

# Efficacy and safety data of VagiVital®

## A water-based vaginal gel for treatment of vaginal atrophy

### Objective

The objective of the study was to evaluate the efficacy and safety of a novel vaginal gel for the treatment of vaginal atrophy. The patient population consisted of 90 post menopausal women aged 40 to 65.

### Background

40-60% of all women suffer from vaginal atrophy during or after menopause. Today, the standard of care treatment alternatives are estrogen therapies generally showing good efficacy and safety. However, there is a sizeable patient group e.g. breast cancer patients and other patients undergoing cancer treatments, that are contraindicated to estrogens. In addition, there is a sizeable group of women that simply do not want estrogen or other hormone treatments. For these women, there is a need for a well documented, safe and effective alternative.

### Method

A vaginal gel (VagiVital®) based on water, hypromellose, benzoic acid, lactic acid and a pH control substance in the form of a low dose of sodium hydroxide was applied intra-vaginally using a tailored applicator once daily for twelve weeks. The applicator had a pre-set standardised dose of 1 ml.

At start of the study, at 4 weeks and at 12 weeks a number of parameters were measured. The primary objective was to study the development of Most Bothersome Symptoms (MBS). MBS is defined as the symptom each patient chose as the most bothersome to her out of vaginal dryness, pain during intercourse, vaginal pain/itching and pain during urination before starting the treatment. The MBS was measured subjectively by the patient on a graded scale (from 0 to 4) at each follow up point during the study.

Vaginal pH and the proportion of superficial cells in the vaginal mucosa were two objective clinical endpoints of the study.

Principal investigator of the study was Associate Professor Gynaecologist Aino Fianu Jonasson at Karolinska University Hospital in Stockholm, Sweden. In addition, Professor Gynaecologist Marie Bixo at the University Hospital in Umeå in Sweden and Professor/ Gynaecologist Inger Sundström Poromaa at the University Hospital in Uppsala in Sweden participated in the study.

### Results Summary

- Statistically significant improvements were shown for MBS; i.e. subjective parameters such as vaginal dryness, pain, irritation, dyspareunia and dysuria. 79% of the patients reported a significant symptom reduction or that they were symptom free.
- These results on MBS are on par with hormone treatments as reported in the literature.
- Statistically significant improvements on objective parameters such as vaginal pH and superficial cells of the vaginal mucosa were also shown during the course of treatment.

### Results

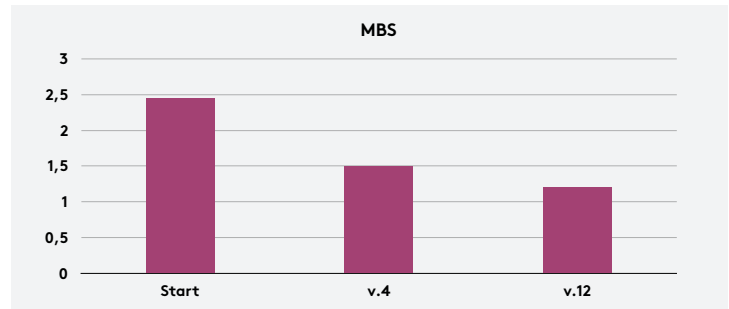


Fig 1. Reduction of MBS during treatment with VagiVital®

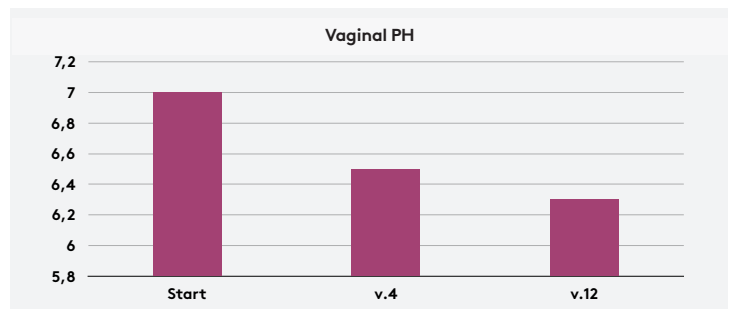


Fig 2. Effect on vaginal pH during treatment with VagiVital®

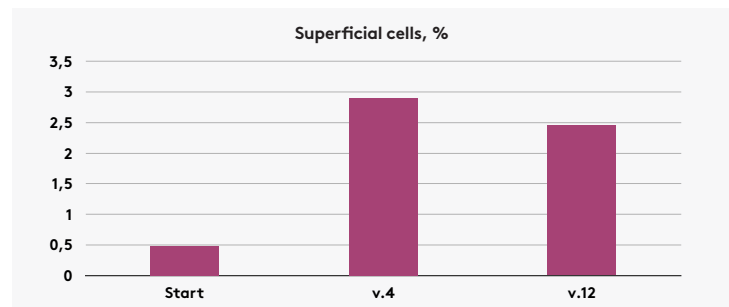


Fig 3. Effect on the proportion of superficial cells of the vaginal mucosa during treatment with VagiVital®

### Adverse events

VagiVital was well tolerated. A few patients reported discharges and one patient reported an unrelated urinary tract infection.

### Conclusions

- VagiVital® showed significant improvements both on objective and subjective parameters, where improvements in MBS were on par with hormone treatments.
- VagiVital® was well tolerated. Including this study, more than 500 patients have used the gel with or without added pharmaceutical ingredients, and no significant adverse events related to the base gel have been reported.
- It is thereby concluded that VagiVital® is a safe and well-documented treatment alternative for patients suffering from vaginal atrophy and dryness that can not or do not want to undergo hormone treatment.
- The very positive and well documented clinical effects of VagiVital® lead to the decision to commercially launch VagiVital® in the self-care segment.