PRACTICE

Buyer Beware

The American Society for Dermatologic Surgery is warning consumers to be careful when undergoing cosmetic procedures. And the group is asking physicians to talk to their patients about the risks of invasive cosmetic procedures performed by practitioners without the proper training. "It is our responsibility to protect consumers from the unfortunate proliferation of non-physician providers who typically don't have the necessary medical training and qualifications to diagnose the condition, perform the procedure, and adequately handle complications when they occur," said ASDS President Rhoda S. Narins, M.D. An ASDS member survey from 2002 showed that 41% of respondents said they had seen a significant increase in the number of patients seeking corrective treatment for damage caused by untrained practitioners. ASDS advises consumers to make sure a physician is on site, to check out the physician's credentials, to be sure a medical history is taken, to insist on having an initial evaluation with a dermatologic surgeon, and to discuss pain management options to avoid risks of general anesthesia.

A Spot in the Shade

The American Academy of Dermatology is providing seven grants to non-profit organizations that build permanent shade structures over outdoor locations such as playgrounds, pools, and eating areas. "As the number of hours people spend outdoors participating in leisure activities continues to rise and as dermatologists note an increase in the number of patients diagnosed with skin cancer, it has never been more important to offer protection from the dangerous rays of the sun," said AAD President Boni E. Elewski, M.D. The academy estimates more than 95,000 new cases of melanoma were diagnosed last year, up 4% from 2003. The grantees were chosen from 95 applications and the projects that were selected are expected to affect more than 3,500 people each day. For more information on the grants, visit www.aad.org.

New Surgical Marker

The Food and Drug Administration cleared for marketing a first-of-its-kind external surgical marker that could minimize the potential for wrong-site, wrong-procedure, and wrong-patient surgeries. The device uses radio frequency identification technology to mark an area of the patient's body for surgery. The patient's name and surgical site are printed on the tag and the inside of the tag is encoded with the date of the surgery, the type of procedure, and the name of the surgeon. Here's how it will work: The tag would be scanned with a desktop reader for confirmation by the patient and placed in the patient's file. On the day of the surgery, the tag would be scanned again and verified by the patient. Then, the tag, which has an adhesive backing,

would be affixed to the patient's body near the surgical site. Once in the operating room, the tag would be scanned and verified again. The system is manufactured by SurgiChip Inc.

Retiree Health Benefits

It's still too early to say what the impact of the 2006 Medicare prescription drug benefit will be on retiree health benefits, Jon Gabel, vice president for health systems studies at the Health Research and Educational Trust told the Medicare Payment Advisory Commission at a recent meeting. Mr. Gabel said that in recent conversations with employers, most say that they don't know how they will adjust retiree health benefits based on the coming benefit. An HRET survey conducted a few months after the passage of the Medicare Modernization Act showed that only about 1% of retirees from firms with 200 or more workers would lose all their health benefits. The majority of retirees currently receiving benefits would continue to receive both health and drug benefits either through Medicare-subsidized employer plans or from employer-sponsored benefits that wrap around the Medicare Part D coverage. "There's a great deal of uncertainty," Mr. Gabel said.

Anthem-WellPoint Merger Finalized

California Insurance Commissioner John Garamendi has approved the \$16.4 billion merger of Anthem Inc., a for-profit BlueCross BlueShield subsidiary with plans in nine states, with WellPoint Health Networks, a Blues plan serving California and several other states. Mr. Garamendi approved the plan only after Anthem agreed to modify it to guarantee that the merger will not result in increased premiums for WellPoint customers. The agreement also calls for a \$35 million contribution to health care clinics in underserved communities in the state, and another \$200 million for health care in underserved communities.

Medicare Settlement

Temple University Physicians has agreed to pay more than \$1.8 million to settle civil charges arising from an investigation into its Medicare Part B billing practices. The Department of Health and Human Services audited Medicare Part B claims submitted by the group between July 1995 and July 1996 and concluded that the group lacked sufficient documentation to support some claims, and that some claims represented a greater level of service than was actually provided. "This settlement ... is intended to correct improper past behavior and to ensure that the physician submitting the claim to Medicare actually rendered the service," Patrick L. Meehan, U.S. Attorney for the Eastern District of Pennsylvania, said in a statement on behalf of HHS. The physician group denies the government's allegations and any liability relating to them.

—Mary Ellen Schneider