Isotretinoin Rx Plan Delayed

BY TIMOTHY F. KIRN
Sacramento Bureau

The implementation of the iPLEDGE program for isotretinoin prescribing has been delayed by 1 month for pharmacies and by 2 months for physicians and patients, the Food and Drug Administration announced last month.

Pharmacies must now register by Dec. 30 to receive new supplies of isotretinoin or see supplies pulled back by the manufacturers starting Dec. 31.

Physicians now must be registered and activated by March 1, 2006, for a prescription written by them to be dispensed to a patient, who must also be registered and activated by that date.

In the meantime, prescriptions written using the yellow stickers of the expiring SMART program, and the analogous programs of the other isotretinoin products, will be dispensed by pharmacies through February 2006.

The delay of iPLEDGE was necessary largely because not enough pharmacies had signed up yet, sources said in an interview.

Implementation of the iPLEDGE program was only publicly announced by FDA in August (FAMILY PRACTICE NEWS, Sept. 15, 2005, p. 8).

"We needed time to iron things out—it's a very complicated task," said a source at FDA. "We've all been having daily meetings on this for months."

By mid-October, only about 15,000 of 55,000 retail pharmacies in the United States had registered with Covance Inc., the company running the iPLEDGE registration system, according to Douglas Hoey, R.Ph., a senior vice president with the National Community Pharmacists Association.

The association was one of several organizations, including the American Academy of Dermatology, that had begun lobbying the FDA for the delay, Mr. Hoey said.

"We wanted to make sure that as many pharmacists as possible were ready to serve patients," he said.

It is expected that most pharmacies will sign up and that physicians who prescribe isotretinoin will not have trouble finding a dispensing pharmacy in their area, Mr. Hoey said. The problem was in the timing, getting the word out, and getting pharmacists informed and up to speed, he added.

The delay comes at a time, however, isotretinoin prescribers are expressing increased irritation about the restrictions being placed on isotretinoin prescribing (FAMILY PRACTICE NEWS, Nov. 1, 2005, p. 33).

'I think it was an intelligent move to put implementation off.'

DR. SHALITA

And, sources said in an interview that physician registration to date in the iPLEDGE program has not been exceptionally brisk.

The number of isotretinoin prescriptions dropped significantly in the year after the implementation of the SMART program.

Alan Shalita, M.D., said he was somewhat relieved to learn of the program implementation delay, adding that he was not worried about being able to prescribe isotretinoin when the time came. He had registered with the iPLEDGE program soon after it came online and by November had still not received his patient materials from the program.

"I think it was an intelligent move to put implementation off," said Dr. Shalita, chair of dermatology at the State University of New York Downstate Medical Center in Brooklyn. ■

Balance Efficacy and Tolerability When Selecting Topical Retinoids for Acne

BY ROBERT FINN
San Francisco Bureau

BLAINE, WASH. — Topical retinoids can be highly effective treatments for acne; however, they come in a bewilderingly wide variety of strengths and formulations.

Clinicians should consider effectiveness, tolerability, and the type of vehicle that would be best for an individual patient in making the choice, Robert Sidbury, M.D., said at a conference sponsored by the North Pacific Pediatric Society.

Physicians must choose among adapalene (Differin) 0.1%, which comes formulated as a gel, a cream, a solution, and as pledgets; tretinoin (Retin-A), which comes in four strengths between 0.01% and 0.1% as a cream and 0.01% and 0.025% as a gel; tretinoin micro (Retin-A Micro) gel, which comes in 0.04% and 0.1% strengths; and tazarotene (Tazorac), which comes as a gel and as a cream in 0.05% and 0.1% strengths.

Adapalene is at the top of the tolerability list, said Dr. Sidbury of the University of Washington in Seattle. Tretinoin micro comes next, followed by tretinoin. Tazarotene is the least tolerable of the retinoids.

Unfortunately, the least tolerable topical retinoid is the most effective, and the most tolerable is the least effective. Those patients who are able to tolerate tazarotene are likely to find that it works better for them than do the alternatives.

Retinoids that are formulated in creams tend to be better tolerated—but less effective in equal strengths—than those formulated in gels, Dr. Sidbury said.

There are things patients can do and things physicians can do to optimize success with topical retinoids, he said. Although all these products are intended to be used daily, patients who are particularly sensitive can apply them every other day or even just twice a week to start.

Retinoids thin the stratum corneum, and this presents as dryness, itchiness, and desquamation. However, the stratum corneum regenerates even as the patient continues to use the retinoids, so tolerability should improve with continued use.

Patients should apply topical retinoids very sparingly. A pea-sized dollop on a fingertip is enough to cover the entire acne-prone "T zone" of the face, said Dr. Sidbury.

And the physician should counsel patience, because it can take quite a long time for the patient to see improvement.

Physicians can help by matching the vehicle to the patient's skin type. Patients with oily skin will do better with a gel, whereas patients with dry skin will do better with a cream. One should start with products at the top of the tolerability scale for patients with sensitive skin, but go with something stronger in patients whose skin is not quite as sensitive, Dr. Sidbury advised. ■

Short-Term, Urea Vehicle Acne Tx Shows Efficacy

BY DOUG BRUNK
San Diego Bureau

LAS VEGAS — Treating acne with 4.5% or 8.5% benzoyl peroxide in a 10% urea vehicle once daily for 4 weeks was effective and well-tolerated, results from a large study demonstrated.

The finding underscores urea's role as an effective moisturizing agent, Michael H. Gold, M.D., reported during a poster session at the Fall Clinical Dermatology Conference.

In an open-label study that Dr. Gold led at 133 clinical sites, 1,089 men and women were prescribed 4.5% or 8.5% benzoyl peroxide in a 10% urea vehicle cleanser (Zoderm) for use in the morning plus an equivalent strength of either Zoderm gel or cream formulation for use in the evening.

Applications were made over a 4-week period. The investigators allowed patients to use additional acne medicines during the study, except for those that contained benzoyl peroxide.

Of the 1,089 patients, 963 completed the second visit of the study, Dr. Gold, a dermatologist with Tennessee Clinical Research Center, Nashville, noted in the text of the poster.

The investigators assessed inflammatory and noninflammatory lesion counts at baseline and at week 4. They rated dryness and erythema on a 0-8 scale in which 8 was defined as severe or deep.

Of the 963 patients, 551 used 4.5% or 8.5% benzoyl peroxide in urea vehicle as monotherapy, 17 used 4.5% or 8.5% benzoyl peroxide in urea vehicle with oral doxycycline, and 21 used 4.5% or 8.5% benzoyl peroxide in urea vehicle with oral minocycline.

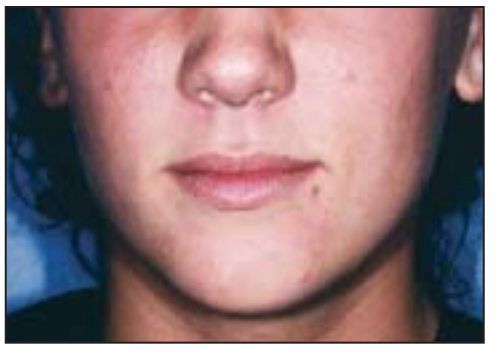
Dr. Gold reported that the 551 patients who used 4.5% or 8.5% benzoyl peroxide in urea vehicle as monotherapy achieved a 44% mean reduction in total lesion count at week 4 vs. baseline.

The 17 patients who used this regimen plus oral doxycycline achieved a 52% mean reduction in their total lesion count at week 4 vs. baseline, whereas those patients who used concomitant oral minocycline achieved a 34% mean reduction in total lesion count at week 4 vs. baseline.

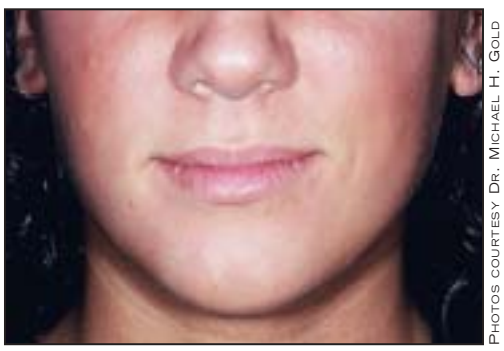
According to the poster, patients experienced little or no increase in skin dryness and a decrease in erythema.

The study was funded by a grant from Doak Dermatologics, a subsidiary of Bradley Pharmaceuticals Inc., makers of Zoderm.

The meeting was sponsored by the Center for Bio-Medical Communication Inc. ■



A female patient is shown here at baseline, before using a urea vehicle cleanser.



Clearance of acne is apparent in the same patient at 4 weeks' follow-up.

PHOTOS COURTESY DR. MICHAEL H. GOLD

Hope for Physical Deformities

Fresh Start Surgical Gifts is offering a patient outreach program to inform U.S. families of children with physical deformities about free reconstructive plastic surgery and related medical services that are available from the nonprofit group. The program includes a video news release and a CD with background information. For more information about the organization, visit www.freshstart.org. To obtain the outreach materials, contact the organization by calling 888-551-1003.