The first new acne treatment active ingredient since the 1980s has just been approved for over-the-counter use.

(Newswire.net -- August 22, 2016) Davis, CA -- FDA Approves OTC Drug for Acne Sufferers

According to Health.com, the Food and Drug Administration approved Differin Gel 0.1% (adapalene), a retinoid anti-acne drug, for OTC treatment of mild to moderate acne. The active ingredient in Differin Gel 0.1% is similar to Vitamin A. It requires a single daily application for users 12 and older. Patients under 12 should consult a dermatologist before beginning treatment.

The results of five separate trials conducted during the past two decades indicate that Differin Gel 0.1% offers a favorable risk-reward profile.

“Differin Gel has had an excellent safety profile and will be a great addition to the over-the-counter options for those suffering with acne who are unable to get to a dermatologist,” said Dr. Doris Day, a New York City-based dermatologist, in a statement to Health.com.

In a long-duration study, researchers found that the drug's skin absorption potential is limited. That reduces the risk of more serious side effects and strengthens the case for over-the-counter indication. Not all OTC acne treatments are effective, as recent reviews and studies indicate, and the drug's effectiveness appears to exceed that of several well-known acne treatments like Proactiv.

Differin Gel 0.1%’s side effects are generally mild. They include skin irritation, rash, and heightened sensitivity to the sun. Users are advised to apply sunblock liberally during treatment, even for short trips outdoors, and to discontinue use if moderate to severe sunburn develops.

Women who are nursing, pregnant, or planning to become pregnant need to exercise special caution when using Differin Gel 0.1%. Little clinical research has been done on the drug’s effects on these groups, but similar drugs have been shown to cause birth defects. Pregnant women are advised to consult a physician prior to beginning an over-the-counter Differin Gel 0.1% regimen.

Differin Gel 0.1% is not indicated for patients with moderate to severe acne. For these groups, prescription-only Differin Gel 0.3%, which contains a higher concentration of the same medicine found in Differin Gel 0.1%, is likely to produce better results. Differin Gel 0.3% is generally well-tolerated and has been heavily prescribed since 1996. Patients unsure about the character and severity of their acne should consult a dermatologist before beginning any skin treatment regimen, over-the-counter or otherwise.

As with any drug, there are limits to Differin Gel 0.1%’s effectiveness, and individual results may vary. “You still need to be aware to see your dermatologist if the acne does not clear or if the acne is scarring,” Dr. Day told Health.com.

Differin Gel 0.1% is distributed by Galderma Laboratories, a Texas-based drug manufacturer that specializes in skin treatments and acne care. More information about Differin Gel 0.1% and Differin Gel 0.3% is available from Galderma and licensed dermatologists nationwide.