



## POLICY & PRACTICE

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### Fight Fat, Clinicians Urged

To curb childhood obesity, health care providers should monitor weight and height as part of every well-child visit, and should teach parents how to increase their children's physical activity and decrease sedentary behavior, according to a report from the Institute of Medicine. The report also urges pediatricians to encourage breastfeeding and provide guidance on healthy eating strategies for children. In addition, health care providers should counsel parents on limiting television and other media use, including banning televisions and other media devices from young children's bedrooms. The IOM report also details steps that policy makers and federal programs can take to curb early childhood obesity.

### Doctors Sue Over Gun Law

The Florida Chapter of the American Academy of Pediatrics has sued Florida Gov. Rick Scott (R) and other state officials in federal court to overturn the new state law that restricts physicians from talking to their patients about gun ownership. The lawsuit, which includes two other physician groups and several individual physicians, says the law violates the First Amendment right to free speech. A health care provider could lose a license to practice and be fined for discussing firearm safety or putting an entry about it a patient's health record. A medical board would have to determine that the information was irrelevant or “unnecessarily harassing.” Florida Pediatric Society President Lisa Cosgrove said in a statement that pediatricians have the responsibility to discuss with patients the “scientifically proven risks to children posed by guns in the home.” With eight children and teens killed by guns every day in the United States, “restricting the ability of pediatricians to fully discuss the significant risks posed by guns is dangerous and a violation of the standard of care we as physicians owe our patients,” she said.

### Children's Weight Is Unchecked

About 58% of pediatricians and family physicians fail to track children's weight over time and to provide counseling on weight-related issues when appropriate, according to a survey conducted by federal researchers. Only 18% of physicians caring for children reported referring overweight or obese patients for further evaluation and management. Pediatricians were slightly more likely than family physicians to assess weight status and to provide related counseling, according to the study published in the American Journal of Preventive Medicine and conducted by scientists at the National Institutes of Health and the Centers for Disease Control and Prevention.

### Brain Testing Offered Free

The Scottsdale, Ariz.-based Mayo Clinic says it will offer free baseline concussion

testing to more than 100,000 high school student athletes statewide. The Computerized Cognitive Assessment Tool, which measures how the brain is working before injury, can be taken over the Internet. Following a concussion, the patient can take the test again — several times, if necessary — to help a physician determine when the student-athlete can

return to play safely, according to the Mayo Clinic. A new Arizona state law bars injured high school athletes from play until cleared by a licensed health care provider. The law also requires schools to educate coaches, students, and parents about the dangers of concussions.

### Pediatricians' Income Grew Little

Pediatricians and adolescent medicine specialists earned a median income of \$192,148 in 2010, an increase of just 0.39% from 2009, according to the Medical Group Management Association's annual survey on physician compensa-

tion. During the 4 years from 2006 to 2010, the child-and-adolescent doctors gained slightly more than 10.3% in income, the survey found. However, with the figures adjusted for inflation, the doctors gained only 1.97% for 2006-2010 and lost 1.23% for 2009-2010, the group found. Although pediatrics was the only primary care specialty to lose inflation-adjusted income last year, family practice and general internal medicine physicians failed to gain much ground, seeing growth of only 1.28% and 2.53% last year, respectively.

—Jane Anderson

#### BRIEF SUMMARY

**VELTIN™ (clindamycin phosphate and tretinoin) Gel 1.2%/0.025%**  
The following is a brief summary only; see full prescribing information for complete product information.

#### INDICATIONS AND USAGE

VELTIN Gel is indicated for the topical treatment of acne vulgaris in patients 12 years or older.

#### CONTRAINDICATIONS

VELTIN Gel is contraindicated in patients with regional enteritis, ulcerative colitis, or history of antibiotic-associated colitis.

#### WARNINGS AND PRECAUTIONS

##### Colitis

Systemic absorption of clindamycin has been demonstrated following topical use. Diarrhea, bloody diarrhea, and colitis (including pseudomembranous colitis) have been reported with the use of topical clindamycin. If significant diarrhea occurs, VELTIN Gel should be discontinued.

Severe colitis has occurred following oral or parenteral administration of clindamycin with an onset of up to several weeks following cessation of therapy. Antiperistaltic agents such as opiates and diphenoxylate with atropine may prolong and/or worsen severe colitis. Severe colitis may result in death.

Studies indicate a toxin(s) produced by clostridia is one primary cause of antibiotic-associated colitis.

##### Ultraviolet Light and Environmental Exposure

Exposure to sunlight, including sunlamps, should be avoided during the use of VELTIN Gel, and patients with sunburn should be advised not to use the product until fully recovered because of heightened susceptibility to sunlight as a result of the use of tretinoin. Patients who may be required to have considerable sun exposure due to occupation and those with inherent sensitivity to the sun should exercise particular caution. Daily use of sunscreen products and protective apparel (e.g., a hat) are recommended. Weather extremes, such as wind or cold, also may be irritating to patients under treatment with VELTIN Gel.

#### ADVERSE REACTIONS

##### Adverse Reactions in Clinical Studies

The safety data reflect exposure to VELTIN Gel in 1,104 patients with acne vulgaris. Patients were 12 years or older and were treated once daily in the evening for 12 weeks. Observed local treatment-related adverse reactions ( $\geq 1\%$ ) in clinical studies with VELTIN Gel were application site reactions, including dryness (6%), irritation (5%), exfoliation (5%), erythema (4%), pruritus (2%), and dermatitis (1%). Sunburn (1%) was also reported. Incidence of skin reactions peaked at week 2 and then gradually decreased.

Local skin reactions were actively assessed at baseline and at the end of 12 weeks of treatment in patients exposed to VELTIN Gel. At baseline (N=476), local skin reactions included erythema (24%), scaling (8%), dryness (11%), burning (8%), and itching (17%). At 12 weeks of treatment (N=409), local skin reactions included erythema (21%), scaling (19%), dryness (22%), burning (13%), and itching (15%). During the 12 weeks of treatment, each local skin reaction peaked at week 2 and gradually reduced thereafter.

#### DRUG INTERACTIONS

##### Erythromycin

VELTIN Gel should not be used in combination with erythromycin-containing products due to possible antagonism to the clindamycin component. *In vitro* studies have shown antagonism between these 2 antimicrobials. The clinical significance of this *in vitro* antagonism is not known.

##### Neuromuscular Blocking Agents

Clindamycin has been shown to have neuromuscular blocking properties that may enhance the action of other neuromuscular blocking agents. Therefore, VELTIN Gel should be used with caution in patients receiving such agents.

#### USE IN SPECIFIC POPULATIONS

##### Pregnancy

Pregnancy Category C. There are no well-controlled studies in pregnant women treated with VELTIN Gel. VELTIN Gel should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. A limit teratology study performed in Sprague Dawley rats treated topically with VELTIN Gel or 0.025% tretinoin gel at a dose of 2 mL/kg during gestation days 6 to 15 did not result in teratogenic effects. Although no systemic levels of tretinoin were detected, craniofacial and heart abnormalities were described in drug-treated groups. These abnormalities are consistent with retinoid effects and occurred at 16 times the recommended clinical dose assuming 100% absorption and based on body surface area comparison. For purposes of comparison of the animal exposure to human exposure, the recommended clinical dose is defined as 1 g of VELTIN Gel applied daily to a 50 kg person.

*Tretinoin:* Oral tretinoin has been shown to be teratogenic in mice, rats, hamsters, rabbits, and primates. It was teratogenic and fetotoxic in Wistar rats when given orally at doses greater than 1 mg/kg/day (32 times the recommended clinical dose based on body surface area comparison). However, variations in teratogenic doses among various strains of rats have been reported. In the cynomolgous monkey, a species in which tretinoin metabolism is closer to humans than in other species examined, fetal malformations were reported at oral doses of 10 mg/kg/day or greater, but none were observed at 5 mg/kg/day (324 times the recommended clinical dose based on body surface area comparison), although increased skeletal variations were observed at all doses. Dose-related teratogenic effects and increased abortion rates were reported in pigtail macaques.

With widespread use of any drug, a small number of birth defect reports associated temporally with the administration of the drug would be expected by chance alone. Thirty cases of temporally associated congenital malformations have been reported during two decades of clinical use of another formulation of topical tretinoin. Although no definite pattern of teratogenicity and no causal association have been established from these cases, 5 of the reports describe the rare birth defect category, holoprosencephaly (defects associated with incomplete midline development of the forebrain). The significance of these spontaneous reports in terms of risk to fetus is not known.

#### Nursing Mothers

It is not known whether clindamycin is excreted in human milk following use of VELTIN Gel. 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. It is not known whether tretinoin is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when VELTIN Gel is administered to a nursing woman.

#### Pediatric Use

Safety and effectiveness of VELTIN Gel in pediatric patients below the age of 12 years have not been established. Clinical trials of VELTIN Gel included 2,086 patients 12-17 years of age with acne vulgaris. [See Clinical Studies (14) of full prescribing information.]

#### NONCLINICAL TOXICOLOGY

##### Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term animal studies have not been performed to evaluate the carcinogenic potential of VELTIN Gel or the effect of VELTIN Gel on fertility. VELTIN Gel was negative for mutagenic potential when evaluated in an *in vitro* Ames *Salmonella* reversion assay. VELTIN Gel was equivocal for clastogenic potential in the absence of metabolic activation when tested in an *in vitro* chromosomal aberration assay.

*Clindamycin:* Once daily dermal administration of 1% clindamycin as clindamycin phosphate in the VELTIN Gel vehicle (32 mg/kg/day, 13 times the recommended clinical dose based on body surface area comparison) to mice for up to 2 years did not produce evidence of tumorigenicity.

*Tretinoin:* In two independent mouse studies where tretinoin was administered topically (0.025% or 0.1%) three times per week for up to two years no carcinogenicity was observed, with maximum effects of dermal amyloidosis. However, in a dermal carcinogenicity study in mice, tretinoin applied at a dose of 5.1  $\mu$ g (1.4 times the recommended clinical dose based on body surface area comparison) three times per week for 20 weeks acted as a weak promoter of skin tumor formation following a single application of dimethylbenz[ $\alpha$ ]anthracene (DMBA).

In a study in female SENCAR mice, papillomas were induced by topical exposure to DMBA followed by promotion with 12-O-tetradecanoyl-phorbol 13-acetate or mezerein for up to 20 weeks. Topical application of tretinoin prior to each application of promoting agent resulted in a reduction in the number of papillomas per mouse. However, papillomas resistant to topical tretinoin suppression were at higher risk for pre-malignant progression.

Tretinoin has been shown to enhance photo-carcinogenicity in properly performed specific studies, employing concurrent or intercurrent exposure to tretinoin and UV radiation. The photo-carcinogenic potential of the clindamycin tretinoin combination is unknown. Although the significance of these studies to humans is not clear, patients should avoid exposure to sun.

#### PATIENT COUNSELING INFORMATION

[See FDA-approved Patient Labeling in full prescribing information.]

#### Instructions for Use

- At bedtime, the face should be gently washed with a mild soap and water. After patting the skin dry, apply VELTIN Gel as a thin layer over the entire affected area (excluding the eyes and lips).
- Patients should be advised not to use more than a pea sized amount to cover the face and not to apply more often than once daily (at bedtime) as this will not make for faster results and may increase irritation.
- A sunscreen should be applied every morning and reapplied over the course of the day as needed. Patients should be advised to avoid exposure to sunlight, sunlamp, ultraviolet light, and other medicines that may increase sensitivity to sunlight.
- Other topical products with a strong drying effect, such as abrasive soaps or cleansers, may cause an increase in skin irritation with VELTIN Gel.

#### Skin Irritation

VELTIN Gel may cause irritation such as erythema, scaling, itching, burning, or stinging.

#### Colitis

In the event a patient treated with VELTIN Gel experiences severe diarrhea or gastrointestinal discomfort, VELTIN Gel should be discontinued and a physician should be contacted.

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