

POLICY & PRACTICE

Uninsured Figures Climb

The number of people in the United States without health insurance edged higher in 2005, fueled in part by a drop in employer-sponsored health insurance, according to figures released in August from the U.S. Census Bureau. In 2005, 46.6 million people were uninsured, up from 45.3 million the year before. The percentage of people covered by employer-sponsored health insurance dropped from 59.8% to 59.5% between 2004 and 2005, while the percentage covered by government insurance stayed the same, according to the

census figures. The new figures, compiled as part of the Current Population Survey, showed that the number of uninsured children also increased. Between 2004 and 2005, the number of uninsured children rose from 7.9 million to 8.3 million. And children living in poverty were the most likely to be uninsured, with the uninsured rate in 2005 at 19% for children living in poverty, compared with 11.2% of children overall. The American Medical Association issued a statement calling for action to address the uninsured problem. "The AMA plan for reducing the number of the

uninsured advocates expanded coverage and choice through a system of refundable tax credits based on income, individually selected and owned health insurance, and market reforms that will enhance new, affordable insurance options," Dr. Ardis Hoven, an AMA board member, said in a statement.

Teen Risky Behavior Declines

Over the past 15 years, fewer U.S. high school students have been engaging in sexual behaviors that would put them at risk for HIV, according to data from the Centers for Disease Control and Prevention (CDC). The percentage of high

school students who reported ever having had sexual intercourse dropped from 1991 to 2005, along with the percentage of students reporting multiple sexual partners and current sexual activity, the CDC reported in the Morbidity and Mortality Weekly Report. For example, the prevalence of multiple sexual partners among U.S. high school students decreased 24% from 1991 to 2005, dropping from 18.7% to 14.3%. In addition, condom use is on the rise among U.S. teens. The CDC found that among currently sexually active students, condom use increased from 46.2% in 1991 to 62.8% in 2005, or about a 36% increase. Officials at the CDC analyzed data from eight national Youth Risk Behavior Surveys.

BenzaClin® Topical Gel

(clindamycin - benzoyl peroxide gel)

Brief summary. Please see full prescribing information for complete product information.

Topical Gel: clindamycin (1%) as clindamycin phosphate, benzoyl peroxide (5%) For Dermatological Use Only - Not for Ophthalmic Use *Reconstitute Before Dispensing*

INDICATIONS AND USAGE

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

CONTRAINDICATIONS

BenzaClin 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, 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 *C. 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 *C. 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 **BenzaClin Topical Gel** should receive the following information and instructions:

- BenzaClin 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 physician.
- Patients should minimize or avoid exposure to natural or artificial sunlight (tanning beds or UVA/B treatment) while using **BenzaClin Topical Gel**. To minimize exposure to sunlight, a wide-brimmed hat or other protective clothing should be worn, and a sunscreen with SPF 15 rating or higher should be used.
- Patients should report any signs of local adverse reactions to their physician.
- BenzaClin Topical Gel** may bleach hair or colored fabric.
- BenzaClin Topical Gel** can be stored at room temperature up to 25°C (77°F) for 3 months. Do not freeze. Discard any unused product after 3 months.
- Before applying **BenzaClin Topical Gel** to affected areas wash the skin gently, then rinse with warm water and pat dry.

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 skin tumors in transgenic Tg.AC mice in a study using 20 weeks of topical treatment.

In a 52 week dermal photocarcinogenicity study in hairless mice, the median time to onset of skin tumor formation was decreased and the number of tumors per mouse increased following chronic concurrent topical administration of **BenzaClin Topical Gel** with exposure to ultraviolet radiation (40 weeks of treatment followed by 12 weeks of observation).

Genotoxicity studies were not conducted with **BenzaClin Topical Gel**. Clindamycin phosphate was not genotoxic in *Salmonella typhimurium* or in a rat micronucleus test. Clindamycin phosphate sulfoxide, an oxidative degradation product of clindamycin phosphate and benzoyl peroxide, was not clastogenic in a mouse micronucleus test. Benzoyl peroxide has been found to cause DNA strand breaks in a variety of mammalian cell types, to be mutagenic in *S. 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 **BenzaClin 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 **BenzaClin Topical Gel**, based on mg/m²) revealed no effects on fertility or mating ability.

Pregnancy: Teratogenic Effects: Pregnancy Category C:

Animal reproductive/developmental toxicity studies have not been conducted with **BenzaClin Topical Gel** or benzoyl peroxide. Developmental toxicity studies performed in rats and mice using oral doses of clindamycin up to 600 mg/kg/day (240 and 120 times 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.

There are no well-controlled trials in pregnant women treated with **BenzaClin Topical Gel**. It also is not known whether **BenzaClin Topical Gel** can cause fetal harm when administered to a pregnant woman.

Nursing Women: It is not known whether **BenzaClin Topical Gel** is excreted in 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, the most frequently reported adverse event in the **BenzaClin** treatment group was dry skin (12%). The Table below lists local adverse events reported by at least 1% of patients in the **BenzaClin** and vehicle groups.

Local Adverse Events - all causalities in >= 1% of patients		
	BenzaClin n = 420	Vehicle n = 168
Application site reaction	13 (3%)	1 (<1%)
Dry skin	50 (12%)	10 (6%)
Pruritus	8 (2%)	1 (<1%)
Peeling	9 (2%)	-
Erythema	6 (1%)	1 (<1%)
Sunburn	5 (1%)	-

The actual incidence of dry skin might have been greater were it not for the use of a moisturizer in these studies.

DOSAGE AND ADMINISTRATION

BenzaClin Topical Gel should be applied twice daily, morning and evening, or as directed by a physician, to affected areas after the skin is gently washed, rinsed with warm water and patted dry.

HOW SUPPLIED AND COMPOUNDING INSTRUCTIONS

Size (Net Weight)	NDC 0066-	Benzoyl Peroxide Gel	Active Clindamycin Powder (In plastic vial)	Purified Water To Be Added to each vial
25 grams	0494-25	19.7g	0.3g	5 mL
50 grams	0494-50	41.4g	0.6 g	10 mL
50 grams (pump)	0494-55	41.4g	0.6 g	10 mL

Prior to dispensing, tap the vial until powder flows freely. Add indicated amount of purified water to the vial (to the mark) and immediately shake to completely dissolve clindamycin. If needed, add additional purified water to bring level up to the mark. Add the solution in the vial to the gel and stir until homogenous in appearance (1 to 1½ minutes). For the 50 gram pump only, reassemble jar with pump dispenser. **BenzaClin Topical Gel** (as reconstituted) can be stored at room temperature up to 25°C (77°F) for 3 months. Place a 3 month expiration date on the label immediately following mixing.

Store at room temperature up to 25°C (77°F) (See USP).

Do not freeze. Keep tightly closed. Keep out of the reach of children.

US Patents 5,446,028; 5,767,098; 6,013,637

Brief Summary of Prescribing Information as of February 2006.

Rx Only

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WIC Would Add Vegetables, Fruits

More vegetables, fruits, and whole grains would be available to beneficiaries of the Special Supplemental Nutrition Program for Women, Infants and Children (WIC) program, under a proposal issued last month by the U.S. Department of Agriculture. Based in large part on the findings of Institute of Medicine report published last year, the proposed rules would promote greater consistency with established dietary guidelines for infants and children under age 2 years, and would better support breast-feeding, according to USDA. Current WIC-covered foods help increase beneficiaries' intake of protein, iron, calcium, vitamin A, and vitamin C—nutrients that were found lacking in the WIC population when the program was started in 1974, USDA said. When drafting the proposal, USDA used guidelines from the American Academy of Pediatrics and the 2005 Dietary Guidelines for Americans, as well as the IOM report. The department is taking comments until Nov. 6.

Medicare Proposes 5.1% Pay Cut

Unless Congress intervenes by the end of the year, physicians are scheduled to face a 5.1% cut in Medicare payments starting Jan. 1, 2007. Officials at the Centers for Medicare and Medicaid Services published the proposed physician fee schedule changes in the Aug. 22 issue of the Federal Register; the final regulation is expected in the fall. The proposed cut, which comes on the heels of years of pay freezes and minor increases, will have a significant impact on pediatricians since most major payers and the majority of state Medicaid programs base their payments on the Medicare physician fee schedule, said Dr. Richard H. Tuck, the American Academy of Pediatrics' representative on the American Medical Association's Relative Value Update Committee. The RUC makes annual payment recommendations to CMS. The proposed payment cut comes just a few weeks after CMS officials announced plans to change the way Medicare pays for evaluation and management services, with physicians who provide more cognitive services getting a bigger piece of the Medicare pie. Under that proposal, pediatricians who see Medicare beneficiaries are expected to see a 2% increase in allowed charges under Medicare, compared with 2006. But the proposed overall payment cut is likely to neutralize much of that increase, Dr. Tuck said.

—From staff reports