

Tort Reform High on Priority List

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group's annual meeting in February. The medical community is in the best position yet to accomplish this goal, he said.

As president, Dr. Cockerell plans to focus on training a group of dermatologists who can be leaders in academia and energize that segment of the field. An AAD task force is working on this issue, and Dr. Cockerell said he hopes it can turn the tide on the decline of academic dermatology.

Over the next 3 years, Dr. Cockerell said he wants to double the amount of mon-

ey in the American Academy of Dermatology Association's Political Action Committee (SkinPAC).

Among his long-term goals is to work to decrease the incidence of skin cancer over the next 10-20 years. Dr. Cockerell cited the work that dentists have done to decrease the incidence of tooth decay as a model.

"I get tired of every year hearing that the incidence of melanoma keeps going up and up and up," he said.

And Dr. Cockerell asked the members

of AAD to go back to their communities to teach and set an example.

Dr. Cockerell also pledged to continue the initiatives started by outgoing AAD President Boni E. Elewski, M.D., professor of dermatology at the University of Alabama, Birmingham, including her efforts to increase unity within the dermatology community.

On the education front, Dr. Elewski said AAD has developed and begun to conduct regional continuing medical education (CME) courses on psoriasis therapies in conjunction with the National Psoriasis Foundation. AAD has also established a committee on maintenance of certifica-

tion that will work with the American Board of Dermatology to develop educational programs.

In the future, AAD officials plan to develop Web-based CME, Dr. Elewski said.

In addition, AAD is collaborating with the American Society for Dermatologic Surgery to explore the need for procedure credentialing as a way to protect the scope of practice.

AAD is also working to quantify the burden of skin disease in the United States and demonstrate the need for increased funding for skin disease research. The results of this study are expected to be announced this month. ■

BRIEF SUMMARY OF PRESCRIBING INFORMATION

Duac® Topical Gel (clindamycin, 1% - benzoyl peroxide, 5%)

For Dermatological Use Only.
Not for Ophthalmic Use.

Rx Only

INDICATIONS AND USAGE

Duac Topical Gel is indicated for the topical treatment of inflammatory acne vulgaris.

Duac Topical Gel has not been demonstrated to have any additional benefit when compared to benzoyl peroxide alone in the same vehicle when used for the treatment of non-inflammatory acne.

CONTRAINDICATIONS

Duac Topical Gel is contraindicated in those individuals who have shown hypersensitivity to any of its components or to clindamycin. It is also contraindicated in those having a history of regional enteritis, ulcerative colitis, pseudomembranous colitis, or antibiotic-associated colitis.

WARNINGS

ORALLY AND PARENTERALLY ADMINISTERED CLINDAMYCIN HAS BEEN ASSOCIATED WITH SEVERE COLITIS WHICH MAY RESULT IN PATIENT DEATH. USE OF THE TOPICAL FORMULATION OF CLINDAMYCIN RESULTS IN ABSORPTION OF THE ANTIBIOTIC FROM THE SKIN SURFACE. DIARRHEA, BLOODY DIARRHEA, AND COLITIS (INCLUDING PSEUDOMEMBRANOUS COLITIS) HAVE BEEN REPORTED WITH THE USE OF TOPICAL AND SYSTEMIC CLINDAMYCIN. STUDIES INDICATE A TOXIN(S) PRODUCED BY CLOSTRIDIA IS ONE PRIMARY CAUSE OF ANTIBIOTIC-ASSOCIATED COLITIS. THE COLITIS IS USUALLY CHARACTERIZED BY SEVERE PERSISTENT DIARRHEA AND SEVERE ABDOMINAL CRAMPS AND MAY BE ASSOCIATED WITH THE PASSAGE OF BLOOD AND MUCUS. ENDOSCOPIC EXAMINATION MAY REVEAL PSEUDOMEMBRANOUS COLITIS. STOOL CULTURE FOR *Clostridium difficile* AND STOOL ASSAY FOR *Clostridium difficile* TOXIN MAY BE HELPFUL DIAGNOSTICALLY. WHEN SIGNIFICANT DIARRHEA OCCURS, THE DRUG SHOULD BE DISCONTINUED. LARGE BOWEL ENDOSCOPY SHOULD BE CONSIDERED TO ESTABLISH A DEFINITIVE DIAGNOSIS IN CASES OF SEVERE DIARRHEA. ANTIPERISTALTIC AGENTS SUCH AS OPIATES AND DIPHENOXYLATE WITH ATROPINE MAY PROLONG AND/OR WORSEN THE CONDITION. DIARRHEA, COLITIS AND PSEUDOMEMBRANOUS COLITIS HAVE BEEN OBSERVED TO BEGIN UP TO SEVERAL WEEKS FOLLOWING CESSATION OF ORAL AND PARENTERAL THERAPY WITH CLINDAMYCIN.

Mild cases of pseudomembranous colitis usually respond to drug discontinuation alone. In moderate to severe cases, consideration should be given to management with fluids and electrolytes, protein supplementation and treatment with an antibacterial drug clinically effective against *Clostridium difficile* colitis.

PRECAUTIONS

General: For dermatological use only; not for ophthalmic use. Concomitant topical acne therapy should be used with caution because a possible cumulative irritancy effect may occur, especially with the use of peeling, desquamating, or abrasive agents.

The use of antibiotic agents may be associated with the overgrowth of nonsusceptible organisms, including fungi. If this occurs, discontinue use of this medication and take appropriate measures.

Avoid contact with eyes and mucous membranes.

Clindamycin and erythromycin containing products should not be used in combination. *In vitro* studies have shown antagonism between these two antimicrobials. The clinical significance of this *in vitro* antagonism is not known.

Information for Patients: Patients using Duac Topical Gel should receive the following information and instructions:

- Duac Topical Gel is to be used as directed by the physician. It is for external use only. Avoid contact with eyes, and inside the nose, mouth, and all mucous membranes, as this product may be irritating.
- This medication should not be used for any disorder other than that for which it was prescribed.
- Patients should not use any other topical acne preparation unless otherwise directed by their physician.
- Patients should report any signs of local adverse reactions to their physician.
- Duac Topical Gel may bleach hair or colored fabric.
- Duac Topical Gel can be stored at room temperature up to 25°C (77°F) for up to 2 months. Do not freeze. Keep tube tightly closed. Keep out of the reach of small children. Discard any unused product after 2 months.
- Before applying Duac Topical Gel to affected areas, wash the skin gently, rinse with warm water, and pat dry.
- Excessive or prolonged exposure to sunlight should be limited. To minimize exposure to sunlight, a hat or other clothing should be worn.

References: 1. Leyden JJ. A review of the use of combination therapies for the treatment of acne vulgaris. *J Am Acad Dermatol.* 2003;49:5200-5210. 2. Vernon P. Acne vulgaris: current treatment approaches. *Adv Nurse Pract.* 2003;11:59-62. 3. Toyoda M, Morohashi M. An overview of topical antibiotics for acne treatment. *Dermatology.* 1998;196:130-134. 4. Tan H-H. Topical antibacterial treatments for acne vulgaris: comparative review and guide to selection. *Am J Clin Dermatol.* 2004;5:79-84. 5. Lookingbill DP, Chalker DK, Lindholm JS, et al. Treatment of acne with a combination clindamycin/benzoyl peroxide gel compared with clindamycin gel, benzoyl peroxide gel and vehicle gel: combined results of two double-blind investigations. *J Am Acad Dermatol.* 1997;37:590-595. 6. Fagundes DS, Fraser JM, Klauda HC. Difference in the irritation potential and cosmetic acceptability of two combination topical acne gels—combined results of two comparative studies. *Today's Ther Trends.* 2003;21:269-275. 7. Tanghetti EA, Gold MH. A two-center patient preference study comparing two benzoyl peroxide/clindamycin gels in acne vulgaris patients. Poster presented at: 63rd Annual Meeting of the American Academy of Dermatology; February 18-22, 2005; New Orleans, La.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Benzoyl peroxide has been shown to be a tumor promoter and progression agent in a number of animal studies. The clinical significance of this is unknown.

Benzoyl peroxide in acetone at doses of 5 and 10 mg administered twice per week induced squamous cell skin tumors in transgenic TgAC mice in a study using 20 weeks of topical treatment.

Genotoxicity studies were not conducted with Duac Topical Gel. Clindamycin phosphate was not genotoxic in *Salmonella typhimurium* in a rat micronucleus test. Benzoyl peroxide has been found to cause DNA strand breaks in a variety of mammalian cell types, to be mutagenic in *Salmonella typhimurium* tests by some but not all investigators, and to cause sister chromatid exchanges in Chinese hamster ovary cells. Studies have not been performed with Duac Topical Gel or benzoyl peroxide to evaluate the effect on fertility. Fertility studies in rats treated orally with up to 300 mg/kg/day of clindamycin (approximately 120 times the amount of clindamycin in the highest recommended adult human dose of 2.5 g Duac Topical Gel, based on mg/m²) revealed no effects on fertility or mating ability.

Pregnancy: Teratogenic Effects: Pregnancy Category C: Animal reproduction studies have not been conducted with Duac Topical Gel or benzoyl peroxide. It is also not known whether Duac Topical Gel can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Duac Topical Gel should be given to a pregnant woman only if clearly needed.

Developmental toxicity studies performed in rats and mice using oral doses of clindamycin up to 600 mg/kg/day (240 and 120 times the amount of clindamycin in the highest recommended adult human dose based on mg/m², respectively) or subcutaneous doses of clindamycin up to 250 mg/kg/day (100 and 50 times the amount of clindamycin in the highest recommended adult human dose based on mg/m², respectively) revealed no evidence of teratogenicity.

Nursing Women: It is not known whether Duac Topical Gel is secreted into human milk after topical application. However, orally and parenterally administered clindamycin has been reported to appear in breast milk. Because of the potential for serious adverse reactions in nursing infants, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

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

ADVERSE REACTIONS

During clinical trials, all patients were graded for facial erythema, peeling, burning, and dryness on the following scale: 0 = absent, 1 = mild, 2 = moderate, and 3 = severe. The percentage of patients that had symptoms present before treatment (at baseline) and during treatment were as follows:

	Local reactions with use of Duac Topical Gel % of patients using Duac Topical Gel with symptom present Combined results from 5 studies (n = 397)					
	Before Treatment (Baseline)			During Treatment		
	Mild	Moderate	Severe	Mild	Moderate	Severe
Erythema	28%	3%	0	26%	5%	0
Peeling	6%	<1%	0	17%	2%	0
Burning	3%	<1%	0	5%	<1%	0
Dryness	6%	<1%	0	15%	1%	0

(Percentages derived by # subjects with symptom score/# enrolled Duac subjects, n = 397).

HOW SUPPLIED

Duac® (clindamycin, 1% - benzoyl peroxide, 5%) Topical Gel is available in a 45 gram tube - NDC 0145-2371-05.

Prior to Dispensing: Store in a cold place, preferably in a refrigerator, between 2°C and 8°C (36°F and 46°F). Do not freeze.

Dispensing Instructions for the Pharmacist: Dispense Duac Topical Gel with a 60 day expiration date and specify "Store at room temperature up to 25°C (77°F). Do not freeze."

Keep tube tightly closed. Keep out of the reach of small children.

U.S. Patent Nos. 5,466,446, 5,446,028, 5,767,098, and 6,013,637
Patents Pending



Stiefel Laboratories, Inc.
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833185 Rev. 0504

Senator Pushes For Individual Insurance Rule

NEW ORLEANS — The real social crisis facing America right now isn't fixing Social Security but tackling the problem of the uninsured, former Sen. John Breaux said at the annual meeting of the American Academy of Dermatology.

"The crisis that I see in health care in this country is the fact that we have 44 million Americans who have no form of health insurance whatsoever," he said.

And the crisis is likely to get worse as more and more companies are opting not to provide health insurance to their employees, said Mr. Breaux, a Democrat who represented Louisiana in the U.S. Senate for the past 18 years.

But the problem isn't how much money is being spent on the system, he said, it's the way the system is organized. Currently, most individuals receive their health coverage either through their employer or through Medicare, Medicaid, or the Department of Veterans Affairs. If they don't fit into one of these eligible groups, or their employer doesn't provide coverage, they are unlikely to be insured.

One way to get away from this traditional system of coverage would be to create a federal mandate that every individual must have health insurance, Mr. Breaux said. Under this type of plan, the government would offer subsidies to low-income individuals to purchase coverage.

The government would also need to create some type of state or multistate purchasing pools and ensure that the system prevents adverse risk selection so that insurance could be purchased at a reasonable price, he said.

Under such a system, if an individual without insurance sought care in an emergency department, he or she would be enrolled in a purchasing pool at that time, he said. Or people might need to show proof of health insurance when they get their driver's license, he said.

And providing insurance to more Americans would cut down on overall costs because it would allow more people to have access to preventive treatments. The best way to get a handle on health care costs is through disease management, Mr. Breaux said, but you have to get the patients into the physician's office to do that.

—Mary Ellen Schneider