



BY WILLIAM G. WILKOFF, M.D.

LETTERS FROM MAINE

No Child Left Alone

I recently stumbled across a reference to the fact that several colleges have felt the need to hire security guards to keep parents out of some freshman orientation activities. In a brief and unsuccessful at-

tempt to find out exactly which colleges these were, I discovered that most other colleges offered flowery invitations to parents of incoming freshman to attend their own parent orientations. I suspect that in most cases these are attempts to distract the parents while the matriculating masses are hustled off to undisclosed locations for the real thing.

Regardless of whether they resort to uniformed guards or poorly disguised di-

versions, obviously college officials realize that one of their first challenges is to pry apart the Velcro attachments that bind many parents to their nearly adult children. This should not come as a surprise to those of us who practice general pediatrics. But it does represent a significant change in parenting styles over the last half century.

When I was in grade school there were no such things as parent-teacher confer-

ences. Communication between my teacher and my parents consisted of a few handwritten phrases on the bottom of quarterly report cards. No one would have ever imagined that someday parents would receive weekly or even daily electronic reports on their children's activities.

Parents ventured inside schools only when summoned by the principal or the school nurse. If your parent was seen in the school, everyone knew that you had a big problem.

But that was back when a small-screen, black-and-white TV was a luxury few families could afford. Today, parental involvement has become an integral part of almost every school system. Fueled by budgetary shortfalls, volunteerism has been actively promoted and some parents play an important role as teachers' aides and classroom assistants. Many parents spend a half day or more every week in their children's classes.

Volunteering offers parents an opportunity to see exactly what and how their children are being taught. For some parents it is a step in the process of separating that may have been difficult, particularly if they had been practitioners of "attachment parenting." Some parents have grown to see themselves as a friend and primary playmate for their child. I can imagine that for these parents the chance to spend a few hours in the child's classroom can be comforting.

But, parents volunteering in their children's classrooms can have a dark side. I suspect you have seen it in your own office. In some situations the presence of the child's parent inflames a preexisting classroom behavior problem. In other cases a usually well-behaved child will exhibit an uncharacteristic behavior when his parent is in the class. The child may appear unusually withdrawn and shy or may act out and misbehave.

Another more serious scenario occurs when a child is struggling with separation anxiety or school phobia. For these children, the goodbye at the bus stop in the morning has been a painful parting that they have mastered temporarily. Once in school with the support of a knowledgeable and compassionate teacher, the anxiety has abated. However, the arrival of the parent-volunteer in the classroom later in the morning is likely to fan the fading embers of uncertainty into a raging inferno of separation anxiety.

One of our newest and most difficult challenges as new-millennium pediatricians is to help parents learn to supervise without meddling. As soon as I e-mail this letter to the editor, I'm going to cc it to the school board and suggest that they continue to promote volunteerism. But, tactfully encourage parents to avoid regular assignments to their own children's classes. If I'm successful, maybe one less college will feel the need to call out the troops during freshman orientation. ■

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*Vusion™ Ointment is indicated for the adjunctive treatment of diaper dermatitis only when complicated by documented candidiasis (microscopic evidence of pseudohyphae and/or budding yeast) in immunocompetent pediatric patients 4 weeks and older. A positive fungal culture for *C albicans* is not adequate evidence of candidal infection since colonization with *C albicans* can result in a positive culture. The presence of candidal infection should be established by microscopic evaluation prior to initiating treatment.

Vusion™ Ointment should be used as part of a treatment regimen that includes measures directed at the underlying diaper dermatitis, including gentle cleansing of the diaper area and frequent diaper changes.



Vusion™ Ointment should not be used as a substitute for frequent diaper changes. Vusion™ Ointment should not be used to prevent the occurrence of diaper dermatitis, since preventative use may result in the development of drug resistance.

The safety of Vusion™ Ointment when used for longer than 7 days is not known.

Vusion™ Ointment should not be used in cases of known hypersensitivity to any of its components, in which case treatment should be discontinued.

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BRIEF SUMMARY

Rx only.
FOR TOPICAL USE ONLY.
NOT FOR OPHTHALMIC, ORAL, OR INTRAVAGINAL USE.

INDICATIONS AND USAGE

VUSION Ointment is indicated for the adjunctive treatment of diaper dermatitis only when complicated by documented candidiasis (microscopic evidence of pseudohyphae and/or budding yeast), in immunocompetent pediatric patients 4 weeks and older. A positive fungal culture for *Candida albicans* is not adequate evidence of candidal infection since colonization with *C albicans* can result in a positive culture. The presence of candidal infection should be established by microscopic evaluation prior to initiating treatment.

VUSION Ointment should be used as part of a treatment regimen that includes measures directed at the underlying diaper dermatitis, including gentle cleansing of the diaper area and frequent diaper changes.

VUSION Ointment should not be used as a substitute for frequent diaper changes. VUSION Ointment should not be used to prevent the occurrence of diaper dermatitis, since preventative use may result in the development of drug resistance.

CONTRAINDICATIONS

VUSION Ointment is contraindicated in those patients with a history of sensitivity reactions to any of its components. It should be discontinued if hypersensitivity is noted.

PRECAUTIONS

General: If irritation occurs or if the disease worsens, use of the medication should be discontinued, and the health care provider should be contacted. For external use only. VUSION Ointment is for topical use only, and not for ophthalmic, oral or intravaginal use.

The safety and efficacy of VUSION Ointment has not been demonstrated in immunocompromised patients, or in infants less than 4 weeks of age (premature or term).

The safety and efficacy of VUSION Ointment have not been evaluated in incontinent adult patients. **VUSION Ointment should not be used to prevent the occurrence of diaper dermatitis, such as in an adult institutional setting, since preventative use may result in the development of drug resistance.**

Information for Patients: Patients using VUSION Ointment should receive the following information and instructions: (See Patient Package Insert)

1. VUSION Ointment is to be used only for diaper dermatitis that is complicated by documented candidiasis (i.e. documented by microscopic testing).
2. VUSION Ointment should not be used as a substitute for frequent diaper changes.
3. VUSION Ointment should not be used to prevent diaper dermatitis.
4. VUSION Ointment should not be used long term.
5. VUSION Ointment is to be used only as directed by the health care provider.
6. VUSION Ointment is for external use only. It is not to be used orally, intravaginally, or for the eyes.
7. Gently cleanse the diaper area with lukewarm water or a very mild soap and pat the area dry with a soft towel before applying VUSION Ointment.
8. Gently apply VUSION Ointment to the diaper area with the fingertips after each diaper change. Do not rub VUSION Ointment into the skin as this may cause additional irritation.
9. Thoroughly wash hands after applying VUSION Ointment.
10. Treatment should be continued for 7 days, even if there is improvement. Do not use VUSION Ointment for longer than 7 days. If symptoms have not improved by day 7, see your health care provider.
11. VUSION Ointment should not be used on children for whom it is not prescribed.

Drug Interactions: Drug-drug interaction studies were not conducted. Although women who take a warfarin anticoagulant and use a miconazole intravaginal cream or suppository may be at risk for developing an increased prothrombin time, international normalized ratio (INR) and bleeding, the potential for this interaction to occur between warfarin and VUSION Ointment is unknown.

Carcinogenesis, Mutagenesis, Impairment of fertility: Studies to evaluate the carcinogenic potential of VUSION Ointment in animals have not been performed.

Miconazole nitrate was negative in a bacterial reverse mutation test, a chromosome aberration test in mice, and micronucleus assays in mice and rats.

Miconazole nitrate had no adverse effect on fertility in a study in rats at oral doses of up to 320 mg/kg/day, which is 89 times the maximum possible topical exposure of caregivers, assuming 100% absorption.

Pregnancy Category C:

There are no adequate and well-controlled studies of VUSION Ointment in pregnant women. Miconazole nitrate administration has been shown to result in prolonged gestation and decreased numbers of live young in rats and in increased number of resorptions and decreased number of live young in rabbits at oral doses of 100 mg/kg/day and 80 mg/kg/day, which are 28 and 45 times the maximum possible topical exposure of caregivers, respectively, assuming 100% absorption.

Pregnant women should exercise appropriate precautions when administering the product.

Nursing Mothers: Safety and efficacy of the product have not been established in nursing mothers. It is not known if the active components of VUSION Ointment may be present in milk. Nursing mothers should exercise appropriate precautions when administering the product.

Pediatric Use: Efficacy was not demonstrated in infants less than 4 weeks of age. Use in infants below the age of 4 weeks is not recommended. Safety and efficacy have not been established in very-low-birth-weight infants.

VUSION Ointment should not be used to prevent diaper dermatitis.

The safety of VUSION Ointment when used for longer than 7 days is not known.

Geriatric Use: Clinical studies of VUSION Ointment did not include any subjects aged 65 and over. Safety and effectiveness in a geriatric population have not been evaluated.

ADVERSE REACTIONS

A total of 835 infants and young children were evaluated in the clinical development program. Of 418 subjects in the VUSION Ointment group, 58 (14%) reported one or more adverse events. Of 417 subjects in the zinc oxide/white petrolatum control group, 85 (20%) reported one or more adverse events. Adverse events that occurred at a rate of $\geq 1\%$ for subjects who were treated with VUSION were approximately the same in type and frequency as for subjects who were treated with zinc oxide/white petrolatum ointment.

The potential for dermal toxicity of VUSION Ointment formulation was investigated in healthy adult volunteers in four topical safety studies. These studies were conducted to assess the potential for contact phototoxicity, photoallergy, sensitization, and cumulative irritation potential. Phototesting was conducted with UV-A only. Results indicated that VUSION Ointment did not induce a contact dermal phototoxic response, contact dermal photoallergic response, or contact dermal sensitization in adult subjects. In addition, VUSION Ointment did not show any evidence of cumulative irritation potential in adult subjects.

OVERDOSAGE

VUSION Ointment is intended for topical use only. Young children are at risk for accidentally ingesting VUSION Ointment. A health care provider or poison control center should be contacted in the event of accidental ingestion.

Keep out of reach of children.

For additional information, please call toll free 1-866-440-5508.

Manufactured By:

DSM Pharmaceuticals, Inc.
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For:

Barrier Therapeutics, Inc.
600 College Road East
Princeton, NJ 08540
www.barriertherapeutics.com
VU-008 February, 2006
U.S. Patent No. 4,911,932

Reference: 1. Data on file, Barrier Therapeutics, Inc.

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