# What is Human Papillomavirus (HPV)?

HPV stands for 'Human Papillomavirus', which is a group of more than 100 viruses. HPV is very common, an estimated 80% of sexually active women and men become infected with at least one type of HPV by age 50 years. 70% of genital HPV infections clear within one year and >90% within two years. High-risk HPV types are more likely to result in persistent infection.

There are **14 high risk types** (HPV 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68). In Europe, types **16** and **18** cause **over 70% of cervical cancers**. Low-risk types 6 and 11 are associated with over 90% of genital warts.

The most common manifestation of persistent HPV infection is cervical intraepithelial neoplasia (CIN). Over a number of years, low-grade CIN1, also known as Low grade squamous intraepithelial lesion (LSIL), may progress to CIN2 or CIN3 which are considered cervical cancer precursors.

# **Cancers caused by HPV in Ireland**

#### Each year:

- HPV causes 406 cancers in women and men
- over 6,500 women need hospital treatment for pre-cancer of the cervix
- 300 women get cervical cancer
- 90 women die from cervical cancer

(Source of information: HSE.ie, 2021)

#### Who can use Papilocare?

The use of Papilocare is recommended in women (over 18 years of age) infected by the human papillomavirus (HPV), independently of whether they have virus-induced lesions (ASCUS or LSIL).

# **Does Papilocare replace vaccination as a preventive method?**

No, Papilocare does not replace vaccination. Vaccination is used for primary prevention, which is not an indication for Papilocare. Papilocare is recommended for both vaccinated and unvaccinated women.

# What is Papilocare used for?

- Controlling and helping to re-epithelialise the cervical transformation zone to prevent the risk of HPV-induced lesions (LSIL).
- Adjuvant treatment of HPV-induced intra-epithelial lesions.
- Repairing and helping re-epithelialise lesions of the cervical-vaginal mucosa.
- Treating cervical-vaginal mucosal dryness.
- Rebalancing vaginal microbiota.
- Improving vaginal health.
- Creating the conditions for rapid healing of lesions caused by scratching due to burning or itching.
- Forming a protective film that rapidly reduces irritation, creating suitable conditions to promote the natural healing process.

#### How to use Papilocare

Insert a single-dose cannula into the vagina, preferably before bedtime. Start treatment after your period. If you do not have periods, follow the same treatment plan outlined in the diagram below.

#### **Recommended treatment duration: 6 months**



 Wonths 2-6 (11 Cannulas per month)

 Use every second day for 3 weeks. Do not use on week 4.

 Week 1
 Week 2
 Week 3
 Week 4

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• TREATMENT DAYS O NON-TREATMENT DAYS

For questions or further information relating to Papilocare<sup>®</sup>, please visit the FAQ section on **www.premierwellbeing.ie** or contact the **Premier Wellbeing Customer Care Team at** +353 (0)61 550 124 (Monday to Friday 9am to 5pm)



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CLINICALLY PROVEN

Gynaecologist Recommended

Patented

Formulation

Specifically formulated to repair HPV-induced low grade cervical lesions

# Patient Information

# What is Papilocare®?

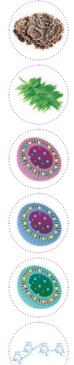
Papilocare is the first **clinically proven** treatment solution for HPV-induced low grade (ASCUS, LSIL, CIN1) lesions of the cervical transformation zone.

# How does Papilocare® work?

The Coriolus versicolor-based vaginal gel is specifically formulated to activate the **three modifiable HPV-induced low grade lesion clearance factors:** 

- 1. Re-epithelialisation of the cervical transformation zone
- 2. Rebalancing the vaginal microbiota
- 3. Counteracting the non-inflammatory microenvironment that HPV creates

# **Ingredients & Actions**



#### **Coriolus Versicolor Extract**

Re-epithelialising and restorative action for cervical-vaginal lesions and microlesions.

# Neem Extract (Azadirachta indica)

Emollient properties that promote the natural healing process.

#### **Hyaluronic Acid Niosomes**

Hydrating action to help maintain tissue elasticity.

#### **B-Glucan Niosomes**

Antioxidant properties that maintain the structure and natural functionality of the skin and mucous membranes.

Centella Asiatica Phytosomes Acts to repair mucosal lesions.

#### BioEcolia<sup>®</sup> (α-Glucan Oligosaccharide)

A prebiotic that stimulates the growth of beneficial bacterial flora and rebalances the microbiota in the cervical-vaginal zone.

#### Aloe Vera Extract

Hydrating, re-epithelialising and restorative action for the cervical-vaginal zone.

# Four Factors that impact the persistence of HPV

The viral genotype	
HPV High Risk Types	HPV Low Risk Types
<b>16</b> , <b>18</b> , 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68	6, 11, 34, 40, 42, 43, 44, 61, 70, 72, 81, 89

# 2 The histological structure of the cervix

Papilocare reepethialises the cervical transformation zone.

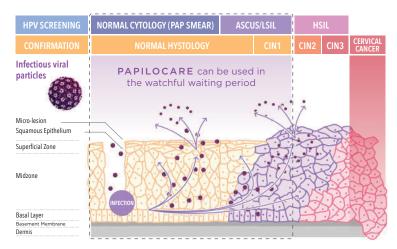
# **3** The status of the vaginal microbiota

Papilocare rebalances the vaginal microbiota.

### 4 The immune status of the woman

Papilocare counteracts the non-inflammatory microenvironment.

# When can Papilocare be used?



ASCUS: Atypical Squamous Cells of Undetermined Significance LSIL: Low-grade squamous intraepithelial lesion CIN: Cervical intraepithelial neoplasia HSIL: High-Grade Squamous Intraepithelial Lesions

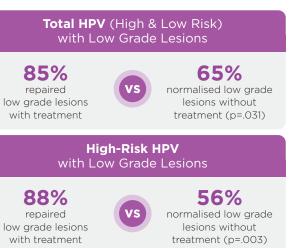
# Clinical Efficacy of Papilocare

# 'The Paloma Study' Final Clinical Trial Results

Published in the American Society for Colposcopy and Cervical Pathology's Journal of Lower Genital Tract Disease, Vol 25, No. 2, April 2021



#### Patient Groups (After 6 months treatment)



#### High-risk HPV types are more likely to result in persistent infection.

# **Clinical Trial Conclusions**

"Treatment with Papilocare has demonstrated a better clinical benefit than the conventional watchful waiting approach in clinical practice for HPV-positive patients, especially for those with HR-HPV. Papilocare has shown significant efficacy in the treatment of low-grade cervical lesions associated with HPV and a positive trend in increasing HPV clearance after a 6 month period."

Luis Serrano MD, Andrés Carlos López MD, Silvia P González MD, Santiago Palacios MD, Damián Dexeus MD, Cristina Centeno-Mediavilla MD PhD, Pluvio Coronado MD, Jesús de la Fuente MD, José Antonio López MD, Cristina Vanrell MD, Javier Cortés MD PhD