

# SUPPLEMENT

## Salicylic Acid and Salicylates

CIR EXPERT PANEL MEETING  
DECEMBER 3-4, 2018



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Memorandum

To: CIR Expert Panel Members and Liaisons  
From: Wilbur Johnson, Jr.  
Senior Scientific Analyst  
Date: November 19, 2018  
Subject: Wave 2 Data on Salicylic Acid and Salicylates

A clinical study on a 2% Salicylic Acid hydrogel cream is summarized below. This study was previously identified in the published literature and ordered, but was not received prior to the mail date for Panel meeting materials. The study summary will be added to the safety assessment after the Panel meeting.

**CLINICAL STUDIES**

**Other Clinical Reports**

**Salicylic Acid**

A clinical trial was conducted using 34 patients with mild to moderate acne who were selected for treatment with a Salicylic Acid hydrogel and a benzoyl peroxide + adapalene gel.<sup>1</sup> A 2% Salicylic Acid cream (hydrogel) was applied randomly to one side of the face for 28 days. Benzoyl peroxide (5%) + 0.1% adapalene gel was applied to the other side of the face according to the same procedure. Common side effects, such as desquamation, dryness, burning, erythema, and pruritus, were recorded and classified into mild, moderate, and severe grades. Three patients withdrew from the study due to the irritant contact dermatitis that was induced by benzoyl peroxide. There was no evidence of side effects to the 2% Salicylic Acid cream.

**REFERENCES**

1. Zheng Y, Yin S, Xia Y, et al. Efficacy and safety of 2% supramolecular salicylic acid compared with 5% benzoyl peroxide/0.1% adapalene in the acne treatment: A randomized, split-face, open-label, single-center study. *Cutan.Ocul.Toxicol.* 2018;3:1-21.