

POLICY & PRACTICE

FDA Says Humira Ad Misleading

The Food and Drug Administration said that Abbott Laboratories downplayed the risks associated with the psoriasis therapy Humira (adalimumab) in an ad intended for dermatologists. The ad was misleading because it “suggests that Humira is useful in a broader range of conditions or patients than has been demonstrated by substantial evidence or substantial clinical experience,” the FDA noted. The drug has many risks, including tuberculosis and invasive fungal infections, and its use should be carefully weighed, the agency wrote in a December letter to Abbott, which contended that the ad gave a full description of the drug’s approved use only in small, “nearly illegible” text. Also, the patient pictured in the ad was not representative of approved users since the model showed only a small area of plaque psoriasis. The agency said Abbott should immediately stop the ads. A company spokeswoman said the ad was discontinued in October and that it will “work with the agency to address their concerns.”

Phototherapy Copays Prompt Action

The National Psoriasis Foundation has written to insurance commissioners in six states to request that they encourage health plans to eliminate or reduce patients’ copayments for phototherapy

sessions. Members of a foundation task force on the issue—who are primarily dermatologists—decided to target commissioners in California, Massachusetts, Missouri, New York, Texas, and Utah. The foundation has received two responses, neither of which was very encouraging, said Sheila Rittenberg, the organization’s senior director of advocacy and external affairs. The task force effort came after a failed attempt to convince 85 health insurers around the country to cut copayments, she said in an interview. Patients are paying anywhere from \$5 to \$50 per psoriasis-phototherapy session, and most need several a week, said Ms. Rittenberg. In some cases, she added, patients are being prescribed biologics because they can’t afford phototherapy.

Colorings Must Be Declared

Many foods and cosmetics contain carmine and cochineal, but they have been hidden under the rubric of “artificial coloring” or “colors added.” The FDA has ruled that manufacturers must clearly state on labels that carmine and cochineal are in those products. The final rule, published Jan. 5, is partly in response to a petition filed by the Center for Science in the Public Interest in 1998. The nonprofit advocacy group contended that because carmine and cochineal extracts—which give products

red hues—come from insects, they were the most likely causes of dozens of allergic reactions. The FDA acknowledged that reactions and anaphylaxis have been associated with carmine- and cochineal-colored products, and the agency first proposed requiring disclosure of the two extracts in 2006. But the FDA has refused to ban the colorants. Manufacturers have 2 years to comply with the new labeling requirements.

2009 Predictions on Cosmetic Front

There will be an increase in horror stories about consumers having bargain cosmetic

procedures, and Botox will finally get some competition this year, according to a list of predictions from the American Society for Aesthetic Plastic Surgery. The professional society said that the injectable botulinum toxin Reloxin should gain approval in 2009. The organization also said that noninvasive fat-removal techniques will gain credence as they are tested in clinical trials and that men will continue to be a growing segment of the market for cosmetic procedures. The society said its predictions are based on interviews with plastic surgeons.

—Alicia Ault

MANAGING YOUR DERMATOLOGY PRACTICE
Protect Your Data!

Last month I wrote about a dermatologist from the Midwest whose office was ransacked and then set on fire. I covered the steps necessary to file a timely and accurate insurance claim.

No amount of insurance, however, will recoup one of his worst losses: the data on his destroyed computers.

Industry statistics show that fully 10% of hard drives fail in any given year and that 43% of computer users lose one or more files every year. Recovery of lost data, when it’s possible at all, can be very expensive.

Despite that, a Harris Interactive study found that 35% of Americans admitted they never back up their computers. My guess is that the actual percentage is substantially higher. And amazingly, many people who have lost important, irretrievable data in a crash still refuse to do regular backups.

Why do so many of us neglect such a basic precaution? Because it’s an annoyance and an inconvenience and takes too much time. Clearly, the only way to get many people to back up their data regularly is to make the process automatic.

Some computer companies have taken steps in that direction. Apple, for example, has a feature called Time Machine that backs up Macs to an external drive automatically. But that does you no good if, as happened to the Midwestern dermatologist, the fire that destroys the computers also incinerates the backup drives.

So, the first rule is to store your backup drives in a different location from your computers. Unfortunately, that’s a pain, too, and external drives can be lost or stolen, creating a HIPAA nightmare. So an increasingly popular alternative is automatic remote backup.

There are several companies that offer this service: two of the most popular are Mozy (www.mozy.com) and Carbonite (www.carbonite.com).

(As always, I have no financial interest in any product or service discussed in this column.)

The cost is very reasonable. In fact, Mozy lets you store up to two gigabytes of data for free. Its basic package, which includes unlimited storage, costs \$4.95 a month per computer. Carbonite is a bit

cheaper (\$49.95 per year, also for unlimited capacity), but Mozy is a little more customizable, and you can specify the files you want regularly backed up and when it will be done. Backing up an entire office costs more, depending on how many computers and/or servers you have, but it’s still very reasonable and includes other services such as operating system and network share support.

The procedure is simple: You create an account and tell the service which files you want copied. Your first backup can take a long time, often days, depending on how much data you are sending and the speed of your Internet connection. After that, the program runs in the background, copying only those files that have changed since the previous backup. Files are encrypted before leaving your computer, and they remain encrypted at the service’s data center, making them HIPAA compliant and, theoretically, accessible only to you.

To restore files, you open a sort of virtual representation of your backed-up files and click on what you want restored. You also can log into the Web site from any other computer and pick any file or folder to retrieve. If your computer is stolen or the hard drive is destroyed, you can go to a site to initiate a full restore to a new computer.

If you ever decide to terminate the service or simply want a hard copy of your data, Mozy will send you a DVD of all your files, for a fee.

Mozy’s parent company, EMC, has announced a new subsidiary called Decho (www.decho.com), which it says will soon offer the same services for information that banks offer for money. Not only will you be able to store your data, you’ll also be able to share it, move it around, put it to work, and access it no matter where you are. Such a centralized “information bank in the sky” could change the way we perceive and use computers.

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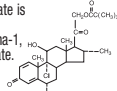


BY JOSEPH S. EASTERN, M.D.

Rx Only
Cloderm® Cream, 0.1%
(clocortolone pivalate)

FOR TOPICAL DERMATOLOGIC USE ONLY—NOT FOR OPHTHALMIC, ORAL, OR INTRAVAGINAL USE. WARNING: KEEP OUT OF REACH OF CHILDREN

DESCRIPTION: Cloderm Cream 0.1% contains the medium potency topical corticosteroid, clocortolone pivalate, in a specially formulated water-washable emollient cream base consisting of purified water, white petrolatum, mineral oil, stearic alcohol, polyoxy 40 stearate, carbomer 934P, edetate disodium, sodium hydroxide, with methylparaben and propylparaben as preservatives. Chemically, clocortolone pivalate is

**CLINICAL PHARMACOLOGY:**

Topical corticosteroids share anti-inflammatory, antipruritic and vasoconstrictive actions.

The mechanism of anti-inflammatory activity of the topical corticosteroids is unclear. Various laboratory methods, including vasoconstrictor assays, are used to compare and predict potencies and/or clinical efficacies of the topical corticosteroids. There is some evidence to suggest that a recognizable correlation exists between vasoconstrictor potency and therapeutic efficacy in man.

Pharmacokinetics: The extent of percutaneous absorption of topical corticosteroids is determined by many factors including the vehicle, the integrity of the epidermal barrier, and the use of occlusive dressings. Topical corticosteroids can be absorbed from normal intact skin. Inflammation and/or other disease processes in the skin increase percutaneous absorption. Occlusive dressings substantially increase the percutaneous absorption of topical corticosteroids. Thus, occlusive dressings may be a valuable therapeutic adjunct for treatment of resistant dermatoses. (See **DOSAGE AND ADMINISTRATION**).

Once absorbed through the skin, topical corticosteroids are handled through pharmacokinetic pathways similar to systemically administered corticosteroids. Corticosteroids are bound to plasma proteins in varying degrees. Corticosteroids are metabolized primarily in the liver and are then excreted by the kidneys. Some of the topical corticosteroids and their metabolites are also excreted into the bile.

INDICATIONS AND USAGE:

Topical corticosteroids are indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.

CONTRAINDICATIONS:

Topical corticosteroids are contraindicated in those patients with a history of hypersensitivity to any of the components of the preparation.

PRECAUTIONS:

General: Systemic absorption of topical corticosteroids has produced reversible hypothalamic-pituitary-adrenal (HPA) axis suppression, manifestations of Cushing’s syndrome, hyperglycemia, and glucosuria in some patients.

Conditions which augment systemic absorption include the application of the more potent steroids, use over large surface areas, prolonged use, and the addition of occlusive dressings.

Therefore, patients receiving a large dose of a potent topical steroid applied to a large surface area or under an occlusive dressing should be evaluated periodically for evidence of HPA axis suppression by using the urinary free cortisol and ACTH stimulation tests. If HPA axis suppression is noted, an attempt

should be made to withdraw the drug, to reduce the frequency of application, or to substitute a less potent steroid.

Recovery of HPA axis function is generally prompt and complete upon discontinuation of the drug. Infrequently, signs and symptoms of steroid withdrawal may occur, requiring supplemental systemic corticosteroids.

Children may absorb proportionally larger amounts of topical corticosteroids and thus be more susceptible to systemic toxicity. (See **PRECAUTIONS: Pediatric Use**).

If irritation develops, topical corticosteroids should be discontinued and appropriate therapy instituted. In the presence of dermatological infections, the use of an appropriate antifungal or antibacterial agent should be instituted. If a favorable response does not occur promptly, the corticosteroid should be discontinued until the infection has been adequately controlled.

Information for the Patient: Patients using topical corticosteroids should receive the following information and instructions:

1. This medication is to be used as directed by the physician. It is for external use only. Avoid contact with the eyes.
2. Patients should be advised not to use this medication for any disorder other than for which it was prescribed.
3. The treated skin area should not be bandaged or otherwise covered or wrapped as to be occlusive unless directed by the physician.
4. Patients should report any signs of local adverse reactions especially under occlusive dressing.
5. Parents of pediatric patients should be advised not to use tight-fitting diapers or plastic pants on a child being treated in the diaper area, as these garments may constitute occlusive dressings.

Laboratory Tests: The following tests may be helpful in evaluating the HPA axis suppression:
Urinary free cortisol test
ACTH stimulation test

Carcinogenesis, Mutagenesis, and Impairment of Fertility: Long-term animal studies have not been performed to evaluate the carcinogenic potential or the effect on fertility of topical corticosteroids.

Studies to determine mutagenicity with prednisolone and hydrocortisone have revealed negative results. **Pregnancy Category C:** Corticosteroids are generally teratogenic in laboratory animals when administered systemically at relatively low dosage levels. The more potent corticosteroids have been shown to be teratogenic after dermal application in laboratory animals. There are no adequate and well-controlled studies in pregnant women on teratogenic effects from topically applied corticosteroids. Therefore, topical corticosteroids should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Drugs of this class should not be used extensively on pregnant patients, in large amounts, or for prolonged periods of time.

Nursing Mothers: It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in breast milk. Systemically administered corticosteroids are secreted into breast milk in quantities not likely to have deleterious effect on the infant. Nevertheless, caution should be exercised when topical corticosteroids are administered to a nursing woman.

Pediatric Use: Pediatric patients may demonstrate greater susceptibility to topical corticosteroid-induced HPA axis suppression and Cushing’s syndrome than mature patients because of a larger skin surface area body weight ratio.

Hypothalamic-pituitary-adrenal (HPA) axis suppression, Cushing’s syndrome, and intracranial hypertension have been reported in children receiving topical corticosteroids. Manifestations of adrenal suppression in children include linear growth retardation, delayed weight gain, low plasma cortisol levels, and absence of response to ACTH stimulation. Manifestations of intracranial hypertension include bulging fontanelles, headaches, and bilateral papilloedema.

Administration of topical corticosteroids to children should be limited to the least amount compatible with an effective therapeutic regimen. Chronic corticosteroid therapy may interfere with the growth and development of children.

ADVERSE REACTIONS:

The following local adverse reactions are reported infrequently with topical corticosteroids, but may occur more frequently with the use of occlusive dressings. These reactions are listed in an approximate decreasing order of occurrence:

- Burning
- Itching
- Irritation
- Dryness
- Folliculitis
- Hypertrichosis
- Aceiform eruptions
- Hypopigmentation
- Perioral dermatitis
- Allergic contact dermatitis
- Maceration of the skin
- Secondary infection
- Skin atrophy
- Striae
- Miliaria

OVERDOSAGE:

Topically applied corticosteroids can be absorbed in sufficient amounts to produce systemic effects (see **PRECAUTIONS**).

DOSAGE AND ADMINISTRATION:

Apply Cloderm (clocortolone pivalate) Cream 0.1% sparingly to the affected areas three times a day and rub in gently.

Occlusive dressings may be used for the management of psoriasis or recalcitrant conditions.

If an infection develops, the use of occlusive dressings should be discontinued and appropriate antimicrobial therapy instituted.

HOW SUPPLIED:

Cloderm (clocortolone pivalate) Cream 0.1% is supplied in a 30 gram pump bottle, 45 gram and 90 gram tubes.

Store Cloderm Cream between 15° and 30° C (59° and 86° F). Avoid freezing.

Distributed by:

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LABORATORIES, LTD.

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Fort Worth, Texas 76107

Manufactured by:
DPT LABORATORIES, LTD.
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