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Topical retinoid acne treatment approved for OTC use

December 16, 2016

Food and Drug Administration Office of Pediatric Therapeutics, Division of Pediatric and Maternal Health, and Division of Nonprescription Drug Products

Article type: FDA Update

Topics: Adolescent Health/Medicine , Dermatology

The Food and Drug Administration (FDA) has approved Differin Gel 0.1% (adapalene), a once-daily topical retinoid gel, for over-the-counter (OTC) treatment of acne in individuals 12 years of age and older.

Acne affects approximately 50 million people in the United States and is the most common skin condition in adolescents and young adults. Although the exact mechanism of action is unknown, topical retinoid products may modulate keratinization, decreasing microcomedone formation, and appear to have anti-inflammatory effects.

While topical retinoid products often are prescribed as first-line therapies for acne, Differin Gel 0.1% is the first retinoid to be made available OTC for the treatment of acne. It contains the first new OTC active ingredient for acne treatment since the 1980s.

Differin Gel 0.1% originally was approved in 1996 as a prescription product.

The approval for OTC use was based on studies showing that consumers can understand the OTC label, decide whether the product is right for them and use the product appropriately. Supporting data included post-marketing safety data accrued from 1996-2016 and a skin absorption study demonstrating that absorption is limited when adapalene is applied daily over a large skin surface. Common adverse reactions include erythema, scaling, dryness, pruritus, burning/stinging and photosensitivity.

Although other retinoids have been associated with birth defects, the FDA, along with its Nonprescription Drugs Advisory Committee, has determined that there is no evidence that topical Differin Gel 0.1%, given limited absorption, causes birth defects. Nonetheless, women who are pregnant, planning to become pregnant or breastfeeding should ask a doctor before use.

Resources

- FDA advisory committee meeting materials
- OTC product labeling