

**A EUROPEAN PROSPECTIVE, RANDOMIZED PLACEBO-CONTROLLED DOUBLE-BLIND STUDY ON THE EFFICACY AND SAFETY OF DR MICHAELS® (ALSO BRANDED AS SORATINEX®) PRODUCT FAMILY FOR STABLE CHRONIC PLAQUE PSORIASIS**

K. FRANÇA<sup>1,14</sup>, J. HERCOGOVÁ<sup>2,3</sup>, M. FIORANELLI<sup>4</sup>, S. GIANFALDONI<sup>5</sup>,  
A.A. CHOKOEVA<sup>6,7</sup>, G. TCHERNEV<sup>8</sup>, U. WOLLINA<sup>9</sup>, M. TIRANT<sup>10</sup>, F. NOVOTNY<sup>11</sup>,  
M.G. ROCCIA<sup>12</sup>, G.K. MAXIMOV<sup>13</sup> and T. LOTTI<sup>15</sup>

<sup>1</sup>Department of Dermatology & Cutaneous Surgery, Department of Psychiatry & Behavioral Sciences Institute for Bioethics & Health Policy, University of Miami, Miller School of Medicine, Miami, FL, USA; <sup>2</sup>2nd Medical Faculty, Charles University, Bulovka Hospital, <sup>3</sup>Institute of Clinical and Experimental Medicine, Prague, Czech Republic; <sup>4</sup>Department of Nuclear Physics, Sub-nuclear and Radiation, G. Marconi University, Rome, Italy, <sup>5</sup>Dermatological Department, University of Pisa, Pisa, Italy; <sup>6</sup>"Onkoderma" - Policlinic for dermatology and dermatologic surgery, Sofia, Bulgaria; <sup>7</sup>Department of Dermatology and Venereology, Medical University of Plovdiv, Medical faculty, Plovdiv, Bulgaria; <sup>8</sup>Medical Institute of Ministry of Interior (MVR), Department of Dermatology, Venereology and Dermatologic Surgery, Sofia, Bulgaria; <sup>9</sup>Department of Dermatology and Allergology, Academic Teaching Hospital Dresden-Friedrichstadt, Dresden, Germany; <sup>10</sup>Psoriasis & Skin Clinic, Melbourne, Australia, <sup>11</sup>PRO SANUM Ltd., Sanatorium of Prof. Novotný, Štěpánská Prague 1, Czech Republic; <sup>12</sup>University B.I.S. Group of Institutions, Punjab Technical University, Punjab, India; <sup>13</sup>Department "Medicinal Information and Non-interventional studies", Bulgarian Drug Agency; Sofia, Bulgaria; <sup>14</sup>Centro Studi per la Ricerca Multidisciplinare e Rigenerativa, Università Degli Studi "G. Marconi" - Rome, Italy; <sup>15</sup>Chair of Dermatology, University of Rome "G. Marconi" Rome, Italy

Psoriasis is a chronic, inflammatory, recurrent, genetically determined dermatitis that affects the skin and joints. Many patients affected by this condition seek alternatives and complementary treatment options such as herbal medicines. In order to establish the safety of these products, trials, according to medical standards should be performed to provide the highest quality of data. The aim of this study was to assess the efficacy and safety of an Australian series of herbal skin-care products [Dr. Michaels® (Soratinex®) skin-care products for psoriasis] for the management of stable chronic plaque psoriasis. We studied 142 patients (68 females and 74 males) with mild to moderate, stable, chronic plaque psoriasis and they were randomly assigned to either *verum* or control group. Exclusion criteria were: severe psoriasis, arthropathic psoriasis, intertriginous psoriasis, palmoplantar psoriasis, use of any antipsoriatic treatment and any medication which could influence or interfere with the course of the disease. Both groups consisted of a cleansing gel, an ointment and an oil blend (skin conditioner), packed in neutral bottles, used twice daily for all lesions except the scalp, for 8 weeks. As control products, we used compositions of well-known neutral ointments and medicinal bathing oil. Assessment, using the Psoriasis Activity Severity Index (PASI) scores, was done before treatment and after 2, 4, 6 and 8 weeks. Patient improvement was determined by the percentage reduction of the PASI scores. Statistical analysis was carried out using the Mann-Whitney-U Test with SPSS for Windows. Our investigation demonstrates that complementary methods can play a role in dermatologic therapy as long as they undergo standardised clinical trials and fulfil the basic requirements such as product safety and quality assurance. This study shows that Dr Michaels (Soratinex®) herbal skin-care products improve mild to moderate stable chronic plaque psoriasis significantly.

0393-974X (2016)

Copyright © by BIOLIFE, s.a.s.

This publication and/or article is for individual use only and may not be further reproduced without written permission from the copyright holder.

Unauthorized reproduction may result in financial and other penalties  
DISCLOSURE: ALL AUTHORS REPORT NO CONFLICTS OF INTEREST RELEVANT TO THIS ARTICLE.