



Differin™ (adapalene) – New Over-The-Counter Drug Approval

- On July 8, 2016, the [FDA announced](#) the approval of over-the-counter (OTC) use of [Galderma's Differin \(adapalene\)](#) 0.1% gel for the treatment of acne in people 12 years of age and older.
- Differin gel 0.1% is the first retinoid acne treatment to be made available OTC.
 - Differin is also available generically by prescription as 0.1% [cream](#), [gel](#) and [lotion](#) and [0.3% gel](#).
- Acne is a common skin disease that affects approximately 50 million people in the U.S.
- Adapalene is a retinoid, which is clinically proven to treat current and future breakouts. According to the [American Academy of Dermatology](#), topical retinoids are indicated as first-line treatment in the management of acne.
- Support for OTC approval was based on data accrued from 1996 - 2016 on post-marketing safety and data from consumer studies.
 - Results from the consumer studies showed that consumers can understand the information on the OTC label, appropriately select whether the product is right for them, and use the product appropriately.
 - A separate study demonstrated that absorption of Differin is limited, thus supporting safe use of Differin Gel 0.1% by people using it OTC.
- Differin should be applied once daily in a thin layer on the affected areas of the skin. Differin should not be used on damaged skin. People using Differin should avoid sunburn and avoid contact with the eyes, lips and mouth.
 - In the first few weeks of use, skin may become irritated (redness, itching, dryness, burning).
 - Consumers should stop use and ask a doctor if irritation becomes severe, if there is no improvement in acne after 3 months of daily use, if symptoms of allergic reaction appear, or if they become pregnant or are planning to become pregnant while using the drug.
- Galderma's launch plans for OTC Differin 0.1% gel are pending.



OptumRx® specializes in the delivery, clinical management and affordability of prescription medications and consumer health products. We are an Optum® company — a leading provider of integrated health services. Learn more at [optum.com](#).

All Optum® trademarks and logos are owned by Optum, Inc. All other brand or product names are trademarks or registered marks of their respective owners.

This document contains information that is considered proprietary to OptumRx and should not be reproduced without the express written consent of OptumRx.

Rx News® is published by the OptumRx Clinical Services Department.

©2016 Optum, Inc. All rights reserved.