

Placebo-controlled study confirms: Allpresan® diabetic INTENSIVE Foam Cream displays excellent moisturizing effects and improvement in the skin barrier/condition

In a double-blind, randomized and placebo-controlled study with 50 diabetics suffering from very dry to chapped skin on their feet, the excellent effects displayed by the medical device Allpresan® diabetic INTENSIVE Foam Cream on the skin moisture and skin condition were confirmed. The verum (Allpresan® diabetic INTENSIVE Foam Cream) and placebo foam cream were applied twice per day (mornings and evenings) over a period of four weeks. In order to evaluate the effectiveness of the products used, the skin moisture and transepidermal water loss (TEWL) were determined, and an objective evaluation of defined xerosis parameters was conducted. Both products improved the skin. However, Allpresan® diabetic INTENSIVE Foam Cream proved significantly superior to the placebo foam cream with regard to all aforementioned parameters.

Introduction

Dry skin on the feet is particularly widespread among diabetics and is frequently associated with an increased risk of infection in connection with the resulting complications. It is therefore especially important for dry skin on the feet of diabetics to receive adequate care.

Objective of the study

In a double-blind, randomized and placebo-controlled study, the effect of the medical device Allpresan® diabetic INTENSIVE Foam Cream on very dry to chapped skin on the feet of diabetics was examined.

Methods

The study was conducted with 50 adult diabetics (type I and type II), 49 of whom finished the study in accordance with the protocol. The test subjects were aged 18 years or older. The verum and placebo were applied twice per day (mornings and evenings) over a period of four weeks in a right/left comparison. The measurement and examination days were directly before initial application and also after the product had been used for two and four weeks. The skin moisture was measured using corneometry and the skin

barrier function was determined using the TEWL. In addition, the skin condition was evaluated for the parameters dryness, chapped skin and calluses by assistants with relevant training using high-resolution photographs.

Results

The use of both products increased the skin moisture compared to the baseline value. However, Allpresan® diabetic INTENSIVE Foam Cream achieved significantly better results than the placebo after both two and four weeks of application (Fig. 1).

The visual evaluation of the skin condition by trained assistants revealed that both products caused an improvement in the skin condition with regard to all observed parameters (dryness, chapped skin and calluses) compared to the baseline value. Allpresan® diabetic INTENSIVE Foam Cream proved significantly superior to the effects achieved by the placebo foam cream with regard to all observed parameters (Fig. 2-4).

After both two and four weeks of using Allpresan® diabetic INTENSIVE Foam Cream, the skin barrier function had improved significantly compared to the initial situation. Although use of the

Why placebo-controlled?

The placebo effect familiar from pharmaceuticals also exists for skin care products.

- Any type of care, including care from a placebo without any effective ingredients, achieves positive effects

The comparison with the placebo shows the actual effectiveness of a product.

Allpresan® placebo foam cream

- This is the 'backbone' of the BarrioExpert® Foam Cream Technology, without any additional effective ingredients, i.e. it contains basic lipids, but no other effective ingredients that care for the skin

Effects that are achieved by the placebo foam cream are due to the BarrioExpert® Foam Cream Technology alone, and are the basic effects achieved with all BarrioExpert® Foam Creams.

Allpresan®

Change in the skin moisture compared to the baseline value (n=49)

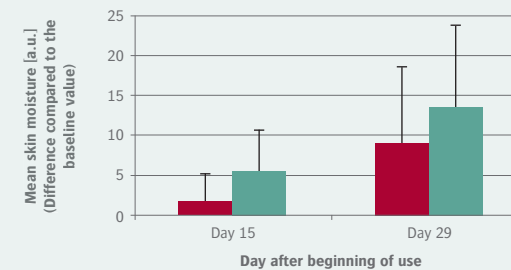


Fig. 1: Change in the skin moisture compared to the baseline value. Both the verum and the placebo improve the skin moisture compared to the initial situation. Allpresan® diabetic INTENSIVE Foam Cream is significantly superior to the placebo at all times.

Change in the skin dryness compared to the baseline value (n=49)

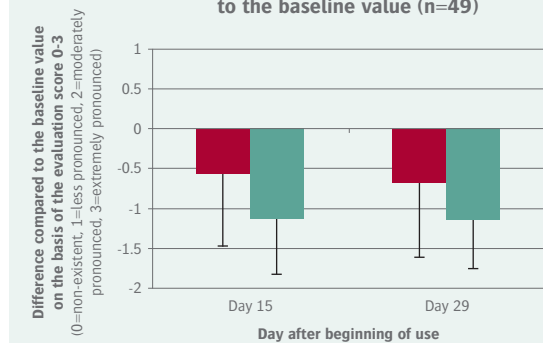


Fig. 2: Change in the skin dryness compared to the baseline value. Both the verum and the placebo improve the skin dryness compared to the initial situation. Allpresan® diabetic INTENSIVE Foam Cream is significantly superior to the placebo at all times.

Change in chapped skin compared to the baseline value (n=49)

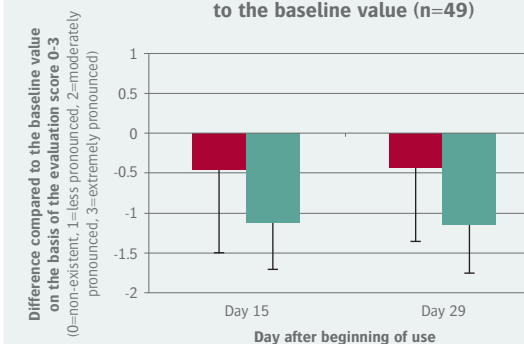


Fig. 3: Change in chapped skin compared to the baseline value. Both the verum and the placebo reduce chapped skin compared to the initial situation. Allpresan® diabetic INTENSIVE Foam Cream is significantly superior to the placebo at all times.

Change in calluses compared to the baseline value (n=49)

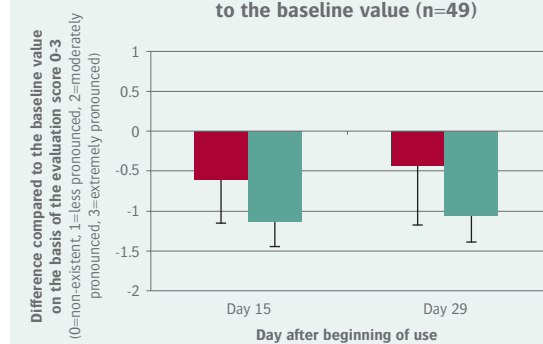


Fig. 4: Change in calluses compared to the baseline value. Both the verum and the placebo improve calluses compared to the initial situation. Allpresan® diabetic INTENSIVE Foam Cream is significantly superior to the placebo at all times.

placebo foam cream reduced the TEWL after four weeks of application, the effects of the placebo foam cream did not equal those of Allpresan® diabetic INTENSIVE Foam Cream. After two weeks of application, the effects achieved by Allpresan® diabetic INTENSIVE Foam Cream were significantly superior to the effects achieved by the placebo foam cream (data not shown). Both foam creams are well tolerated.

Summary

Allpresan® diabetic INTENSIVE Foam Cream improves the skin moisture, the skin barrier function and the skin condition significantly both compared to the baseline value and also compared to the placebo foam cream. Given that dry to chapped skin on the

feet increases the risk of infection, the results displayed here are particularly significant as they show that the skin improves considerably during use of Allpresan® diabetic INTENSIVE Foam Cream. This leads to the conclusion that the existing risk of infection experienced with dry, chapped skin and the associated risks such as the development of mixed infections that are difficult to treat, which at worst can result in amputations, can be reduced with use of Allpresan® diabetic INTENSIVE Foam Cream.

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