Breakthrough natural Eczema treatment: Takzema Tablets showed positive results in 88% of patients

Biogetica is pleased to announce latest clinical trials that have shown dramatic results (88% positive) using advanced natural herbs for eczema relief.

Nov. 5, 2009 - PRLog -- Biogetica Offers treatments for Eczema that includes Takzema Tablets and Ointments. These Takzema Tablets showed positive results in 88% of Eczema patients.

Evaluation of Takzema Tablets and Ointment (Multi-Ingredient Ayurvedic Formulation) in the Management of Eczema

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Eczematous diseases affect more than 10% of the general population and 15-25% of all dermatological patients suffer from eczema. Children are more prone to the disease and a significant number of affected children continue to experience symptoms in their adulthood. Surveys have shown that the prevalence of eczema is increasing.

Although a large number of drugs are used for treating eczema, there is either no scientific evidence to support their use or they have undesirable side effects. The current management of eczema revolves around the use of topical and systemic steroids, antihistamines and soothing and moisturizing agents. Use of steroids (topical and systemic) is fraught with side-effects. Antihistamines have practically very little to offer in eczema.

Therefore, there is a need to introduce treatment approaches that are effective and do not produce undesirable side-effects. Takzema (tablets and ointment) is one such Ayurvedic formulation that contains ingredients such as Rubia cordifolia, Tinospora cordifolia, Berberis aristata, Azadirachta indica, Swertia chirata, Aloe barbadensis, Curcuma longa, Linum usitatissimum and others.

The present study was conducted to assess the efficacy and safety of one such multi-ingredient formulation, Takzema, in patients with mild to moderate eczema.

MATERIALS AND METHODS

This was an open labeled study of Takzema tablets and ointment in 50 sequential patients of either sex between 18 to 55 years of age suffering from mild to moderate eczema.

Patients who attended our Dermatology OPD and were willing to participate and give written informed consent were enrolled in the study. Patients were followed-up for a period of 8 weeks. Necessary approval for the protocol was obtained from our Institutional Ethics Committee before initiation of the trial.

Ambulatory patients of both sexes freshly diagnosed as well as pre-existing patients (with a wash out interval of 2 weeks if on treatment) with eczema and clinical diagnosis of eczema in any location of the body were included. The patients had clinical symptoms associated with eczema such as itching, oozing and desquamation.

The exclusion criteria included patients with infected lesions, history of ischemic heart disease, pregnant and lactating women; patients receiving corticosteroid treatment; patients with history of gastritis, peptic
ulcer, bleeding ulcers; HIV, HBV and known allergic reaction to systemic/topical study drugs. Patients were required to be administered other concomitant medications such as anti-hypertensive and oral hypoglycemic agents at stable dosage for at least 1 month.

Patients could be withdrawn from the study at their own request or if they experienced intolerable adverse events, showed insufficient therapeutic effect, or needed deviations from the protocol at the discretion of the investigator. A thorough physical examination and necessary laboratory investigations, which included hemoglobin, CBC count, ESR, liver and kidney function tests were carried out before drug administration and after completion of treatment.

After confirmation of diagnosis, patients meeting the inclusion and exclusion criteria were included in the study and received 2 Takzema tablets BID for 8 weeks and Takzema Ointment to be applied over the affected area/s thrice daily as a thin film and rubbed in gently and completely for 8 weeks.

Safety and efficacy evaluation of patients’ clinical response to treatment was monitored from screening (day 0) till the end of therapy (end of 8 weeks). All data were carefully entered in the Case Record Form provided. Side effects were closely monitored in all patients. All adverse events were recorded by the investigator, and rated for severity and relationship to the study medication. However, significant exacerbations or worsening of pre-existing conditions were recorded. Drop out cases with reasons (non-compliance, side-effects or others) were noted. Any abnormal laboratory values were also noted.

The efficacy was evaluated on the basis of parameters of modified eczema area sensitivity index (EASI), physicians and patient’s global evaluation at follow-up visits.

The investigator global assessment (IGA) on efficacy and tolerability was performed. Patient’s global assessment on the efficacy and tolerability of treatment was similarly performed.

Patients lost to follow-up or withdrawn from the study at any time, whether due to inadequate response or adverse events, was also considered as failure. The results were analyzed on an intention-to-treat basis. The t-test was used to compare the statistical significance of outcome over baseline at 95% confidence interval.

Treatment with the Takzema tablets and Takzema ointment was well tolerated and did not lead to any abnormalities in the laboratory investigations as compared to the baseline values.

Patients tolerated the trial medications without any major adverse events that needed discontinuation. However, a few patients did experience minor adverse effects.

At the end of 2nd, 4th and 8th week, mean score of erythema had a reduction of 12.7%, 37% and 55%, respectively from baseline. At the end of 2nd, 4th and 8th week, mean score of oozing had a fall of 6.3%, 17.7% and 17.7%, respectively from baseline. At the end of 2nd, 4th and 8th week, mean score of indurations had a fall of 4%, 19.33% and 19.33%, respectively. At the end of 2nd, 4th and 8th week mean score of pruritus had a fall of 6%, 31.33% and 44% respectively from baseline.

At the end of 8 weeks, intensity of individual parameters like erythema and pruritus showed a statistically significant improvement from the baseline (P

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