DIFFERIN® (adapalene) Gel, 0.1%
Rx Only
BRIEF SUMMARY
INDICATIONS AND USAGE: DIFFERIN® Gel is indicated for the topical treatment of acne vulgaris in patients 12 years of age and older.

CONTRAINDICATIONS: DIFFERIN® Gel should not be administered to patients who are hypersensitive to adapalene or any of the components of the drug.

ADVERSE REACTIONS:
1. Adverse reactions in patients treated with DIFFERIN® Gel may include dryness, pruritus, burning, and redness of the skin. Some adverse effects such as erythema, scaling, swelling, tenderness, and pruritus may occur in 10-40% of patients. Pruritus or tenderness may be treated with nonsteroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen (Advil®) or naproxen (Naprosyn®) or antihistamines such as diphenhydramine (Benadryl®) or loratadine (Claritin®).

2. Over 1% of patients may experience local irritation. If irritation occurs, use of the medication should be discontinued. Exposure to sunlight, including sunlamps, should be minimized during use of adapalene.

3. Phototoxicity has been observed in patients treated with adapalene at oral doses of 0.15 to 5.0 mg/kg/day, up to 120 times the maximum human topical dose. Cutaneous route teratogenicity studies have been used, it is advisable not to start therapy with DIFFERIN® Gel to a nursing woman.

PEDIATRIC USE:
DIFFERIN® Gel is indicated for the topical treatment of acne vulgaris in patients 12 years of age and older. Safety and effectiveness in pediatric populations have not been established. The clinical studies of DIFFERIN® Gel were conducted in patients 12 years of age and older. There are no data from adequate and well-controlled studies in infants and children under the age of 12.

NURSING MOTHERS:
It is not known whether this drug is excreted in human milk. Taking into account the potential for adverse effects in the infant, a decision should be made whether to discontinue use of the drug or to discontinue breastfeeding.

OVERDOSAGE:
If a reaction suggesting sensitivity or chemical irritation occurs, the medication should be discontinued. Exposure to sunlight, including sunlamps, should be minimized during use of adapalene.

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REFERENCES:
Child Care Providers Go Easier on Antibiotic Use

BY HEIDI SPLETE
Senior Writer

ATLANTA — Child care providers surveyed in 2004 were significantly less likely to exclude a sick child who had not received antibiotics, compared with child care providers surveyed in 2001, Shelly Feaver reported in a poster presented at the International Conference on Emerging Infectious Diseases.

Of 1,409 Minnesota child care center teachers surveyed in 2004 and 421 surveyed in 2001, the 2004 teachers were significantly less likely to exclude a child with a fever, a runny nose without mucus, or a chest cold who had not received antibiotics. In addition, the teachers surveyed in 2004 were significantly more likely than those surveyed in 2001 to believe that physicians should not prescribe antibiotics for children with fevers, middle ear infections, runny noses with green or yellow mucus, conjunctivitis with pus, and conjunctivitis with watery discharge.

Ms. Feaver and her colleagues at the Minnesota Department of Health in St. Paul developed an educational intervention program based on the results of the 2001 surveys. The program included a child care provider curriculum with education slides, and viral excuse pads. The Minnesota Department of Human Services Child Care Licensing Division approved the curriculum for continuing education credit for licensed child care providers prior to the second survey in 2004, but there were no significant differences in the 2004 survey responses between teachers who reported completing the curriculum and those who had not completed the curriculum.

In addition, messages about judicious antibiotic use were distributed to child care health consultants and were posted on the Web site of the Minnesota Infectious Research Collaborative during the study period.

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5,000 or greater than 15,000 per mm$^3$ (odds ratio 1.9).

- The combination of chronic illness and prematurity (odds ratio 9.7). The investigators defined chronic illness as any major anatomic abnormality or major immune deficiency, and they defined prematurity as a gestational age of 37 weeks or less.

Together they refer to these four criteria as the “Modified Rochester Criteria” (MRC).

In addition, high-risk infants (by MRC) aged 29-90 days had a 42% smaller chance of having a serious bacterial infection than high-risk infants between 1-28 days old. And infants with a confirmed viral illness were 70% less likely to have a serious bacterial infection than those with no confirmed viral illness.

When age and viral illness are added to the MRC, the sensitivity rises to 96%, while the negative predictive value remains at 97%.

In fact, this combination of factors can be used to stratify patients into low-, medium-, and high-risk categories. Patients who are negative for the MRC and positive for virus are at low risk, having only a 0.7% chance of serious bacterial infection if they are 29 days or older, and a 1.7% risk if they are younger.

Patients who have at least one positive MRC finding and who are positive for virus form the medium-risk group. The older infants have a 3.8% chance of having a serious bacterial infection, while the younger ones have a 6.5% chance.

Patients who are MRC positive and negative for virus are at the highest risk. The older infants have a 22% chance of having a serious bacterial infection, and the younger infants have a 33% chance.

“We believe that the diagnosis of viral infections should be a standard component of a rule-out-sepsis evaluation,” she said.

In response to a question from the audience, Dr. Byington agreed that even a 1% chance of serious bacterial infection merits consideration. She said that her goal is not to identify a group of infants that can be safely left untreated, but rather to decrease the length of time it takes to do a full sepsis evaluation from 53-72 hours to 24 hours.

“My take-home message is not to stop looking for bacteria, but to speed up the way we can make that decision,” she said.

“I am working toward developing diagnostic technology that can diagnose both bacterial and viral pathogens—15 pathogens in 15 minutes.”

Important Safety Information

In clinical studies, adverse events included pain, redness, and swelling at the injection site, headache, fatigue, and gastrointestinal symptoms. As with other vaccines, rare adverse events may occur. As with any vaccine, vaccination with BOOSTRIX may not protect 100% of susceptible individuals. Hypersensitivity to any component of BOOSTRIX is a contraindication.

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