## Simple Label Makers Sub for Electronic Records

GALD Fort V

#### BY BRUCE K. DIXON Chicago Bureau

f you're not ready to invest thousands of dollars in an electronic medical records system, a desktop label writer may be just what the doctor ordered.

'This is a very cost-effective alternative for anyone who doesn't have an EMR system," said Dr. Stephanie Lucas, who equipped her two-physician Detroit practice with several Dymo Twin Turbo label

#### DIFFERIN® (adapalene) Cream, 0.1% **BRIEF SUMMARY Rx Only**

#### For topical use only. Not for ophthalmic, oral, or intravaginal use. INDICATIONS AND USAGE: DIFFERIN® Cream is indicated for the topical

treatment of acne vulgaris. CONTRAINDICATIONS: DIFFERIN® Cream should not be administered to ndividuals who are hyperse the cream vehicle. isitive to adapalene or any of the components

PRECAUTIONS: General: If a reaction suggesting sensitivity or chemical irritation occurs, use of the medication should be discontinued. Exposure to Irritation occurs, use of the medication should be discontinued. Exposure to sunlight, including sunlamps, should be minimized during use of adapalene. Patients who normally experience high levels of sun exposure, and those with inherent sensitivity to sun, should be warned to exercise caution. Use of sunscreen products and protective clothing over treated areas is recommended when exposure cannot be avoided. Weather extremes, such as wind or cold, also may be irritating to patients under treatment with adapalene. Avoid constact with the even

Avoid contact with the eyes, lips, angles of the nose, and mucous membranes The product should not be applied to cuts, abrasions, eczematous or sunburned skin. As with other retinoids, use of "waxing" as a depilatory method should be avoided on skin treated with adapalene.

Information for Patients: Patients using DIFFERIN® Cream should receive the following information and instructions: 1. This medication is to be used only as directed by the physician.

- . It is for external use only.
- 3. Avoid contact with the eyes, lips, angles of the nose, and mucous membranes 4. Cleanse area with a mild or soapless cleanser before applying this
- medication. 5. Moisturizers may be used if necessary: however, products containing
- Anotalizzation may be used in the second statement, protects containing alpha hydroxy or glycolic acids should be avoided.
  Exposure of the eye to this medication may result in reactions such as swelling, conjunctivitis, and eye irritation.
- 7. This medication should not be applied to cuts, abrasions, eczematous or
- sunburned skin 8. Wax epilation should not be performed on treated skin due to the potential for skin erosions.
- During the early weeks of therapy, an apparent exacerbation of acne may occur. This is due to the action of this medication on previously unseen lesions and should not be considered a reason to discontinue therapy. Overall clinical benefit may be noticed after two weeks of therapy, but at least eight weeks are required to obtain consistent beneficial effects.

Drug Interactions: As DIFFERIN® Cream has the potential to produce local irritation in some patients, concomitant use of other potentially irritating topical products (medicated or abrasive soaps and cleansers, soaps and topical products (medicated or abrasive scaps and cleansers, scaps and cosmetics that have a strong drying effect, and products with high concentra-tions of alcohol, astringents, spices or lime rind) should be approached with caution. Particular caution should be exercised in using preparations containing sulfur, resorcinol, or salicylic acid in combination with DIFFERIN® Cream. If these preparations have been used, it is advisable not to start therapy withd DIFFERIN® Cream until the effects of such preparations in the skin have subsided. DIFFEIN® Cream until the effects of such preparations in the skin have subsided. *Carcinogenesis, Mutagenesis, Impairment of Fertility:* Carcinogenicity studies with adapaten have been conducted in mice at topical doses of 0.4, 1.3, and 4.0 mg/kg/day, and in rats at oral doses of 0.15, 0.5, and 1.5 mg/kg/day. These doses are up to 8 times (mice) and 6 times (rats) in terms of mg/m/day the maximum potential exposure at the recommended topical human dose (MRHD), assumed to be 2.5 grams DIFFERIN° Cream, which is approximately 1.5 mg/m² adapatene. In the oral study, increased incidence of benign and malig-nant pheochromocytomas in the adrenal medullas of male rats was observed. nant pneochromocytomas in the adrenal medullas of male rats was observed. No photocarcinogenicity studies were conducted. Animal studies have shown an increased risk of skin neoplasms with the use of pharmacologically similar drugs (e.g., retinoids) when exposed to UV irradiation in the laboratory or to sunlight. Although the significance of these studies to human use is not clear, patients should be advised to avoid or minimize exposure to either sunlight or artificial UV irradiation sources.

Adapalene did not exhibit mutagenic or genotoxic effects *in vivo* (mouse micronucleus test) and *in vitro* (Ames test, Chinese hamster ovary cell assay, mouse lymphoma TK assay) studies. Reproductive function and fertility studies were conducted in rats administered

oral doses of adapalene in amounts up to 20 mg/kg/day (up to 80 times the MRHD based on mg/m<sup>2</sup> comparisons). No effects of adapalene were found on the reproductive performance or fertility of the F<sub>0</sub> males or females. There

the reproductive performance or refunity of the F<sub>0</sub> makes or remains. There were also no detectable effects on the growth, development and subsequent reproductive function of the F, generation. **Nursing Mothers:** It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when DIFFERIN® Cream is administered to a nursing woman. Pediatric Use: Safety and effectiveness in pediatric patients below the age of 12 have not been established

ADVERSE REACTIONS: In controlled clinical trials, local cutaneous irritation was monitored in 285 acne patients who used DIFFERIN™ Cream once daily for 12 weeks. The frequency and severity of erythema, scaling, dryness, pruritus and burning were assessed during these studies. The incidence of local cutaneous irritation with DIFFERIN® Cream from the controlled clinical studies is provided in the following table

Incidence of Local Cutaneous Irritation with DIFFERIN® Cream from Controlled Clinical Studies (N=285)					
	None	Mild	Moderate	Severe	
Erythema	52% (148)	38% (108)	10% (28)	<1% (1)	
Scaling	58% (166)	35% (100)	6% (18)	<1% (1)	
Dryness	48% (136)	42% (121)	9% (26)	<1% (2)	
Pruritus (persistent)	74% (211)	21% (61)	4% (12)	<1% (1)	
Burning/Stinging (persistent)	71% (202)	24% (69)	4% (12)	<1% (2)	

makers at a cost of about \$150 apiece.

"I have all my prescriptions on the attached software, so all I have to do to print a label is go to the list on my computer, click on the prescription, and it comes out of the machine," said Dr. Lucas, who puts one label into the patient's chart and gives a second, signed, copy to the patient to take to the pharmacy. "Or I stick the label or labels on a sheet of paper and fax it to the pharmacy."

The internist and endocrinologist take

Other reported local cutaneous adverse events in patients who used DIFFERIN® Cream once daily included: sunburn (2%), skin discomfort-burning and stinging (1%) and skin irritation (1%). Events occurring in less than 1% of patients treated with DIFFERIN® Cream included: acne flare, dermatitis and contact dermatitis, eyelid edema, conjunctivitis, erythema, mutitus gid inclustories rock and course. pruritus, skin discoloration, rash, and eczema.

pruftus, skin discoloration, rasn, and eczema. **OVERDOSAGE:** DIFFERIN® Gream is intended for cutaneous use only. If the medication is applied excessively, no more rapid or better results will be obtained and marked redness, scaling, or skin discomfort may occur. The acute oral toxicity of DIFFERIN® Gream in mice and rats is greater than 10 mL/kg. Chronic ingestion of the drug may lead to the same side effects as those associated with excessive oral intake of Vitamin A.

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#### DIFFERIN® (adapalene gel) Gel, 0.1%

**Rx Only BRIEF SUMMARY** INDICATIONS AND USAGE: DIFFERIN® Gel is indicated for the topical

CONTRAINDICATIONS: DIFFERIN® Gel should not be administered to dividuals who are hypersensitive to adapalene or any of the components in the vehicle gel.

WARNINGS: Use of DIFFERIN<sup>®</sup> Gel should be discontinued if hypersensitivity to any of the ingredients is noted. Patients with sunburn should be advised not to use the product until fully recovered.

not to use the product until fully recovered. PRECAUTIONS: General: If a reaction suggesting sensitivity or chemical irritation occurs, use of the medication should be discontinued. Exposure to sunlight, including sunlamps, should be minimized during the use of adapatene. Patients who normally experience high levels of sun exposure, and those with inherent sensitivity to sun, should be warned to exercise caution. Use of sunscreen products and protective clothing over treated areas is recommended when exposure cannot be avoided. Weather extremes, such as wind or cold, also may be irritating to patients under treatment with adapatene. Avoid context with the eves

Avoid contact with the eves, lips, angles of the nose, and mucous membranes. The product should not be applied to cuts, abrasions, eczematous skin, or

ned skin Certain cutaneous signs and symptoms such as erythema, dryness, scaling, burning, or pruritus may be experienced during treatment. These are most likely to occur during the first two to four weeks and will usually lessen with continued use of the medication. Depending upon the severity of adverse events, patients should be instructed to reduce the frequency of application of discontinue use

Drug Interactions: As DIFFERIN® Gel has the potential to produce local irr tation in some patients, concomitant use of other potentially irritating topical products (medicated or abrasive soaps and cleansers, soaps and cosmetics that have a strong drying effect, and products with high concentrations of alcohol, astringents, spices, or linne) should be approached with caution. Particular caution should be exercised in using preparations containing sulfur, resorcinol, or salicylic acid in combination with DIFFERIN® Gel. If these preparations have been used, it is advisable not to start therapy with DIFFERIN® Gel until the effects of such preparations in the skin have subsided.

*Carcinogenesis, Mutagenesis, Impairment of Fertility:* Carcinogenicity studies with adapalene have been conducted in mice at topical doses of 0.3, 0.9, and 2.6 mg/kg/dav and in rats at oral doses of 0.15, 0.5, and 1.5 mg/kg/dav approximately 4-75 times the maximal daily human topical dose. In the ora approximately 4-75 times the mana damp furning the product uses in the oral study, positive linear trends were observed in the incidence of follicular cell adenomas and carcinomas in the thyroid glands of female rats, and in the incidence of benign and malignant pheochromocytomas in the adrenal medullas of male rats.

No photocarcinogenicity studies were conducted. Animal studies have shown an increased tumorigenic risk with the use of pharmacologically similar drugs (e.g., retinoids) when exposed to UV irradiation in the laboratory or to sunlight. bugh the significance of these studies to human use is not clear, patients should be advised to avoid or minimize exposure to either sunlight or artificial UV irradiation source

In a series of in vivo and in vitro studies, adapalene did not exhibit mutagenic or genotoxic activities.

or genotoxic activities. **Pregnancy:** Teratogenic effects. Pregnancy Category C. No teratogenic effects were seen in rats at oral doses of adapalene 0.15 to 5.0 mg/kg/day, up to 120 times the maximal daily human topical dose. Cutaneous route teratology studies conducted in rats and rabbits at doses of 0.6, 2.0, and 6.0 mg/kg/day, up to 150 times the maximal daily human topical dose exhibited no fetotoxicity and only minimal increases in supernumerary ribs in rats. There are no adequate and well-controlled studies in pregnant women. Adapalene should be used dur-ing pregnancy only if the potential benefit justifies the potential risk to the fetus. **Numeris Methoders** II is not known whether this druce is exercised in human Nursing Mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when DIFFERIN® Gel is administered to a nursing woman.

Pediatric Use: Safety and effectiveness in pediatric patients below the age of 12 have not been established.

ADVERSE REACTIONS: Some adverse effects such as erythema, scaling, dyness, pruritus, and burning will occur in 10-40% of patients. Pruritus or burning immediately after application also occurs in approximately 20% of patients. The following additional adverse experiences were reported in security of the state of extents divident initiation, burning clinicing, and the approximately 1% or less of patients: skin irritation, burning/stinging, erythema, sunburn, and acne flares. These are most commonly seen during the first month of therapy and decrease in frequency and severity thereafter. All adverse effects with use of DIFFERIN® Gel during clinical trials were reversible upon discontinuation of therapy

an extra step to ensure that patients know what their medications are for. For example, in addition to printing "Statin 20 mg #90," the label also says "cholesterol med."

"Patients love it, and pharmacists appreciate being able to read the prescriptions without ever having to call and ask me what I wrote," said Dr. Lucas.

The desktop labeling system also integrates with software programs to pro-duce individual labels. "It's nice because it has an optional mailing bar code to facili-

OVERDOSAGE: DIFFERIN® Gel is intended for cutaneous use only. If the OVERDUSACE: DIFFERING GeT is intended for cutatious use only. If the medication is applied excessively, no more rapid or better results will be obtained and marked redness, peeling, or discomfort may occur. The acute oral toxicity of DIFFERIN® GeT in mice and rats is greater than 10 mL/kg. Chronic ingestion of the drug may lead to the same side effects as those associated with excessive oral intake of Vitamin A.

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Vorth, Texas 76177 USA	San Antonio, Texas 78215 USA
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 3. Thiboutot D, Gold MH, Jarratt MT, et al. Randomized controlled trial of the tolerability, safety, and efficacy of adapalene gel 0.1% and tretinoin microsphere gel 0.1% for the treatment of acne vulgaris. *Cutis.* 2001;68:10-19. 4. Dosik JS, Homer K, Arsonnaud S. Cumulative irritation phetratial of adapalene 0.1% cream and gel compared with tazarotene cream 0.05% and 0.1%. *Cutis.* 2005;75:289-293. 5. Data on file. Galderma Laboratories, L.P. 6. NDC Health data, 2005.

# Tough and Tender.

In treating acne: the efficacy you expect and the tolerability your patients deserve.



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www.differin.com www.galdermausa.com



tate mailing," she added. The label maker also prints individual postage stamps using the Web site www.stamps.com.

In addition, the data management software that comes with the machine contains



**Pharmacists** appreciate not having to call and ask me what I wrote for a prescription.

DR. LUCAS

our entire Rolodex file of physicians, so that patients referred to another facility get a legible copy of the name, address, and phone number on a printed label that can be affixed to the lab sheets or tickler file."

Dr. Lucas also prints legible, customized instructions for each patient, and puts a second copy into each chart. 

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