EFFICACY, TOLERABILITY AND SAFETY OF A NEW MEDICAL DEVICE, MONURELLE BIOGEL® VAGINAL GEL, IN THE TREATMENT OF VAGINAL DRYNESS IN ADULT CHILDBEARING POTENTIAL WOMEN.

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ABSTRACT.
We conducted a multicenter, randomized, placebo-controlled, open-label study in Italy to assess the efficacy of a 3 week-treatment with a bovine colostrum vaginal gel (Monurelle Biogel® - Zambon SpA) vs. no treatment in adult women of childbearing potential. The primary endpoint was the change from baseline to study end in patient-reported total symptoms scores of vaginal discomfort (vaginal dryness, vaginal and/or vulvar irritation/itching, vaginal soreness, dysuria, and dyspareunia). Secondary endpoints included an objective measurement (Vaginal Health Index) and a validated questionnaire to assess sexual function (FSFI). Vaginal gel usability was also recorded. A significant higher number of subjects, receiving vaginal gel, achieved clinical success in terms of total symptom scores, in comparison with the control group (p<0.0001). An improvement in vaginal dryness was observed starting from day 10 to the end of the study, more than 70% of subjects receiving vaginal gel reported no vaginal dryness (p<0.0001 vs. control group). The use of vaginal gel was associated with improvement in VHI and FSFI (p<0.0001 for both vs. control group). Most subjects judged the vaginal gel easy to administer and the application was rated as "comfortable" or "acceptable" by 92.6% of the study sample. Median compliance to vaginal gel during the study was 100%. We did not observe any severe or serious AE.
In conclusion, colostrum vaginal gel is a valid non-hormonal treatment option for vaginal dryness in adult fertile women and it alleviates vaginal symptoms, an effect that it is likely due to the restoration of vaginal physiology.