

Of Indoor Tanners, Men Less Aware of Risk

BY BRUCE JANCIN

DENVER — Less than 12% of women and less than 7% of men who tan indoors are regular users of sunscreen, according to a national survey of white adults.

Overall, women who use tanning parlors have a better understanding of the associated risks than men who do so.

Of women who tan indoors, 38% are

aware that the practice increases their skin cancer risk, compared with only 11% of men who tan indoors, Kelvin Choi reported at the annual meeting of the American Association for Cancer Research.

Similarly, 27% of women who tan indoors perceive themselves as being at high risk of skin cancer, and another 17% see themselves as at moderate risk. In contrast, only 3% of men who tan in-

doors see themselves as at high risk, and 4% perceive themselves as at moderate risk for skin cancer, according to Mr. Choi of the University of Minnesota, Minneapolis.

Most studies on indoor tanning practices have focused on adolescents and young adult women.

Addressing this limitation, Mr. Choi and his coinvestigators analyzed data from the National Cancer Institute 2005

Health Information National Trends Survey.

The investigators zeroed in on the knowledge and attitudes regarding skin cancer prevention among a randomly selected subset that included 2,869 white men and women aged 18-64 years.

Overall, 18% of the women and 6% of men reported tanning indoors within the prior year.

Indoor tanning was most popular in the Midwest; women living there were 2.5 times more likely to use tanning beds than those in the West, where the use was least frequent. Midwestern men were 2.9-fold more likely to tan indoors than Westerners.

Both women and men who tan indoors tended to be younger. In the peak age category for indoor tanning—the

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18- to 24-year-olds—36% of women and 12% of men reported having used a tanning parlor in the past year. Individuals with at least some college education and who earned more than \$35,000 annually were more likely to tan indoors, according to Mr. Choi.

Men who lived in a metropolitan area were 3.3-fold more likely to tan indoors than those living elsewhere. In contrast, women were equally likely to tan indoors regardless of whether they were urbanites or not.

The use of spray tanning products was closely linked to the use of tanning beds. Men who used these products were 7.5-fold more likely to have used a tanning bed in the past year than those who didn't use them.

Women who used spray tanning products were 2.6-fold more likely to have used a tanning bed in the past year, Mr. Choi noted. ■

EPIDUO™

(adapalene and benzoyl peroxide) Gel 0.1% / 2.5%

For Topical Use Only

Not For Ophthalmic, Oral, or Intravaginal Use.

BRIEF SUMMARY

INDICATIONS AND USAGE

EPIDUO Gel is a combination of adapalene, a retinoid, and benzoyl peroxide, and is indicated for the topical treatment of acne vulgaris in patients 12 years of age and older.

CONTRAINDICATIONS

None.

WARNINGS AND PRECAUTIONS

Ultraviolet Light and Environmental Exposure: Avoid exposure to sunlight and sunlamps. Wear sunscreen when sun exposure cannot be avoided.

Erythema, scaling, dryness, and stinging/burning may occur with use of EPIDUO Gel.

ADVERSE REACTIONS

Observed local adverse reactions in patients treated with EPIDUO Gel were erythema, scaling, dryness, stinging, and burning. Other most commonly reported adverse events ($\geq 1\%$) in patients treated with EPIDUO Gel were dry skin, contact dermatitis, application site burning, application site irritation, skin irritation.

DRUG INTERACTIONS

Exercise caution in using preparations containing sulfur, resorcinol, or salicylic acid, medicated or abrasive soaps and cleansers and products with high concentrations of alcohol or astringents in combination with EPIDUO Gel. Concomitant use of topical products with a strong drying effect can increase irritation. Use with caution.

Pregnancy

Pregnancy Category C. There are no well-controlled trials in pregnant women treated with EPIDUO Gel. Animal reproduction studies have not been conducted with the combination gel or benzoyl peroxide. Furthermore, such studies are not always predictive of human response; therefore, EPIDUO Gel should be used during pregnancy only if the potential benefit justifies the risk to the fetus.

No teratogenic effects were observed in rats treated with oral doses of 0.15 to 5.0 mg adapalene/kg/day, up to 25 times (mg/m²/day) the maximum recommended human dose (MRHD) of 2 grams of EPIDUO Gel. However, teratogenic changes were observed in rats and rabbits when treated with oral doses of ≥ 25 mg adapalene/kg/day representing 123 and 246 times MRHD, respectively. Findings included cleft palate, microphthalmia, encephalocele and skeletal abnormalities in rats; and umbilical hernia, exophthalmos and kidney and skeletal abnormalities in rabbits.

Dermal teratology studies conducted in rats and rabbits at doses of 0.6-6.0 mg adapalene/kg/day [25-59 times (mg/m²) the MRHD] exhibited no fetotoxicity and only minimal increases in supernumerary ribs in both species and delayed ossification in rabbits.

Nursing Mothers

It is not known whether adapalene or benzoyl peroxide is excreted in human milk following use of EPIDUO Gel. Because many drugs are excreted in human milk, caution should be exercised when EPIDUO Gel is administered to a nursing woman.

Pediatric Use

Safety and effectiveness of EPIDUO Gel in pediatric patients under the age of 12 have not been established.

Geriatric Use

Clinical studies of EPIDUO Gel did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects.

Carcinogenesis, Mutagenesis, Impairment of Fertility

No carcinogenicity, phototoxicity, genotoxicity, or fertility studies were conducted with EPIDUO Gel.

Carcinogenicity studies with adapalene have been conducted in mice at topical doses of 0.4, 1.3, and 4.0 mg/kg/day (1.2, 3.9, and 12 mg/m²/day), and in rats

Rx only

at oral doses of 0.15, 0.5, and 1.5 mg/kg/day (0.9, 3.0, and 9.0 mg/m²/day). In terms of body surface area, the highest dose levels are 9.8 (mice) and 7.4 times (rats) the MRHD of 2 grams of EPIDUO Gel. In the rat study, an increased incidence of benign and malignant pheochromocytomas in the adrenal medulla of male rats was observed.

No significant increase in tumor formation was observed in rodents topically treated with 15-25% benzoyl peroxide carbopol gel (6-10 times the concentration of benzoyl peroxide in EPIDUO Gel) for two years. Rats received maximum daily applications of 138 (males) and 205 (females) mg benzoyl peroxide/kg. In terms of body surface area, these levels are 27-40 times the MRHD. Similar results were obtained in mice topically treated with 25% benzoyl peroxide carbopol gel for 56 weeks followed by intermittent treatment with 15% benzoyl peroxide carbopol gel for rest of the 2 years study period, and in mice topically treated with 5% benzoyl peroxide carbopol gel for two years.

The role of benzoyl peroxide as a tumor promoter has been well established in several animal species. However, the significance of this finding in humans is unknown.

In a phototoxicity study conducted with 5% benzoyl peroxide carbopol gel, no increase in UV-induced tumor formation was observed in hairless mice topically treated for 40 weeks.

No phototoxicity studies were conducted with adapalene. However, 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 sunlight. Although the significance of these findings to humans is not clear, patients should be advised to avoid or minimize exposure to either sunlight or artificial irradiation sources.

Adapalene did not exhibit mutagenic or genotoxic effects *in vitro* (Ames test, Chinese hamster ovary cell assay, mouse lymphoma TK assay) or *in vivo* (mouse micronucleus test).

Bacterial mutagenicity assays (Ames test) with benzoyl peroxide has provided mixed results, mutagenic potential was observed in a few but not in a majority of investigations. Benzoyl peroxide has been shown to produce single-strand DNA breaks in human bronchial epithelial and mouse epidermal cells, it has caused DNA-protein cross-links in the human cells, and has also induced a dose-dependent increase in sister chromatid exchanges in Chinese hamster ovary cells. In rat oral studies, 20 mg adapalene/kg/day (120 mg/m²/day; 98 times the MRHD based on mg/m²/day comparison) did not affect the reproductive performance and fertility of F₀ males and females, or growth, development and reproductive function of F₁ offspring.

No fertility studies were conducted with benzoyl peroxide.

PATIENT COUNSELING INFORMATION

– Advise patients to cleanse the area to be treated with a mild or soapless cleanser; pat dry. Apply EPIDUO Gel as a thin layer, avoiding the eyes, lips and mucous membranes.

– Advise patients not to use more than the recommended amount and not to apply more than once daily as this will not produce faster results, but may increase irritation.

– EPIDUO Gel may cause irritation such as erythema, scaling, dryness, stinging or burning.

– Advise patients to minimize exposure to sunlight, including sunlamps. Recommend the use of sunscreen products and protective apparel, (e.g., hat) when exposure cannot be avoided.

– EPIDUO Gel may bleach hair and colored fabric.

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References: 1. Data on file. Galderma Laboratories, L.P. Phase 3 data. 2. Thiboutot DM, Weiss J, Bucko A, et al; Adapalene-BPO Study Group. Adapalene-benzoyl peroxide, a fixed-dose combination for the treatment of acne vulgaris: results of a multicenter, randomized double-blind, controlled study. *J Am Acad Dermatol*. 2007;57(5):791-799.

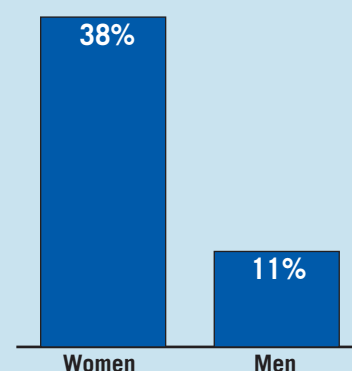
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peroxide) Gel 0.1% / 2.5%

Indoor Tanners Aware of Their Increased Cancer Risk



Note: Based on data from 2,869 white men and women aged 18-64 years.
Source: Mr. Choi