**DIFFERIN® (adapalene) Cream, 0.1% Rx Only**

**BRIEF SUMMARY**

**INDICATIONS AND USAGE:**

DIFFERIN® Cream is indicated for the topical treatment of acne vulgaris in adults and adolescents from 12 years of age and older.

**CONTRAINDICATIONS:**

DIFFERIN® Cream should not be administered to patients who are hypersensitive to adapalene or any of the components in the cream vehicle.

**WARNINGS/ PRECAUTIONS:**

1. Unwanted local adverse events in patients who used DIFFERIN® Cream in clinical studies included: dryness, pruritus, erythema, burning, or pruritus may be experienced during treatment. These are most likely to occur during the first 2 to 4 weeks of therapy and will usually decrease in frequency and severity thereafter. All patients should be instructed about the potential for these reactions and be advised that they may be reversible upon discontinuation of therapy.

2. Increased incidence of skin findings such as erythema, dryness, scaling, pruritus, or irritation may be experienced during treatment. These are most likely to occur during the first 2 to 4 weeks of therapy and will usually decrease in frequency and severity thereafter. All patients should be instructed about the potential for these reactions and be advised that they may be reversible upon discontinuation of therapy.

3. In a 12-month study of 897 patients, the most frequent adverse event was dryness (48%), followed by scaling (58%), irritation (52%), and erythema (52%).

4. In a 4-month study of 136 patients, the most frequent adverse events were dryness (42%), scaling (58%), irritation (42%), and erythema (48%).

**ADVERSE REACTIONS:**

Adverse reactions include: dryness, pruritus, erythema, burning, or pruritus.

**DOSAGE AND ADMINISTRATION:**

DIFFERIN® Cream should not be used in patients with skin diseases that are associated with excessive oral intake of Vitamin A.

**PREGNANCY:**

Pregnancy Category B. Reproductive function and fertility studies were conducted in rats administered topical doses of 0.3, 0.9, and 3.0 mg/kg/day; and in mice administered oral doses of 0.15, 0.5, and 1.5 mg/kg/day. In the oral study, positive linear trends were observed in the incidence of follicular cell neoplasms (adenomas and carcinomas) in the thyroid glands of female rats, and in the incidence of pheochromocytomas in the adrenal medullas of male rats.

**NURSING MOTHERS:**

Because many drugs are excreted in human milk, caution should be exercised when DIFFERIN® Cream is administered to nursing women.

**PEDIATRICS:**

Safety and effectiveness in pediatric patients below the age of 12 years has not been established.

**Ocular irritation:**

Ocular irritation was noted in rabbits and guinea pigs. Topical preparations containing apical hydroxy acids or glycolic acids should be avoided near the eye.

**ADDITIONAL ADVERSE REACTIONS:**

1. The most frequent adverse events reported in clinical studies are dryness, pruritus, erythema, burning, or pruritus.

2. Other reported local adverse events in patients who used DIFFERIN® Cream in clinical studies included: dryness, pruritus, erythema, burning, or pruritus in the skin disorder treated with DIFFERIN® Cream. These are most likely to occur during the first 2 to 4 weeks of therapy and will usually decrease in frequency and severity thereafter. All patients should be instructed about the potential for these reactions and be advised that they may be reversible upon discontinuation of therapy.

3. The wound has healed 6 weeks after the “biological debridement.”

**TIPPELT** said at the annual meeting of the American Academy of Hospice and Palliative Medicine.

Since she started using maggot therapy in 2001, Dr. Tippett has treated more than 100 patients.

Perhaps the only drawback to using maggot treatment is that it is time sensitive and requires planning. The single commercial source of medical maggots in the United States is Monarch Labs in Irvine, Calif. Maggots can be ordered on Monday through Thursday for next-day delivery.

Each vial contains about 250-500 larvae and costs about $100, explained Dr. Tippett, who serves as medical director of the Hospice of Southwest Ohio in Cincinnati.

Medical maggots are larvae of the green blowfly, Phaenicia sericata. This treatment received approval by the Food and Drug Administration in 2004.

The dosage is 10 larvae for each cubic centimeter of wound. Dr. Tippett constrains a retention dressing out of chiffon and a nylon footie. A cycle of treatment lasts for 48 hours, after which the larvae are rinsed off as they enter the pupal stage of their life cycle.

A typical wound requires one to six cycles of treatment. Sometimes the treatment cycles are applied one after another, while in other cases Dr. Tippett waits a day or so between the cycles.

Dr. Tippett said that she has not had a patient who was not helped by maggot therapy.

In several cases, severe and infected wounds that she did not believe would heal did in fact heal with maggot therapy.

Not only do the maggots remove dead and infected tissue, but they appear to release growth factors that promote wound healing, Dr. Tippett noted.

Dr. Tippett said that she bills for this treatment as surgical debridement under Medicare Part B. Although Medicare and other insurers will pay for the physician’s services, they will not yet pay for the maggots. Some hospices have paid for the maggots; sometimes Dr. Tippett pays for them herself.