



BY JOSEPH S. EASTERN, M.D.

MANAGING YOUR DERMATOLOGY PRACTICE

Prevent Computer Abuse

As I discussed last month, the rapid evolution of electronic medical records and electronic claims filing has greatly increased the role of computers in our offices, and this trend will continue

for the foreseeable future, largely because the federal government has decreed that it will happen whether we like it or not.

But, of course, with progress comes new problems. As computers become more ubiquitous, computer abuse will become a larger and larger threat.

It is already a major issue in the general business world. Here are some statistics from a recent industry survey:

▶ Two-thirds of employees with Internet

access admit to using it for personal diversion during working hours.

▶ At work, 30%-40% of Internet time is spent on non-work-related browsing, and 60% of all online purchases are made during working hours.

▶ Seventy percent of all Internet porn traffic occurs during the 9-5 workday.

In short, up to 40% of lost productivity can now be blamed on computer abuse.

But lost productivity isn't the only prob-

lem. Unauthorized Internet access increases vulnerability to viruses, worms, and trojans, which can shut down your network.

On top of that, an estimated 80% of computer crime, such as embezzlement and theft of intellectual property, is done by "insiders"—employees working within the victimized companies, on company time.

"Outsiders" can be a problem too. If your office runs an unsecured wireless network, anyone with even a marginal command of network mechanics can easily gain access to your practice finances, your patients' medical records—anything running on your computers.

If you have an application service provider (ASP) system, where your medical records are stored electronically on an off-site server, such potential security breaches are an even bigger issue, for both patient confidentiality and general efficiency. So it behooves you to pay close attention to how your computer network is set up and how your computers are used on your time.

Start with computer monitoring software. Several reasonably-priced programs are available. They automatically and discreetly record everything done on a computer, including Internet activity, chat rooms, instant messages, and Web sites.

Examples include Snapshot Spy (www.snapshotspy.com), Spector Pro (www.spectorsoft.com), and SoftProbe Analyzer (www.softprobe.com). (As always, I have no financial interest in any of the companies or products I discuss.)

Monitoring software runs quietly in the background and cannot be detected by users, but I strongly advise informing your employees that their computer use is being monitored for their safety as well as yours.

Protecting your network from unauthorized access and signal diversion is a more complicated issue. For starters, don't use the default system ID, since any hacker can find that in the user's manual. Change it to something unique—not your birthday or your pet's name. Disable "identifier broadcasting," which announces to the world that you have a wireless connection. Enable any encryption supplied with your network, and get more if you need it. (See below.) Configure your router to allow only incoming or outgoing traffic that you have approved. Depending on the complexity of your network, you may need more sophisticated protection, such as AirDefense (www.airdefense.net), CRYPTOCARD (www.cryptocard.com), or LucidLink (www.lucidlink.com).

It goes without saying that all of your computers, including private ones, need personal firewall software such as Zone Alarm Pro (www.zonelabs.com) and good antivirus, antispyware, and antiadware protection, updated frequently. And change your administrator password often—at a minimum, every time an employee leaves your employ for any reason. ■

DR. EASTERN practices dermatology and dermatologic surgery in Belleville, N.J. To respond to this column, write Dr. Eastern at our editorial offices or e-mail him at sknews@elsevier.com.



BRIEF SUMMARY

For Dermatologic Use Only—Not for Ophthalmic, Oral, or Intravaginal Use
Rx only

CONTRAINDICATIONS

FINACEA[®] Gel, 15%, is contraindicated in individuals with a history of hypersensitivity to propylene glycol or any other component of the formulation.

WARNINGS

FINACEA[®] Gel, 15%, is for dermatologic use only, and not for ophthalmic, oral, or intravaginal use. There have been isolated reports of hypopigmentation after use of azelaic acid. Since azelaic acid has not been well studied in patients with dark complexion, these patients should be monitored for early signs of hypopigmentation.

PRECAUTIONS

General: Contact with the eyes should be avoided. If sensitivity or severe irritation develops with the use of FINACEA[®] Gel, 15%, treatment should be discontinued and appropriate therapy instituted. The safety and efficacy of FINACEA[®] Gel, 15%, has not been studied beyond 12 weeks.

Information for Patients: Patients using FINACEA[®] Gel, 15%, should receive the following information and instructions:

- FINACEA[®] Gel, 15%, is to be used only as directed by the physician.
- FINACEA[®] Gel, 15%, is for external use only. It is not to be used orally, intravaginally, or for the eyes.
- Cleanse affected area(s) with a very mild soap or a soapless cleansing lotion and pat dry with a soft towel before applying FINACEA[®] Gel, 15%. Avoid alcoholic cleansers, tinctures, and astringents, abrasives, and peeling agents.
- Avoid contact of FINACEA[®] Gel, 15%, with the mouth, eyes and other mucous membranes. If it does come in contact with the eyes, wash the eyes with large amounts of water and consult a physician if eye irritation persists.
- The hands should be washed following application of FINACEA[®] Gel, 15%.
- Cosmetics may be applied after FINACEA[®] Gel, 15%, has dried.
- Skin irritation (e.g., pruritus, burning, or stinging) may occur during use of FINACEA[®] Gel, 15%, usually during the first few weeks of treatment. If irritation is excessive or persists, use of FINACEA[®] Gel, 15%, should be discontinued, and patients should consult their physician (See ADVERSE REACTIONS).
- Avoid any foods and beverages that might provoke erythema, flushing, and blushing (including spicy food, alcoholic beverages, and thermally hot drinks, including hot coffee and tea).
- Patients should report abnormal changes in skin color to their physician.
- Avoid the use of occlusive dressings or wrappings.

Drug Interactions: There have been no formal studies of the interaction of FINACEA[®] Gel, 15%, with other drugs.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Long-term animal studies have not been performed to evaluate the carcinogenic potential of FINACEA[®] Gel, 15%. Azelaic acid was not mutagenic or clastogenic in a battery of *in vitro* (Ames assay, HGPRT in V79 cells [Chinese hamster lung cells], and chromosomal aberration assay in human lymphocytes) and *in vivo* (dominant lethal assay in mice and mouse micronucleus assay) genotoxicity tests.

Oral administration of azelaic acid at dose levels up to 2500 mg/kg/day (162 times the maximum recommended human dose based on body surface area) did not affect fertility or reproductive performance in male or female rats.

Pregnancy: Teratogenic Effects: Pregnancy Category B

There are no adequate and well-controlled studies of topically administered azelaic acid in pregnant women. The experience with FINACEA[®] Gel, 15%, when used by pregnant women is too limited to permit assessment of the safety of its use during pregnancy.

Dermal embryofetal developmental toxicology studies have not been performed with azelaic acid, 15%, gel. Oral embryofetal developmental studies were conducted with azelaic acid in rats, rabbits, and cynomolgus monkeys. Azelaic acid was administered during the period of organogenesis in all three animal species. Embryotoxicity was observed in rats, rabbits, and monkeys at oral doses of azelaic acid that generated some maternal toxicity. Embryotoxicity was observed in rats given 2500 mg/kg/day (162 times the maximum recommended human dose based on body surface area), rabbits given 150 or 500 mg/kg/day (19 or 65 times the maximum recommended human dose based on body surface area) and cynomolgus monkeys given 500 mg/kg/day (65 times the maximum recommended human dose based on body surface area) azelaic acid. No teratogenic effects were observed in the oral embryofetal developmental studies conducted in rats, rabbits, and cynomolgus monkeys.

An oral peri- and postnatal developmental study was conducted in rats. Azelaic acid was administered from gestational day 15 through day 21 postpartum up to a dose level of 2500 mg/kg/day. Embryotoxicity was observed in rats at an oral dose that generated some maternal toxicity (2500 mg/kg/day; 162 times the maximum recommended human dose based on body surface area). In addition, slight disturbances in the postnatal development of fetuses was noted in rats at oral doses that generated some maternal toxicity (500 and 2500 mg/kg/day; 32 and 162 times the maximum recommended human dose based on body surface area). No effects on sexual maturation of the fetuses were noted in this study. Because animal reproduction studies are not always predictive of human response, this drug should be used only if clearly needed during pregnancy.

Nursing Mothers:

Equilibrium dialysis was used to assess human milk partitioning *in vitro*. At an azelaic acid concentration of 25 µg/mL, the milk/plasma distribution coefficient was 0.7 and the milk/buffer distribution was 1.0, indicating that passage of drug into maternal milk may occur. Since less than 4% of a topically applied dose of AZELEX[®] Cream, 20%, is systemically absorbed, the uptake of azelaic acid into maternal milk is not expected to cause a significant change from baseline azelaic acid levels in the milk. However, caution should be exercised when FINACEA[®] Gel, 15%, is administered to a nursing mother.

Pediatric Use: Safety and effectiveness of FINACEA[®] Gel, 15%, in pediatric patients have not been established.

Geriatric: Clinical studies of FINACEA[®] Gel, 15%, did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects.

ADVERSE REACTIONS

In the 2 vehicle controlled, identically designed U.S. clinical studies, treatment safety was monitored in 664 patients who used FINACEA[®] Gel, 15%, (N=333), or the gel vehicle (N=331), twice daily for 12 weeks.

Table 3. Cutaneous Adverse Events Occurring in ≥1% of Subjects in the Rosacea Trials by Treatment Group and Maximum Intensity*

	FINACEA [®] Gel, 15% N=333 (100%)			Vehicle N=331 (100%)		
	Mild n=86 (26%)	Moderate n=44 (13%)	Severe n=20 (6%)	Mild n=49 (15%)	Moderate n=27 (8%)	Severe n=5 (2%)
Burning/ stinging/ tingling	66 (20%)	30 (9%)	12 (4%)	8 (2%)	6 (2%)	2 (1%)
Pruritus	24 (7%)	14 (4%)	3 (1%)	9 (3%)	6 (2%)	0 (0%)
Scaling/dry skin/xerosis	21 (6%)	8 (2%)	4 (1%)	33 (10%)	12 (4%)	1 (0%)
Erythema/ irritation	6 (2%)	6 (2%)	1 (0%)	8 (2%)	4 (1%)	2 (1%)
Edema	3 (1%)	2 (1%)	0 (0%)	3 (1%)	0 (0%)	0 (0%)
Contact dermatitis	2 (1%)	2 (1%)	0 (0%)	1 (0%)	0 (0%)	0 (0%)
Acne	2 (1%)	1 (0%)	0 (0%)	1 (0%)	0 (0%)	0 (0%)
Seborrhea	2 (1%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Photo- sensitivity	1 (0%)	0 (0%)	0 (0%)	3 (1%)	1 (0%)	1 (0%)
Skin disease	1 (0%)	0 (0%)	0 (0%)	1 (0%)	2 (1%)	0 (0%)

*Subjects may have >1 cutaneous adverse event; thus, the sum of the frequencies of preferred terms may exceed the number of subjects with at least 1 cutaneous adverse event.

FINACEA[®] Gel, 15%, and its vehicle caused irritant reactions at the application site in human dermal safety studies. FINACEA[®] Gel, 15%, caused significantly more irritation than its vehicle in a cumulative irritation study. Some improvement in irritation was demonstrated over the course of the clinical studies, but this improvement might be attributed to subject dropouts. No phototoxicity or photoallergenicity were reported in human dermal safety studies.

In patients using azelaic acid formulations, the following additional adverse experiences have been reported rarely: worsening of asthma, vitiligo depigmentation, small depigmented spots, hypertrichosis, reddening (signs of keratosis pilaris), and exacerbation of recurrent herpes labialis.

OVERDOSAGE

FINACEA[®] Gel, 15%, is intended for cutaneous use only. If pronounced local irritation occurs, patients should be directed to discontinue use and appropriate therapy should be instituted (See PRECAUTIONS).

January 2005

Distributed under license; U.S. Patent No 4,713,394

© 2005 Intendis Inc. All rights reserved.

AZELEX[®] is a registered trademark of Allergan, Inc.

Manufactured by Schering S.p.A., Segrate, Milan, Italy

Distributed by:

INTENDIS Inc., Montville, NJ 07045

2189827 6058000

INTENDIS
making medicine work
04FNC068A January 2005