

#### 6th Annual Congress on

## Gynecology and Women's Health

November 21, 2022 | Webinar

Received date : 21-07-2022 | Accepted date : 23-07-2022 | Published date : 05-12-2022

### Efficacy of a Multi-ingredient Coriolus Versicolor-Based Vaginal Gel in High-Risk HPV Infected Patients: Results of 6 Different Studies

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Objectives: To evaluate the consistency of the efficacy of a multi-ingredient Coriolus versicolor-based vaginal gel, Papilocare®, on High-Risk Human Papillomavirus (HR-HPV) clearance in 6 different studies1.

Methods: Results from 4 independent observational studies (6 month-treatment period with Papilocare®) were compared to results from a randomized, open, parallel, controlled trial (Paloma: NCT04002154)2 and an observational, multicenter, prospective, one-cohort study (PapilOBS: NCT04199260)3.

- Vigo study: Prospective one-cohort (POC). Secondary endpoint (SE), HPV clearance in 86 patients infected by HPV 16 and/or 18.
- Coruña study: Retrospective one-cohort (ROC). Primary endpoint (PE), HPV clearance assessed in 86 medical patients' records.
- Hospitalet study: ROC. PE, Composite efficacy variable (patients with normal cytology and/or HPV clearance) in 91 HR-HPV patients.
- Roma study4: Retrospective controlled. PE, HR-HPV clearance in 183 patients.
- Paloma trial: RCT, SE, HR-HPV clearance in 91 patients.
- PapilOBS study: POC, SE, HR-HPV clearance in 192 patients.

**Results:** 48% of patients cleared 16/18HPV in Vigo study. 58% of reduction was observed in the number of HR-HPV patients (Coruña) and 72.5% normalized cytology and/or cleared HR-HPV (Hospitalet). 67% HR-HPV clearance was observed (treated group) vs 37.2% (control group), in the Roma study. In the Paloma trial, HR-HPV clearance reached 63% (treated group) vs 40% (control group). 57.4% HR-HPV clearance was observed in the PapilOBS study.

**Conclusions:** Papilocare® has shown significant consistent rates of efficacy with a 64% of HR-HPV clearance in weighted average in 6 different studies involving more than 700 patients. These data reinforce the beneficial effect in HR-HPV patients.

NGHW 2022 November 21, 2022



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#### **Recent Publications**

- 1. Serrano, Luis et al. "Efficacy of a Coriolus versicolor-Based Vaginal Gel in Women With Human Papillomavirus-Dependent Cervical Lesions: The PALOMA Study." Journal of lower genital tract disease vol. 25,2 (2021): 130-136.
- 2. Gaslain Y, et al. 698 Real-life efficacy of a multi-ingredient Coriolus versicolor based vaginal gel in high-risk HPV patients: the PAPILOBS study final results. International Journal of Gynecologic Cancer 2021;31:A314.
- Criscuolo, Anna Angela et al. "Therapeutic Efficacy of a Coriolus versicolor-Based Vaginal Gel in Women with Cervical Uterine High-Risk HPV Infection: A Retrospective Observational Study." Advances in therapy vol. 38,2 (2021): 1202-1211.