



BY WILLIAM G. WILKOFF, M.D.

## LETTERS FROM MAINE

# Low-Impact Parenting

Ask a group of primary care pediatricians who are old enough to have children in college and they will tell you that the mix of patients in their offices has changed significantly since they opened

their practices. The increase in mental health complaints and the decrease in serious bacterial infections such as meningitis and epiglottitis have been striking.

A less talked-about shift in traffic flow has been the decrease in the number of victims of minor trauma who limp or are carried across the threshold of the average general pediatrician's office.

There are several reasons for this decline in the bumps, cuts, and bruises. One is the

advent of emergency medicine as a specialty and the resulting ubiquity of fully staffed emergency departments. A related phenomenon is the realization by hospitals that minor trauma and walk-in illnesses can generate income that can help fund the overhead costs for more serious trauma treatments.

Aggressive marketing by these hungry hospitals has convinced many parents that the hospital "ER" is the place to go when

one's child is injured, regardless of how minor the trauma. The marketing has been so successful in our community that parents are often surprised that we can, and occasionally still do, perform suture repairs and simple casting in our office.

Some recently trained pediatricians may be less comfortable seeing minor trauma victims in the office setting, particularly if they don't have access to the security blankets of lab and x-ray.

Experienced physicians have learned that even a simple three-suture repair can throw their busy offices into chaos, and some may instruct their staff to triage every injured child to the emergency department just to keep some semblance of calm in the waiting room. Not surprisingly, it doesn't take long for parents to catch on that their pediatricians aren't interested in seeing injured children, and they will self-refer to the emergency department the next time their child trips and falls.

I suspect that another and more troubling reason that we are seeing fewer injured children in our offices is that there are fewer children who are active enough to sustain even minor trauma. I don't have any statistics to support this observation, but the math is pretty simple. We know that more children are spending more of their time doing nothing but sitting in front of a video screen.

Couch potatoes can get bruised if they roll off onto the floor, but those injuries don't seem to generate enough discomfort to get the little video addicts to turn off the TV and come to the office. Even the hyperactive kids, a group that I could count on for a steady supply of cuts and dings, are being throttled down with amphetamines.

It is so unusual to see a child with grass stains on his knees that some parents feel the need to apologize for this once commonplace physical finding. Of course, I reassure them that these stains and lower extremity bruises are signs of good health. But, their rarity is troubling.

We adults must certainly shoulder a large part of the blame for this drought in minor trauma. We continue to "make poor choices," which is new millennium—speak for "do stupid things," when it comes to raising our children. For example, many of you have heard that a school system in Massachusetts recently decided to ban from its playgrounds the game of "tag" because it was deemed a dangerous activity.

The trend toward this low-impact style of parenting is so prevalent that I suggest you sell your stock in Johnson & Johnson and invest in bubble wrap! Because I'm sure my great-grandchildren won't know what a Band-Aid is for, and their parents will be swaddling them in protective layers of bubble wrap before allowing them to leave the house. If indeed they are even allowed to step outside!

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### Brief Summary

## 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 lincomycin. 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.

**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* or 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/m<sup>2</sup>) 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/m<sup>2</sup>, 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/m<sup>2</sup>, 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 Patent Pending



Stiefel Laboratories, Inc.  
Coral Gables, FL 33134

833185 Rev. 0504

once-a-day  
**Duac**  
topical gel  
(clindamycin, 1% - benzoyl peroxide, 5%)  
**Your Choice is Clear™**

### REFERENCES:

- IMS Data, Oct. 2006.
- Duac [Prescribing Information]. Stiefel Laboratories, Inc., 2004.

Duac is a registered trademark of Stiefel Laboratories, Inc. Your Choice is Clear, Make the Clear Choice, and Research in Dermatology are trademarks of Stiefel Laboratories, Inc.