

Teledermatology Services Offered Worldwide

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VIENNA — Teledermatology is expanding in Europe through an online international dermatology community that provides open-access consultations, H. Peter Soyer, M.D., reported at the 10th World Congress on Cancers of the Skin.

The consultations are free of charge for now, and they are available in five different languages. Physicians can send in pa-

tient pictures and information, and may request a consultation with a specific clinician from a team of dermatologists. Discussion can be added from about 500 participating dermatologists worldwide.

The idea (www.telederm.org) was conceived in 2002 by Dr. Soyer and his colleagues at the department of dermatology at the Medical University of Graz (Austria), with the goal of creating an online dermatology community.

The first world congress on telederma-

tology will be held in November 2006 in Graz.

Dr. Soyer said teledermatology provides not only a second opinion, but also greater access to care and disease monitoring in remote areas and third world countries. European dermatologists have also gained valuable experience about unfamiliar skin conditions reported by dermatologists in Pakistan and China.

Audience members responded positively to the presentation, but many Ameri-

cans suggested that malpractice insurance will be needed for telemedicine to grow in the United States.

American physicians have been successfully sued for consulting on nondermatologic cases from states where they didn't hold a license.

"We do it bona fide, with good trust," Dr. Soyer said at the meeting, which was cosponsored by the Skin Cancer Foundation. "If you are taking care of the patient, you are responsible, and I am your assistant."

Dr. Soyer said liability is an unresolved issue and that a legal platform may need to be established to address liability for on-line consultations.

Reasonable liability insurance for telemedicine has been slow to happen in the United States, in large part because of limited reimbursement, Hon S. Pak, M.D., a member of the American Academy of Dermatology Telemedicine Task Force and vice president of the American Telemedicine Association, said in an interview.

Although third-party payers are increasingly reimbursing for telemedicine, the Centers for Medicare and Medicaid Services currently reimburses only for rural patients—defined as patients who live in non-metropolitan statistical areas—if teledermatology takes place in a live, interactive mode.

Except in federally designated clinics in Hawaii and Alaska, reimbursement does not exist for store-and-forward consultations that allow for asynchronous communication between clinicians via the Internet.

"It's not that teledermatology increases liability; it's just that insurers don't know enough about it and how to put a risk score on it," Dr. Pak said. "Enough volume has to be generated to get a risk profile, and that requires reimbursement."

Members of both the AAD task force and the ATA appeared on Capitol Hill this spring to educate legislators on the value of teledermatology and to push for reimbursement for store-and-forward teledermatology.

A teledermatology forum is also planned for the AAD annual meeting in 2006. The forum is seen as a way to encourage dermatologists to use the technology to enhance their practices, said Dr. Pak, who is a dermatologist with the Telemedicine and Advanced Research Center at Fort Detrick in Frederick, Md.

Other hurdles still exist for teledermatology. Transmission of multimedia streams has remained a major challenge for real-time consultations, and some asynchronous consultations may or may not provide clinical information, depending on what is requested. ■

ZOVIRAX® (acyclovir) Cream 5% Begins to Comfort on Contact to Heal Herpes Fast

- Targeted treatment begins to comfort at the site¹
- Significantly shortens lesion duration vs placebo*¹
- Significantly shortens pain duration vs placebo*¹

* Shorter duration of episode: in study 1, acyclovir (n=324) 4.3 days vs vehicle (n=346) 4.8 days (P=0.010). In study 2, acyclovir (n=328) 4.6 days vs vehicle (n=343) 5.2 days (P=0.007). Shorter duration of pain: in study 1, acyclovir (n=334) 2.9 days vs vehicle (n=352) 3.2 days (P=0.024). In study 2, acyclovir (n=348) 3.1 days vs vehicle (n=351) 3.5 days (P=0.027).

Reference: 1. Spruance SL, Nett R, Marbury T, Wolff R, Johnson J, Spaulding T, for The Acyclovir Cream Study Group. Acyclovir cream for treatment of herpes simplex labialis: results of two randomized, double-blind, vehicle-controlled, multicenter clinical trials. *Antimicrob Agents Chemother.* 2002;46:2238-2243.

ZOVIRAX® (acyclovir) Cream 5%

INDICATIONS AND USAGE

ZOVIRAX Cream is indicated for the treatment of recurrent herpes labialis (cold sores) in adults and adolescents (12 years of age and older).

CONTRAINDICATIONS

ZOVIRAX Cream is contraindicated in patients with known hypersensitivity to acyclovir, valacyclovir, or any component of the formulation.

PRECAUTIONS

General: ZOVIRAX Cream is intended for cutaneous use only and should not be used in the eye or inside the mouth or nose. ZOVIRAX Cream should only be used on herpes labialis on the affected external aspects of the lips and face. Because no data are available, application to human mucous membranes is not recommended. ZOVIRAX Cream has a potential for irritation and contact sensitization (see ADVERSE REACTIONS). The effect of ZOVIRAX Cream has not been established in immunocompromised patients.

Drug Interactions: Clinical experience has identified no interactions resulting from topical or systemic administration of other drugs concomitantly with ZOVIRAX Cream.

Carcinogenesis, Mutagenesis, Impairment or Fertility: Systemic exposure following topical administration of acyclovir is minimal. Dermal carcinogenicity studies were not conducted. Results from the studies of carcinogenesis, mutagenesis and fertility are not included in the full prescribing information for ZOVIRAX Cream due to the minimal exposures of acyclovir that result from dermal application. Information on these studies is available in the full prescribing information for ZOVIRAX Capsules, Tablets, and Suspension and ZOVIRAX for Injection.

Pregnancy: Teratogenic Effects: Pregnancy Category B. Acyclovir was not teratogenic in the mouse, rabbit, or rat at exposures greatly in excess of human exposure. There are no adequate and well-controlled studies of systemic acyclovir in pregnant women. A prospective epidemiologic registry of acyclovir use during pregnancy was established in 1984 and completed in April 1999. There were 749 pregnancies followed in women exposed to systemic acyclovir during the first trimester of pregnancy resulting in 756 outcomes. The occurrence rate of birth defects approximates that found in the general population. However, the small size of the registry is insufficient to evaluate the risk for less common defects

or to permit reliable or definitive conclusions regarding the safety of acyclovir in pregnant women and their developing fetuses. Systemic acyclovir should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers: It is not known whether topically applied acyclovir is excreted in breast milk. Systemic exposure following topical administration is minimal. After oral administration of ZOVIRAX, acyclovir concentrations have been documented in breast milk in 2 women and ranged from 0.6 to 4.1 times the corresponding plasma levels. These concentrations would potentially expose the nursing infant to a dose of acyclovir up to 0.3 mg/kg/day. Nursing mothers who have active herpetic lesions near or on the breast should avoid nursing.

Geriatric Use: Clinical studies of acyclovir cream did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. Systemic absorption of acyclovir after topical administration is minimal (see CLINICAL PHARMACOLOGY).

Pediatric Use: Safety and effectiveness in pediatric patients less than 12 years of age have not been established.

ADVERSE REACTIONS

In 5 double-blind, placebo-controlled trials, 1,124 patients were treated with ZOVIRAX Cream and 1,161 with placebo (vehicle) cream. ZOVIRAX Cream was well tolerated; 5% of patients on ZOVIRAX Cream and 4% of patients on placebo reported local application site reactions.

The most common adverse reactions at the site of topical application were dry lips, desquamation, dryness of skin, cracked lips, burning skin, pruritus, flakiness of skin, and stinging on skin; each event occurred in less than 1% of patients receiving ZOVIRAX Cream and vehicle. Three patients on ZOVIRAX Cream and 1 patient on placebo discontinued treatment due to an adverse event.

An additional study, enrolling 22 healthy adults, was conducted to evaluate the dermal tolerance of ZOVIRAX Cream compared with vehicle using single occluded and semi-occluded patch testing methodology. Both ZOVIRAX Cream and vehicle showed a high and cumulative irritation potential. Another study, enrolling 251 healthy adults, was conducted to evaluate the contact sensitization potential of ZOVIRAX Cream using repeat insult patch testing methodology. Of 202 evaluable subjects, possible cutaneous sensitization reactions were observed in the same 4 (2%) subjects with both ZOVIRAX Cream and vehicle, and these reactions to both ZOVIRAX Cream and vehicle were confirmed in 3 subjects upon rechallenge. The sensitizing ingredient(s) has not been identified.

The safety profile in patients 12 to 17 years of age was similar to that observed in adults.

Observed During Clinical Practice: In addition to adverse events reported from clinical trials, the following events have been identified during post-approval use of acyclovir cream. Because they are reported voluntarily from a population of unknown size, estimates of frequency cannot be made. These events have been chosen for inclusion due to a combination of their seriousness, frequency of reporting, or potential causal connection to acyclovir cream.

General: Angioedema, anaphylaxis.

Skin: Contact dermatitis, eczema, application site reactions including signs and symptoms of inflammation.

OVERDOSAGE

Overdosage by topical application of ZOVIRAX Cream is unlikely because of minimal systemic exposure (see CLINICAL PHARMACOLOGY).

DOSAGE AND ADMINISTRATION

ZOVIRAX Cream should be applied 5 times per day for 4 days. Therapy should be initiated as early as possible following onset of signs and symptoms (i.e., during the prodrome or when lesions appear). For adolescents 12 years of age and older, the dosage is the same as in adults.

HOW SUPPLIED

Each gram of ZOVIRAX Cream 5% contains 50 mg acyclovir in an aqueous cream base. ZOVIRAX Cream is supplied as follows:

2-g tubes (NDC 64455-994-42).

5-g tubes (NDC 64455-994-45).

Store at or below 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) (see USP Controlled Room Temperature).

Manufactured by

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for

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Comfort Begins on Contact