

## Clinical factsheet

CF-01

# Human lactobacilli as supplementation of clindamycin to patients with bacterial Vaginosis reduce the recurrence rate; a 6-month double blind randomized placebo-controlled study

— Larsson PG et al.; *BMC Women's Health* 2008, 8:3

## CONCLUSION

After EcoVag® treatment given during three menstrual cycles, there is a significant improvement in time to relapse, so more women remain cured, i.e. are BV free after 6 months.

## FACTS

### Study design:

Women diagnosed with Bacterial Vaginosis (by Amsel criteria) were treated with clindamycin vaginal cream for 7 days; directly followed by 1 EcoVag® or Placebo vaginal capsule per day until next menstruation (max. 10 days); of the 100 women enrolled 76 women classified as cured after initial antibiotic treatment, they continued to use 1 EcoVag® or Placebo vaginal capsule per day for 10 days after the following 3 menstrual cycles or until relapse. A 6-month double blind randomized placebo-controlled study.

### Subjects:

100 women, 18-53 years of age, diagnosed with bacterial Vaginosis (Amsel criteria).

### Dosage:

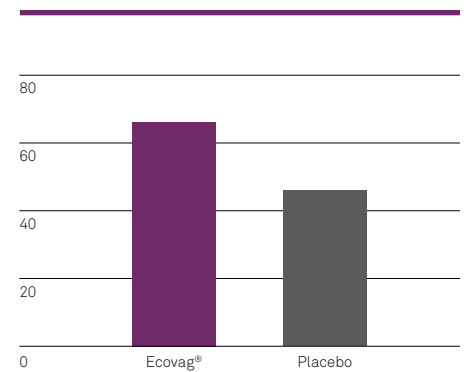
EcoVag® OTC capsule containing minimum 10e8 CFU *L. gasseri* (Lba EB01-DSM 14869) and minimum 10e8 CFU *L. rhamnosus* (Lbp PB01-DSM 14870).

### Duration:

3 menstrual cycles, 6 month follow up.

### Primary endpoint:

At the end of the study 64, 9%, or 24 of 37 of the lactobacilli treated women were still BV free compared to 46, 2% of the placebo treated women (Hazard Risk ratio HR of 0,73 (0,54-0,98) (p<0,05). Statistical significant reduction of recurrent BV infections at 6 month Follow up.



**Figure 1:**  
Cure rate after 6 months after administration in %  
Illustrate the number of cured patients after 6 months. 24 of 37 (65%) in EcoVag® group remained cured 18 of 39 (46%) of placebo group remained cured. Statistical significant result; P=0,042, Hazard Risk ratio: 0,73