



## Intimate Balance and Well-being

- Based on **sodium hyaluronate** and **tindalised probiotics**
- Supports the **prevention and treatment** of severe vaginal infections
- Recommended for **rebalancing the vaginal environment** even after surgery





# Intimique

Highlights



Medical Device Class IIa

CE Mark 0477

**Intended use:** adjuvant in the prophylaxis and treatment of severe vaginal infections and their recurrences, following treatment with antibiotics or surgery.

## Intimique® Ovules

The vaginal ecosystem is a delicate balance between bacteria and metabolic products, in which non-pathogenic species outnumber pathogenic ones in a ratio of approximately 200:1.

**Lactobacilli** play a key role in regulating this balance by producing substances that inhibit the growth of pathogenic bacteria.

An imbalance can therefore favour the **proliferation of harmful bacteria**, increasing the risk of bacterial vaginosis or vaginitis. This kind of conditions affect more than 300 millions of women worldwide every year, with more than 10% of recurrences.

Furthermore, alterations in the vaginal ecosystem may increase the risk of **post-operative complications** in gynaecology.

This is why we developed **Intimique® Ovules together with ROELMI HPC**. Intimique® Ovules is based on an **innovative formulation** designed as an adjunct in the **prophylaxis and treatment of severe vaginal infections and their recurrence**.

It has also been formulated to **rebalance the vaginal environment** following prolonged antibiotic treatment, problems with hormonal imbalances or after surgery.

# The formula

Thanks to its ingredients, **Intimique® Ovules promotes the natural recovery of the vaginal ecosystem**: it helps counteract dryness, relieving symptoms such as itching, redness, burning, and so on. This is possible thanks to the **integrated action of two ingredients: lactic acid and sodium hyaluronate**.

**Lactic acid helps restore the natural physiological vaginal pH**, which is essential for a rebalancing of the entire vaginal environment and the proliferation of lactobacilli.

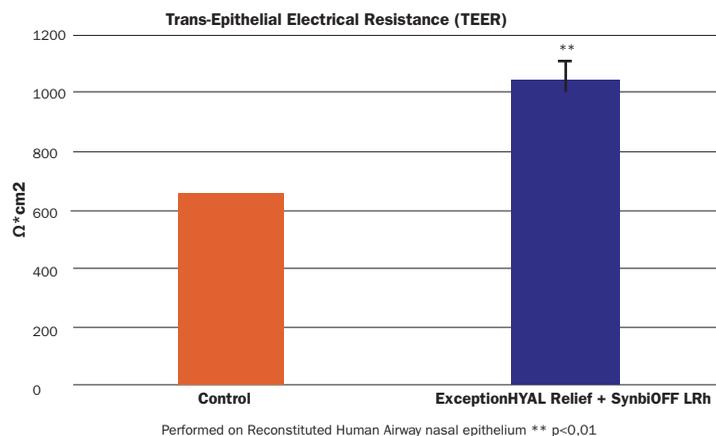
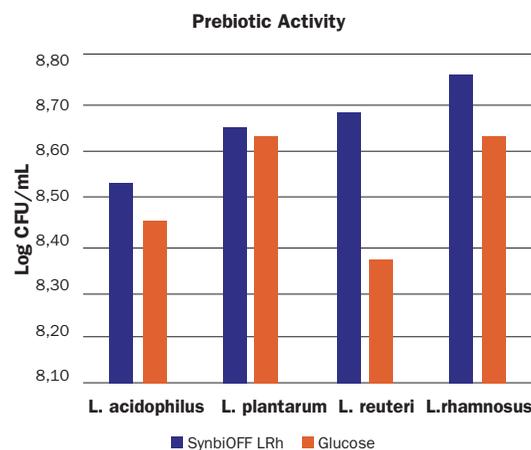
**Sodium hyaluronate ExceptionHYAL® Relief acts in synergy by moisturising and stimulating epithelial regeneration** of the vaginal mucosa and its natural barrier.

**ExceptionHYAL® Relief is an innovative sodium hyaluronate** called "full spectrum", which has a very specific identity as a molecule. This allows this sodium hyaluronate to **mimic the biological needs of the body**, adhering perfectly to the tissues in different areas and helping the process of mucosa restoring.

The most innovative element in the formula of Intimique® Ovules is **SynbiOFF LRh tinalised lactobacilli**: these are *L. Rhamnosus* LRH020, lactobacilli that prevent pathogens such as bacteria, fungi and viruses from taking root. In addition, **lactobacilli allow native microorganisms to thrive, supporting the growth and balance of the microbiota**.

In this way the balance of the vaginal microbiota is protected, while the other ingredients act to **restore it to a normal condition of hydration and balance**.

Other components are **Vitamin E, Vitamin A, galactoarabinan**, a polysaccharide extracted from the bark of the Larch tree, semi-synthetic triglycerides and colloidal silica: these have been included to give Intimique® an **optimal consistency**, and thus enhance the product's **homogenous distribution performance**, which adheres to the mucous membrane effectively. Intimique® Ovules is therefore an excellent ally for intimate well-being, capable of **intervening as adjuvant in the treatment and prevention phases**, supporting the natural balance of the vaginal environment.



## Pre-clinical Safety Studies Performed

Cytotoxicity report number: IT0002943/20 of 29/10/2020, results: Not Citotoxic

Skin Sensitization by Local Lymph Node Assay of Test Item DM Intimique in Mice Report number: 140520-2, results: Not Sensitizing

Vaginal Irritation after Topical Application of the Test Item Intimique in Rabbit, report number: 140520-1, results: Not Irritating Agent

# Clinical data

We conducted a **prospective clinical study** to evaluate the **performance and safety of Intimique®** in women with acute vulvovaginal candidiasis (VVC) or bacterial vaginosis (BV).

A total of **22 women** (10 with BV and 12 with VVC) aged 25 to 33 years were included.

All completed the entire trial, and at the final follow-up visit 6 patients (60%) with BV and 5 patients with VVC (40%) were disease-free. The remainder observed an infection during the reporting period.

**No side effects were observed.**

We also conducted a **prospective study on the efficacy and safety of Intimique®** for the treatment of vaginal dryness and atrophy in post-menopausal women.

A total of **18 women** aged 45-59 years were included and reported their subjective assessment of vulvovaginal dryness. The latter decreased from a mean value of 9.1 to a mean value of 4.8, reaching statistical significance. **The VHI score showed a significant improvement**, with a mean value of 13.9 at baseline compared to a mean value of 20.3 after therapy. No serious side effects were observed.

## How to Use

It is recommended to use **1 ovule per day, preferably before bedtime, 7 consecutive days** for mild symptoms or recurrences and **10 consecutive days if symptoms persist**.

Intimique® provides an innovative and gentle approach to intimate health, ensuring protection and comfort at every stage of life.

# Test for efficacy of Intimique®

## Test for barrel activity and film forming properties

500 µl of VAGINAL OVULES LOT P0038 (000038) were applied on paper filter GE Healthcare Life Sciences Whatman and uniformly distributed. **The filter paper was put in the Franz diffusion cell**, between the donor chamber and the receiving chamber, and left for equilibrating for 20 minutes; the system was then put at 37°C. 500 µl of Trypan Blue 0.5% were applied too through the donor chamber and serial sampling were done after 24 hours, for the spectrophotometer evaluation of the presence of penetrated Trypan Blue (reading at 540 nm).

**3 independent trials were performed and for each experimental time the results were statistically compared to T0** (T-test for paired comparison).

Spectrophotometric analysis of the solutions taken by receiving chamber during the period in which Trypan Blue was applied on the filter treated with the medical device didn't highlight significant variations until 24 hours from test beginning. **The tested product therefore showed film-forming properties.**

FILM-FORMING CAPABILITY						
ROELMI HPC - VAGINAL OVULES LOT P008 (000038)						
	OD1	OD2	OD3	mean	st.dev.	T-Test vs T0
<b>T0</b>	0,067	0,063	0,059	0,063	0,004	
<b>24h</b>	0,068	0,070	0,062	0,067	0,004	0,173

## Test for adesivity

The study concerns the **in vitro evaluation of the mucoadhesive capacity of the product**, tested on reconstructed human buccal mucosa tissue by assessing the percentage of inhibition of lectin-glycoprotein binding.

Specifically, mucoadhesive efficacy is assessed on the product as such, and **the tissues were treated with a biotinylated lectin from Canavalia ensiformis** (Concanavalin A - Con-A), a protein that shows a high affinity for glycosidic and mannosidic residues of membrane glycoproteins.

In this way, mucosal membrane glycoprotein sites are occupied by the biotinylated lectin. **The tissues were then treated with streptavidin peroxidase**, allowing the formation of the protein-glucose-lectin-biotin-streptavidin-peroxidase complex due to the high affinity between biotin and streptavidin; **the complex was quantified by means of an oxidation reaction in a microplate reader.**

The intensity of the colour is proportional to the amount of glycoprotein-lectin bonds and thus to the amount of available sites (glycoproteins). The absorbance value thus determined constitutes the control condition.

**This method uses an indirect technique to identify substances that bind to the surface of the cells of the vaginal mucosa** by means of a colorimetric detection system. The experimental model used in this test is STERLAB Vaginal Epithelium. Conclusions drawn: The sample has mucoadhesive properties in the specific study protocol. There is a significant difference between the sample-treated tissue and the CTR.

TREATMENT	Mean ABS	% MUCOADHESION
Control (CTR-)	3.166	-
VAGINAL OVULES LOT P008 (00008) as neat	1.569	50.4 ± 8.8%*



### Commercial Informations

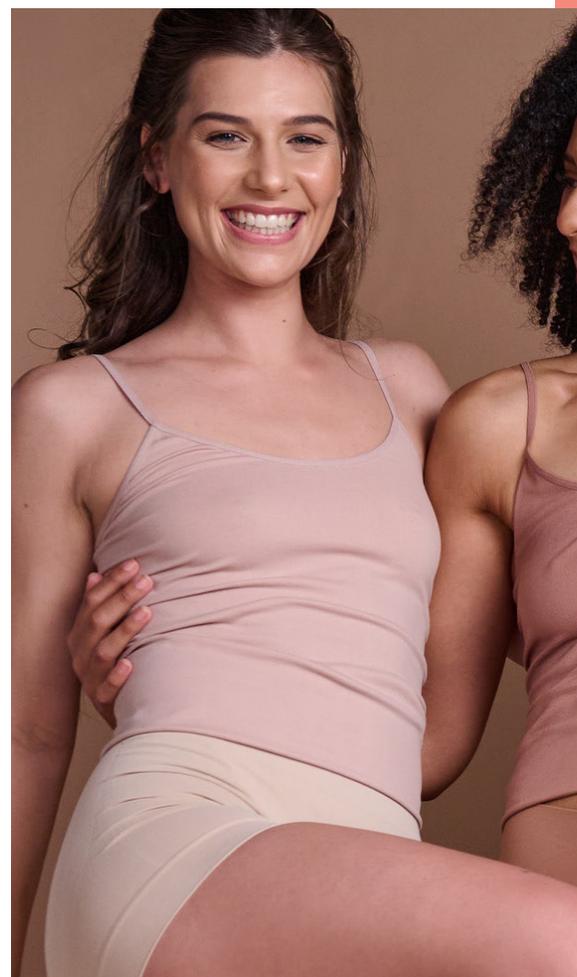
**Intimique®**

**Format:** 10 ovules per unit (2 blisters of 5 ovules each)

**Indication of Use:** one ovule per day for 7 or 10 days -  
Package leaflet in each box

**Shelf Life:** 36 months

**Minimum order quantity:** 10.000 units



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