

## Section-5: Research News

### Klimaktolan™ - Randomised, Double-blind, Multicentric, Placebo Controlled Study in Menopausal Complaints

#### Introduction

Menopause or final menstruation marks the end of reproductive fertility in women. The period of declining sexuality, infertility and hormonal alteration around menopause is known as climacteric. The acute symptoms of hormonal alteration include, vasomotoric symptoms such as hot flushes, vertigo, attacks of perspiration, headache, organic symptoms such as vaginal dryness, breast atrophy, urethritis, incontinence and frequent urinary tract infection; and mental symptoms include tiredness, loss of libido, irritability and depression. The long term effect of menopause is bone-resorption and increased risk of cardiovascular diseases. The prevalent management practices includes hormone replacement therapy, which has many side effects and is advisable only in exceptional cases. Apart from this, the complaints of this condition are being successfully managed by homeopathic medicines.

#### Klimaktolan™ - at a glance

Klimaktolan™ offers an effective alternate therapy for management of the symptomatic complex of menopause. It is composed of a combination of remedies including Cimicifuga racemosa, Sepia officinalis, Lachesis mutus, Ignatia amara and Sanguinaria canadensis. It is indicated in Menopausal symptoms such as hot flushes, cardiac palpitation, dizziness, depression, pruritis, restlessness, attacks of perspiration and sleep disorders. The ingredients are also known for their efficacy in managing pains of the pelvic region, arthralgic, myalgic and neuralgic symptoms, prolapse condition and others. This product has no known side-effects or contraindications and it does not interact with other products. The preferable dose is 1-2 tablets three times per day for an extended period of time or as prescribed by the physician.

#### Study design & objective

It was a randomized, double-blind, multicentric, placebo-controlled study with the objective to evaluate the effectiveness and safety of Klimaktolan™\*\* in the treatment of menopausal complaints compared to placebo.

#### Inclusion & Exclusion criteria

Women, aged 40 - 55 years with acute menopausal complaints (less than 3yrs) in the pre-, peri- and early menopause with a total sum score of the Menopausal Rating Scale\*  $\geq 20$  points along with severe complaints concerning



the symptom “hot flushes, sweating“ were included for the study. Any female with compelling reasons for hormone replacement therapy (HRT) or history of HRT within last 6 months or treatment with herbal or homeopathic medication within the last 3 months was excluded from the study. Severe concomitant diseases, alcohol or drug abuse were also under the exclusion criteria.

#### Results

The data was analysed which included changes in the total sum score of Menopausal Rating Scale (figure 1) and remission rate changes of the symptoms in comparison to placebo group (figure 2, figure 3). The physician outcome and patient satisfaction was also analysed graphically (figure 4 and figure 5 respectively).

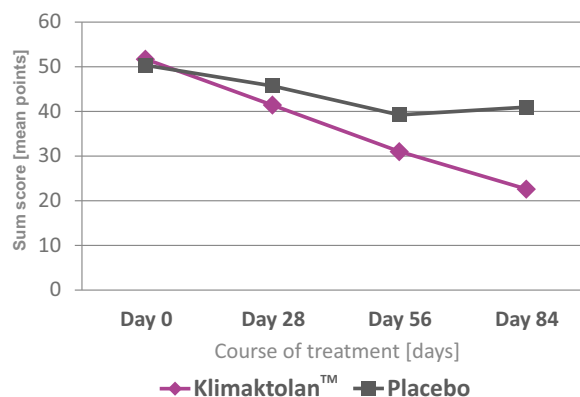


Figure 1: Shows change of total sum score of the Menopause Rating Scale within the course of treatment. Highly significant superiority of Klimaktolan™ compared to Placebo ( $p < 0.0001$ )

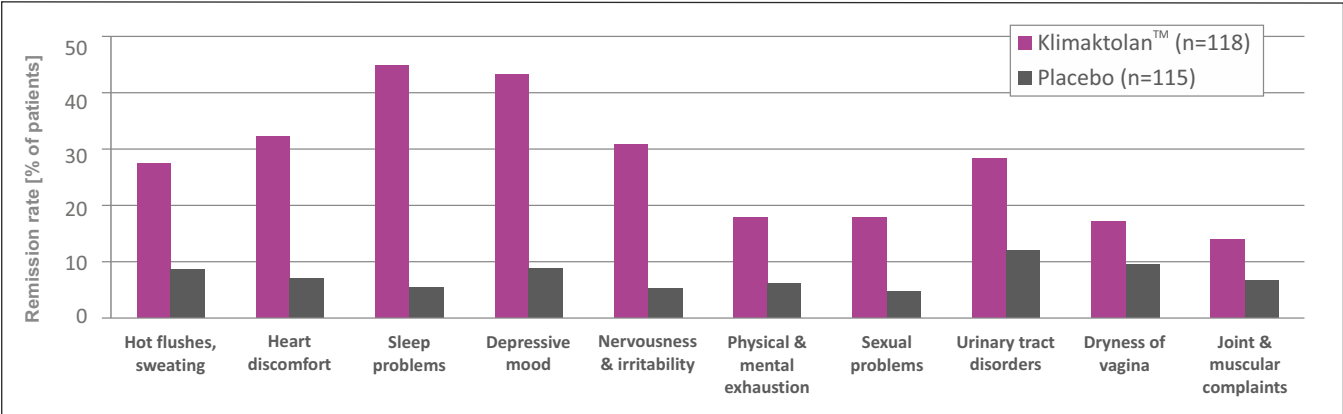


Figure 2: Shows remission of single symptoms of the Menopause Rating Scale on Day 84. In all 10 typical menopausal single symptoms, remission rates were much higher in the Klimaktolan™ group. Furthermore, there were distinctly more patients with unchanged or even worsened symptoms in the Placebo group.

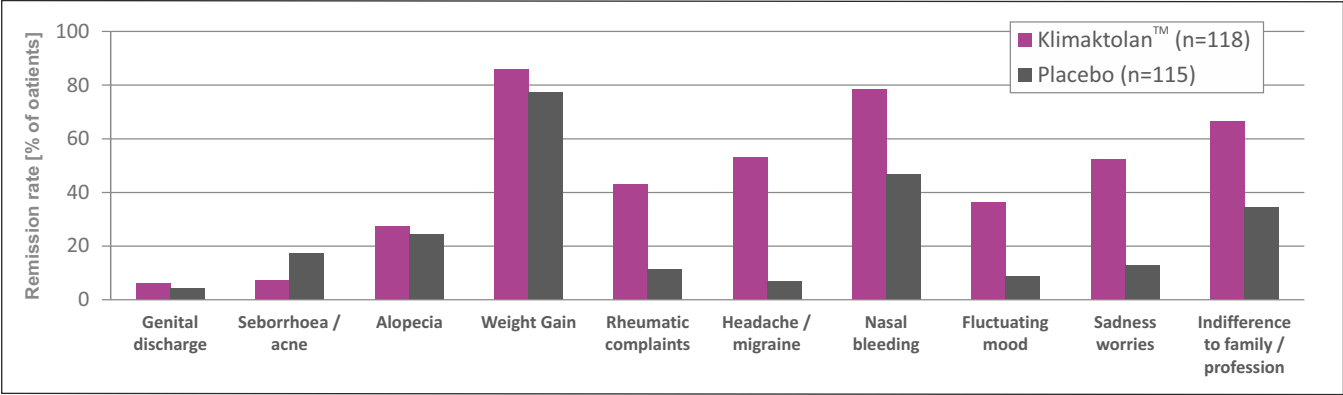


Figure 3: Shows remission of further menopausal complaints on Day 84. Remission rates were – apart of one item (i.e. seborrhoea / acne) – much higher in the Klimaktolan™ group.

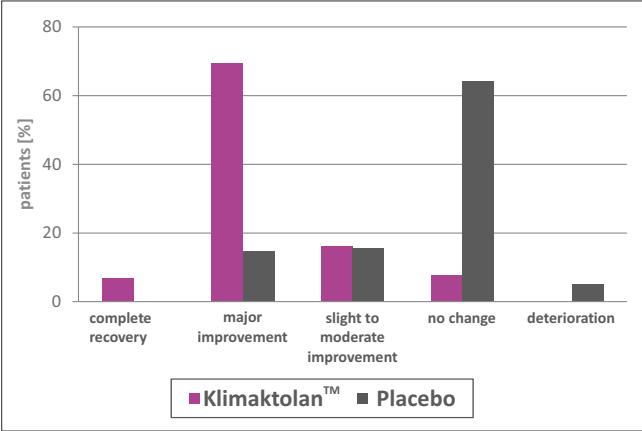


Figure 4: Shows outcome of treatment assessed by the physicians. In almost 65 % of patients symptoms remained unchanged. A deterioration of symptoms (5.2 %) was only observed in patients treated with Placebo.

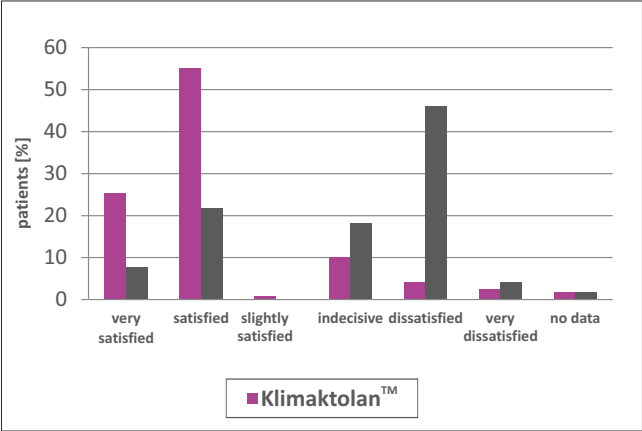


Figure 5: Shows Patient satisfaction with the treatment. Satisfaction with treatment was almost 3-times higher in patients treated with Klimaktolan™ compared to patients treated with Placebo.

Conclusion

This study shows that Klimaktolan™ is clinically effective in menopausal complaints, superior to placebo in treating typical climacteric complaints - the difference is highly significant ( $p < 0.0001$ ). It is safe & tolerable.

Reference

Gerhard I, Ventskovsky B. [Climacteric complaints: The efficacy of a homeopathic combination preparation.] Der Kassenarzt. Sonderbeilage - Heft Nr.15, September 2006 [German].