

Uninsured Rate Climbs, Reflecting 10-Year Trend

BY ALICIA AULT

The number of uninsured Americans rose last year, with 21% of all adults aged 18-64 years reporting that they were uninsured at the time that they were interviewed for the National Health Interview Survey, federal officials reported.

That's up from 19.7% the previous year and reflects a trend over the past decade of an increasing lack of health insurance, at least among adults, according to a survey by the National Center for Health Statistics, a part of the Centers for Disease Control and Prevention. Rates of coverage for children, on the other hand, have mostly improved.

Since 1999, increasing proportions of people have reported that they were uninsured at the time of the annual survey, for part of the year prior to their interviews, and for a year or more, said the NCHS in its report, which was released early and will be published in CDC's Morbidity and Mortality Weekly Report.

Overall, 46.3 million people—or 15.4% of the population—were uninsured at the time they were interviewed in 2009. The survey found that even greater numbers of people reported that they were uninsured for at least part of the year before the interview—about 58.5 million—but that a slightly smaller number, 32.8 million, had been uninsured for more than a year at the time they were queried.

A greater proportion of children than adults were covered by public health plans, which could explain the children's higher rate of coverage, according to the survey. In 2009, 37.7% of children under age 18

were covered by a public plan, up from 34.2% the previous year. Rates of public coverage for low-income children increased. Federal officials in both the Obama and Bush administrations have emphasized enrolling more eligible children in the public Children's Health Insurance Plan, which is administered by states.

Conversely, only 14.4% of adults aged 18-64 years had public coverage. And private coverage for adults declined from

68% in 2008 to 66% in 2009, according to the survey.

There was no significant change in private coverage for children of any income level.

States with larger Hispanic populations had greater proportions of uninsured. One-quarter of Texas and Florida residents under age 65 years were uninsured at the time of the interview. One-fifth did not have coverage in California and Geor-

gia. In Florida, 13% of children lacked coverage when interviewed, and in Texas, that number was almost 17%.

Nine states had lower rates of uninsured than the national average of 17.5%: Illinois, Massachusetts, Michigan, New Jersey, New York, Ohio, Pennsylvania, Washington, and Wisconsin. ■

For more information, go to www.cdc.gov/nchs.

The following is a brief summary only; see full prescribing information for complete product information.

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 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 WORSE 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. Patients who develop allergic symptoms such as severe swelling or shortness of breath should discontinue use and contact their physician immediately.
- 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/m²) revealed no effects on fertility or mating ability.

Pregnancy: Teratogenic Effects: Pregnancy Category C: Animal reproduction studies have not been con-

ducted 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® Topical Gel subjects, n = 397).

Anaphylaxis, as well as allergic reactions leading to hospitalization, has been reported in post-marketing use with Duac® Topical Gel. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

HOW SUPPLIED
Duac® (clindamycin, 1% - benzoyl peroxide, 5%) Topical Gel is available in:

- 45 gram tube NDC 0145-2371-05
- Care System (CS) Convenience Kit NDC 0145-2367-01 (includes Duac® Topical Gel (clindamycin, 1% - benzoyl peroxide, 5%) 45 grams and SFC™ Lotion 106.6 mL (3.6 Fl Oz))

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 No. 5,466,446
Patent Pending
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DTG-28-2009-USA

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