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Aczone Fails to Impress for Rosacea

Written by David Pascoe in Aczone (Dapsone Gel 5%), Allergan, clinical trials with 0 Comments



We don't often get to see the actual results from clinical trials. Companies are happy to receive publicity for their research and development programs, especially if a new product looks promising. If things don't go we during clinical trials, though, it seems that we just never hear about that product again.

Allergan, the makes of Aczone are unusual in this regard.

In 2006 we learnt that Aczone (Topical 5% Dapsone), an approved acne treatment would be trialled as a treatment for rosacea.

The trial, NCT00249782 a multiple arm Phase II trial, would compare Aczone once and twice a day, to the inactive gel vehicle, Metrogel 1% on its own and Aczone in the morning in combination with Metrogel in the evening.

All things going well this sort comparison would be able to position Aczone as a viable adjunct to, or indeed a more effect alternative to the market leading Metrogel.

How Did It Go?

The trial of Aczone as a rosacea treatment can only be described as disappointing.

What Did the Trial Discover?

Some highlights from AZC ROS 01, "A Phase II, Randomized, Partial-Blind, Parallel-Group, Active- and Vehicle-Controlled, Multicenter Study of the Safety and Efficacy of Aczone TM (dapsone) Gel, 5% in Subjects with Papulopustular Rosacea".

- Aczone twice a day was better than Aczone once a day
- $\,\blacksquare\,$ Aczone twice a day was not significantly better than the vehicle gel twice a day
- Combining Aczone and Metrogel 1% was not significantly better than Metrogel 1% on its own.
- None of any combination of the treatments was able to make a significant dent in erythema or telangiectasia.

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Takeaway Points

Notch this up as another data point. Rosacea treatments are hard. Even established acne treatments are no shoe-in to treat the papules and pustules of rosacea. Failures are going to be more common than successes.

Further, bettering the existing established treaments of topical metronidazole, topical azelaic acid, systemic antibiotics is an extra hill to climb for emerging treatments.

Allergan Isn't Giving Up

Despite this set back, Allergan continues the research and development of new treatments for several conditions.

For rosacea sufferers are considered, the most promising would be the Oxymetazoline based topical that they call AGN-199201. This was formerly known as V-101 when it was being development by Vicept Therapeutics.

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aczone (topical dapsone) recruiting trial participants

looking for participants. The trial aims to compare Aczone (5% topical dapsone gel) with April 10, 2006

In "Aczone (Dapsone Gel 5%)"

for rosacea targeting?

A large Phase II Clinical Trial for OK this story is getting so much The U.S. Food and Drug treating rosacea with Aczone is coverage in the online press that I thought I should cover it here too. Allergan is buying the Gel, 5% for the topical topical dapsone product called treatment of acne vulgaris in June 19, 2008

In "Acne Treatments"

Allergan buys Aczone, has plans Aczone Gel (5% Dapsone) gets FDA approval for Acne

Administration (FDA) has approved Aczone (dapsone) August 22, 2005 In "Aczone (Dapsone Gel 5%)"

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About the Author: David Pascoe started the Rosacea Support Group in October 1998. More from this author.





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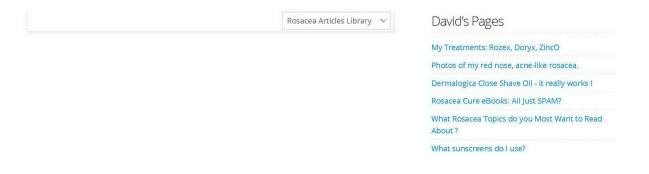
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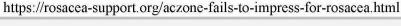
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acne and rosacea?



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