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THE EFFECTS OF REPLENS®, A NON-HORMONAL ALTERNATIVE, FOR THE TREATMENT OF SYMPTOMS RELATED TO POSTMENOPAUSAL VAGINAL ATROPHY

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INTRODUCTION

After menopause, decreased levels of estrogen may result in insufficient maturation of the vaginal epithelium, which may lead to vaginal atrophy and related symptoms such as dyspareunia, dryness, irritation and itching. Estrogen, systemic or local, is an established treatment modality. Replens® is a polycarbophil based bioadhesive gel that adheres to the vaginal epithelium for 72 hours or more; and acts as a non-hormonal vaginal moisturizer.

OBJECTIVE

The objective of this study was to investigate the effects of Replens® on the symptoms of vaginal atrophy.

METHODS

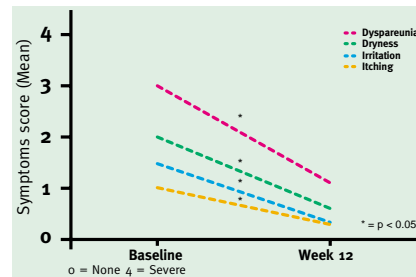
This study was a baseline comparison study. 50 postmenopausal women suffering from vaginal symptoms (dyspareunia, dryness, irritation and itching) were enrolled. 38 patients completed Per Protocol (PP) and 43 patients provided data for the Intention-To-Treat (ITT) analysis. At baseline and after 4 and 12 weeks (study end), subjects scored vaginal symptoms: dyspareunia, dryness, irritation and itching; and the investigator evaluated vaginal parameters: moisture, secretion, irritation and mucosa. Data after 4 and 12 weeks of treatment were compared to baseline by Wilcoxon signed ranks test and Boniferoni's correction. Level of significance was set to 0.05.

DEMOGRAPHICS n = 43 (ITT)

	Mean	+/- SD	Range
Age (years)	57.7	0.7	50-69
Menopause (years)	10.3	1.0	1-27

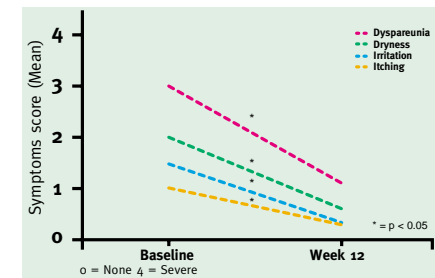
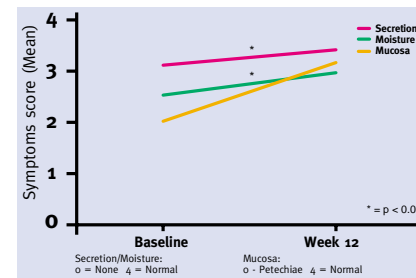
RESULTS: (ITT population n = 43) SUBJECT'S EVALUATION

After 12 weeks, a statistical significant reduction was observed on all 4 symptoms.



RESULTS: INVESTIGATOR'S EVALUATION

After 12 weeks, a statistical significant improvement was observed on vaginal secretion and moisture. Improvements were observed on vaginal mucosa and irritation.



SUMMARY

In this study, Replens® was shown to relieve symptoms related to vaginal atrophy; and to increase vaginal moisture and secretion.

CONCLUSION

Replens® is a non-hormonal alternative for the symptomatic treatment of vaginal atrophy and represents a treatment option for symptomatic atrophic vaginitis in patients with contraindications to estrogen therapy.