

they had connected with often followed.”

Despite the usually frantic pace of activity in the NICU, the staff took the flu shot endeavor quite seriously and managed to find the time to talk often with the parents. “We kept track of who was and who was not getting the shots, and we would talk to the ones who had not—to see if they had any questions or concerns that we could address.”

Among the 11 who refused the vaccine, 5 stated that they simply did not believe in immunization, and 2 said they feared that the shots might induce autism. Others cited religious objections or a reluctance to add anything else to whatever medical

care they were already receiving. One cited an allergy to eggs, which is a legitimate concern since the vaccine contains some egg proteins.

Overall, the NYU NICU-based flu shot program was highly successful. Dr. Shah and colleagues are hoping to do a follow-up to see if the program had any impact on the rate of influenza among the neonates. He cautioned, however, that the sample size may be too small to support any definitive conclusion.

This pilot program did, however, prove that flu shots can be effectively distributed in the NICU setting to parents who for a variety of reasons had not previously got-

ten immunized. The program created very little additional strain on NICU physicians or nursing staff.

“Administration of the trivalent vaccine is very possible in a busy NICU, and implementation markedly increased compliance with recommendations aimed at protecting high-risk neonates,” Dr. Shah told conference participants. “There will always be a small subset of parents who will refuse, no matter what. But we can get to many parents who are willing to take the shots.” He added that this type of program is highly replicable and could be quickly implemented in any family-centered NICU. ■

Influenza Often Missed as a Clinical Dx

BY JOHN R. BELL
Associate Editor

In a prospective analysis of data from children who had laboratory-confirmed influenza, researchers found that most influenza cases were not recognized clinically, and the resulting symptoms were treated on an outpatient basis far more often than through inpatient care.

Dr. Katherine A. Poehling of Vanderbilt University, Nashville, Tenn., and her colleagues reported data from the New Vaccine Surveillance Network, organized by the Centers for Disease Control and Prevention, in which they observed hospitalizations and pediatric clinic visits resulting from acute respiratory illness or fever in children younger than 5 years who were living in one of three U.S. counties during 2000-2004 (N. Engl. J. Med. 2006;355:31-40).

They found that among the outpatient population of 1,668 children, 16% (267 children) tested positive for influenza, compared with less than 6% (160 children) of the 2,797 in the inpatient group. However, discharge diagnoses identified influenza in only 17% of outpatients and 28% of hospitalized patients with laboratory-confirmed influenza.

Outpatient care was overwhelmingly predominant in the study cohort. During the 4-year study period, the average hospitalization rate for all included age groups was 1 per 1,000 children, and outpatient treatment rates for each group (younger than 6 months, 6 months to 1 year old, and 1-2 years old) were 10, 100, and 250 times higher than the rates of hospitalizations, respectively.

Moreover, the investigators found that laboratory-confirmed flu infections accounted for more than 10% of weekly clinic visits for acute respiratory tract infection or fever during the 2002-2003 flu season and more than 19% of such visits during the 2003-2004 season. In the emergency department, laboratory-confirmed flu infections accounted for nearly 6% of weekly visits for acute respiratory tract infection or fever in 2002-2003 and 29% of such visits in 2003-2004.

“Much of this influenza disease burden may be prevented through vaccination,” the researchers wrote. Influenza vaccination for all children aged 6-23 months was recommended beginning in 2004.

Notably, younger patients had greater influenza incidence. In the hospitalized patients, 80% were younger than 2 years and 49% were younger than 6 months. In the outpatient group, 47% were younger than 2 years, and 7% were younger than 6 months.

In an accompanying editorial, Dr. W. Paul Glezen of Baylor College of Medicine, Houston, observed that uninsured families, who compose almost one-fifth of the U.S. population, were underrepresented in the study, which might have contributed to artificially low hospitalization rates in the study (N. Engl. J. Med. 2006;355:79-81). ■

*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.

Vusion™
(0.25% miconazole nitrate/15% zinc oxide/
81.35% white petrolatum) Ointment
Convenience in every tube.

VUSION™
(0.25% miconazole nitrate, 15% zinc oxide, and 81.35% white petrolatum)
Ointment

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.
Greenville, NC 27834

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.

Vusion is a trademark of Barrier Therapeutics, Inc.
Barrier Therapeutics is a registered trademark.