



Heaton

HEALTHCARE GROUP

WE BRING PARTNERSHIP
WITH RESPECT AND TRUST

www.heaton.cz



GYNELLA®

We bring you a ready-made solution to meet women's
needs at all stages of their lives



Patient profiles and their healthcare needs addressed by the GYNELLA range

NON_HORMONAL

PUBERTY

FERTILITY

MENOPAUSE



Kids
(2-12 years)*
Teenage girl
(12-18 years)

GYNELLA®:

- Flora
- Girl Intimate Wash*
- Cystilab



Young Woman
(18-30 years)

GYNELLA®:

- Silver Caps
- Silver Foam
- Silver Gel
- Flora
- Intimate Foam
- Intimate Wash
- Cystilab



Trying to conceive
(20-40 years)

GYNELLA®:

- Natal Ferti Gel
- Flora
- Intimate Foam
- Intimate Wash
- Cystilab



Pregnant woman

GYNELLA®:

- Flora
- Silver Gel
- Silver Foam
- Intimate Wash
- Intimate Foam
- Cystilab



Active woman
(20-45 years)

GYNELLA®:

- Silver Caps
- Silver Foam
- Silver Gel
- Flora
- Balance
- Cystilab
- Intense



Peri and Menopause
45+

GYNELLA®:

- AtroGel
- Meno NRS
- Balance
- Cystilab
- Intimate Foam
- Intimate Wash
- Intense

OTC PORTFOLIO

GYNELLA®

VAGINAL INFECTIONS

GYNELLA® Silver Caps

GYNELLA® Silver Foam

GYNELLA® Silver Gel

URINARY TRACT

GYNELLA® Cystilab

SEXUAL HEALTH

GYNELLA® Intense

VAGINAL MICROFLORA

GYNELLA® Flora

FERTILITY

GYNELLA® Natal Ferti Gel

MENOPAUSE

GYNELLA® Balance

GYNELLA® AtroGel

GYNELLA® Meno NRS

INTIMATE HYGIENE

GYNELLA® Intimate Wash

GYNELLA® Intimate Foam

GYNELLA® Girl Intimate Wash

MEDICAL DEVICES, FOOD SUPPLEMENTS AND COSMETICS FOR WOMEN'S HEALTH

VAGINAL INFECTIONS



GYNELLA® Silver Caps
• 10 vaginal soft gel capsules



GYNELLA® Silver Foam
• 50 ml in foamer bottle



GYNELLA® Silver Gel
• 25 ml of gel in tube

VULVO-VAGINAL ATROPHY



GYNELLA® AtroGel
• 7 single dose applicators of 5 ml for vaginal use

URINARY TRACT



GYNELLA® Cystilab
• 10 sachets

FERTILITY



GYNELLA® Natal Ferti Gel
• 6 single dose applicators of 5 ml for vaginal use

VAGINAL MICROFLORA



GYNELLA® Flora
• 10 vaginal suppositories



GYNELLA® Balance
• 10 vaginal suppositories

MENOPAUSE



GYNELLA® Meno NRS
• 30 sachets

SEXUAL HEALTH



GYNELLA® Intense
• 15 ml oleogel

INTIMATE HYGIENE



GYNELLA® Intimate Wash
• 200 ml



GYNELLA® Intimate Foam
• 150 ml



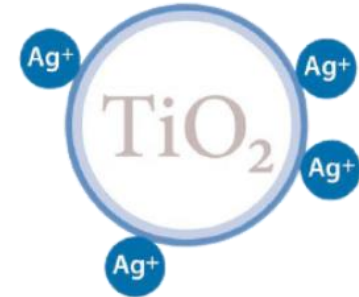
GYNELLA® Girl Intimate Wash
• 100 ml



VAGINAL INFECTION NEW THERAPEUTIC PERSPECTIVE

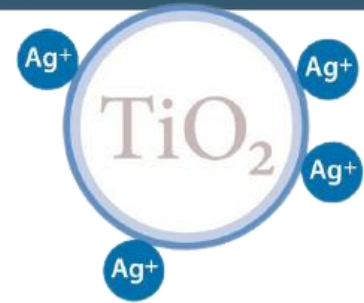
TIAB[®]

= an innovative complex molecular system developed using micro-technologies that contains Ag^+ silver ions in combination with titanium dioxide (TiO_2)



TIAB[®] complex:

- A patented compound of silver ions (Ag^+) covalently bonded to titanium dioxide (TiO_2) particles.
- It shows significantly higher antimicrobial activity at the same concentration of silver ions compared to colloidal silver.
- Silver ions are bound to the surface of TiO_2 by means of a binding ligand that stabilizes Ag^+ ions, thus enabling their concentration to be maintained 1000 times higher than that found naturally in nature, thereby ensuring higher efficiency.
- The covalent bond allows the complex to contain only silver ions (Ag^+), for which it is impossible to pass into the antimicrobially inactive form of metallic silver (Ag_0).

TIAB[®] - triple action on bacteria and fungi cell

No formation of
resistance possible

Destabilization of the bacterial and fungal cell walls, which become permeable

Blocking the enzymatic system of bacterial or fungal cells

Prevention of nutrient transport

Binding to DNA->no more cell division possible

Blocks the antigens of the viruses-no more penetration into the host cell possible

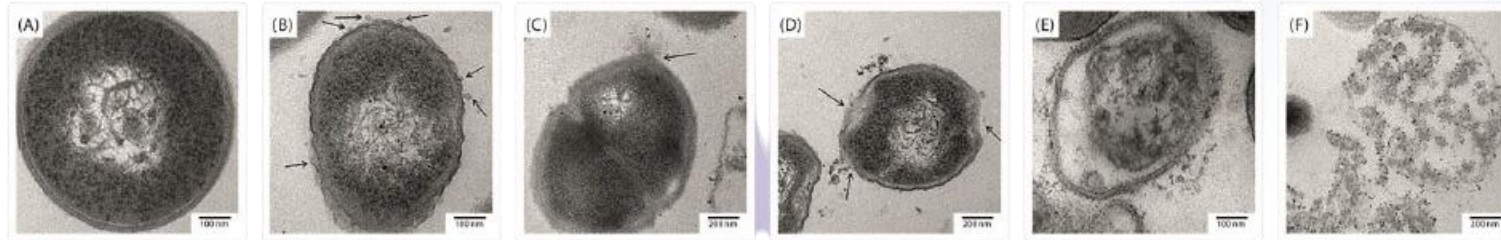


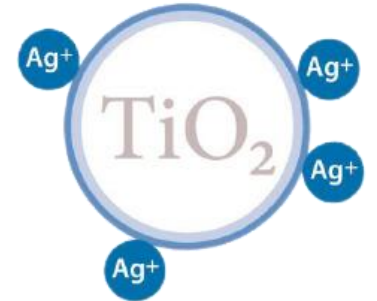
Fig. 1: Transmission electron micrograph of gram-positive bacteria (*Straphylococcus aureus*) (A-D, F) and gram-negative bacteria (*Pseudomonas aeruginosa*) (E) before (A) and after (B-F) contact with silver particles, the ultrastructure shows damage that occurs in the bacterial cells . [2]

1 Mijndoncks et al., 2013

2 Figure taken from Bernacchi et al., 2017

TIAB® affects viruses

- Breaking up the structural proteins of the virus.
- Enzyme denaturation.
- Adheres to the DNA/RNA and damages its effect.



Activity of TIAB® complex

Table 1

Antimicrobial activity of TIAB® complex¹

BACTERIA

Bacillus subtilis
Clostridium difficile
Enterococcus faecalis
Escherichia coli
Legionella pneumophila
Listeria monocytogenes
Mycobacterium avium
Mycobacterium terrae
Neisseria gonorrhoeae
Neisseria meningitidis
Pseudomonas aeruginosa
Salmonella enteridis D1
Staphylococcus aureus (incl. MRSA)
Vibrio cholerae

FUNGI

Aspergillus niger
Candida albicans

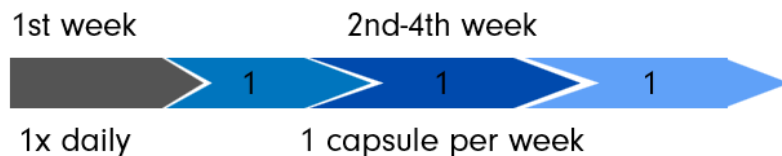
VIRUSES

Influenza A Virus Subtype H1N1
Astroviridae
Adenoviridae
 Avian Influenza Virus
Enteroviridae (inkl. BEV – 1)
Caliciviridae
Cytomegalovirus (CMV)
 Hepatitis A Virus (HAV)
 Hepatitis B Virus (HBV)
 Human Immunodeficiency Virus (HIV)
 Hepatitis C Virus (HCV)
 Hepatitis E Virus (HEV)
Herpes Simplex Virus 1 (HSV-1)
 Human T-lymphotropic Virus 1 (HTLV – 1)
 Measles Virus
Orthomyxoviridae (incl. A H1N1 und Avian Influenza)
Papovaviridae
Paramyxoviridae
 Respiratory syncytial virus (RSV)
 Poliovirus
Poxviridae
Reoviridae
 Rhinovirus
 Rotavirus
Rubella Virus
 SARS – Corona Virus
Varicella Zoster Virus

GYNELLA® Silver Caps



Application:



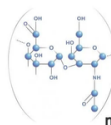
Effect

Unique, innovative silver complex used as adjuvant in treatment of bacterial, fungal and viral vaginal infections and healing of post-partum and surgery lesion. Active substances create high antimicrobial barrier that insulates and protects area of infection against pathogens.

Composition:



TIAB® complex



Sodium hyaluronate



Aloe Barbadensis Extract

Benefits:

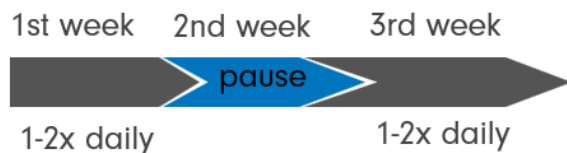
- strong effect due to the silver complex with moisturizing hyaluron and soothing aloe vera
- fast-dissolving soft capsules
- supports tissue regeneration, promotes healing

GYNELLA®

Silver Foam



Application:



Effect

Innovative formulation providing vaginal protection and comfort. Supports healing of delicate tissue, combines multiple beneficial effects, and creates a protective barrier in the external genital area to shield against external irritants.

Various areas of application:

- effectively eliminates disorders of the vulvo-vaginal balance caused by bacteria or fungi
- for viral attacks, e.g. as a preventive measure against recurrent herpes simplex, HPV, genital warts
- Promotes healing of lesions, e.g. after birth
- supports the post-operative re-epithalization of women

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GYNELLA®

Silver Foam

HEALTHCARE GROUP

Composition:



TIAB® complex

Malva Sylvestris

Sodium hyaluronate

Benefits:

- Promotes healing and soothes irritation
- Cooling effect and pleasant consistency

Easy to use: Apply gently to cleansed skin, leaves no residue on clothing



GYNELLA®

Silver Gel



Effect

Innovative silver complex used in vulvovaginal treatment of bacterial, fungal and viral infections and vulva wound healing. Active substances create high antimicrobial barrier against pathogens. Creates the best possible condition for tissue regeneration.

Composition



TIAB® complex

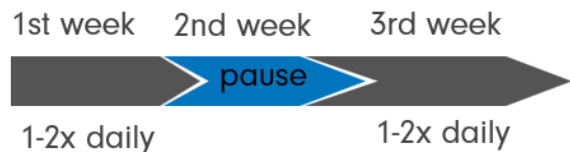


Sodium hyaluronate



Aloe Barbadensis Extract

Application:



Benefits

- Supports the treatment of vaginal infections (bacterial, fungal and viral)
- Adjuvant in the treatment of post-partum lesions
- Calms, soothes, and protects

INNOVATIVE ADJUVANT TREATMENT FOR ALL TYPES OF VAGINAL INFECTIONS

Silver Foam

Composition:	TIAB® (microcrystals of titanium dioxide with covalent bonds of monovalent silver ions), Malva sylvestris extract, Sodium hyaluronate, <u>Aloe barbadensis</u> extract, Benzalkonium chloride
Classification:	Medical device class IIb
Presentation:	50 ml vulvovaginal foam
Shelf life:	24 months

Silver Caps

Composition:	TIAB® (microcrystals of titanium dioxide with covalent bonds of monovalent silver ions), sodium hyaluronate and extract from <u>Aloe barbadensis</u> .
Classification:	Medical device class IIb
Presentation:	10 soft vaginal capsules
Shelf life:	36 months

Silver Foam

Composition:	TIAB® (microcrystals of titanium dioxide with covalent bonds of monovalent silver ions), Sodium hyaluronate, <u>Aloe barbadensis</u> extract
Classification:	Medical device class IIb
Presentation:	25 ml of gel in tube
Shelf life:	24 months



ROLE OF TIAB® VAGINAL FORMULATION IN CERVICAL REEPITHELIALIZATION AND HIGH RISK HPV CLEARENCE IN PATIENTS WITH LOW GRADE CERVICAL LESIONS

Objective

To evaluate the re-epithelializing effect and clinical efficacy of TIAB® vaginal formulation in women with low-grade cervical lesions (ASC-US / L-SIL) who were HPV high-risk positive and presented cervical ectropion/ectopy.

Method

- 19 patients recruited; 18 completed the study (mean age 31)
- All patients had AT1 transformation zone lesions with bleeding ectropion/ectopy
- **Treatment:** TIAB® vaginal formulation once daily for 10 days per month over 4 months.
- **Outcomes assessed at 6 months:** cytological clearance, HPV clearance, colposcopic regression, and ectropion/ectopy re-epithelialization

Results (6-month follow-up):

- **Cytology clearance:** 66.7% (12/18 patients).
- **HPV clearance:** 50% (9/18 patients).
- **Colposcopy:**
 - Complete regression in 50% (9/18).
 - Remaining patients showed stable or improved findings (no progression).
- **Bleeding:** Resolved in all patients.
- **Ectropion/Ectopy:**
 - Fully resolved and re-epithelialized in 55.6% (10/18).
 - ≥25% reduction in 16.6% (3/18).
 - Unchanged in 27.8% (5/18).

Results



Italian Journal of
Gynaecology & Obstetrics

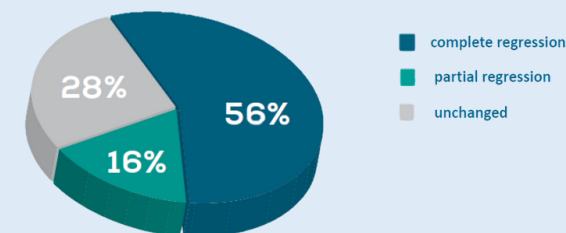
March 2017 - Vol. 29 - N. 1 - Quarterly - ISSN 2385 - 0868

Table 1

Cytological, colposcopic and microbiological development in 18 patients

Pap-Test Negativisation (%)	HPV Clearance (%)	Colposcopy negativisation (%)
12	9	9
67%	50%	50%

Picture 1: Degree of cervical ectropion/ectropion re-epithelialization



TIAB® vaginal formulation has shown itself to be a promising therapeutic aid in the management of low-grade cervical lesions caused by high-risk HPV, and is a valid option for the conservative management of bleeding ectropion/ectopy.

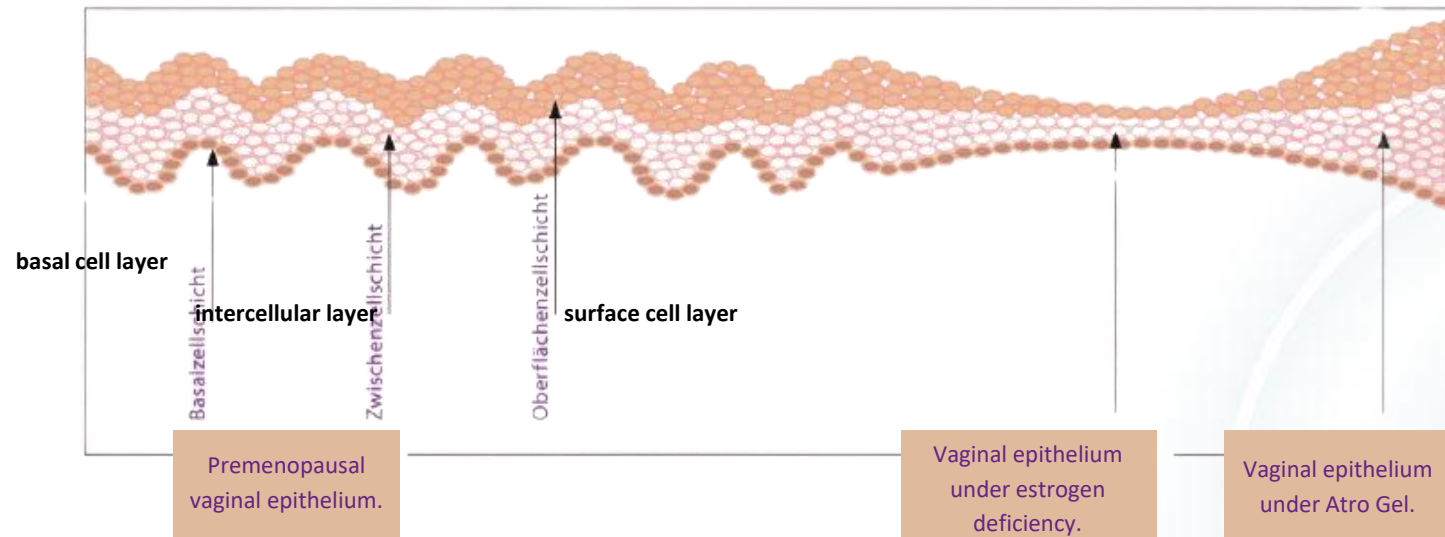


VAGINAL DRYNESS AND ATROPHY

Atrophy

Causes:

- low estrogen levels lead to less supply to the vulvar and vaginal mucosa
- the vaginal epithelial cells shrink due to the loss of organelles, cytoplasm and proteins



Consequences:

- Mucous membrane becomes thinner and loses elasticity
- Mucous membrane dries out, epithelium loses lubricity
- the pH value increases
- the tissue is more susceptible to infection
- Sexual intercourse or sport (e.g. cycling) is painful

Adjuvant treatment and prevention of vaginal symptoms which are often associated with **vulvo-vaginal atrophy** and **other origin vaginitis and vaginosis**. Supports fast restoration of vaginal physiological conditions by creating a nonconventional film-like barrier which protects the underneath tissue from dehydration, external irritant and microbial attacks.

Composition: Silver complex (microcrystalline titanium dioxide with covalently linked monovalent silver ions), Sodium hyaluronate, Genistein

Classification: Medical device class IIa.

Presentation: 7 single dose applicators of 5 ml for vaginal use

Shelf life: 24 months

GYNELLA®

AtroGel



Application:



Suitable for women:

- in menopause with mild to moderate symptoms of vulvo-vaginal atrophy (dryness, burning, itching, dyspareunia, algopareunia),
- with vaginal infections due to vaginal atrophy or dryness,
- with hormonal fluctuations due to impaired or reduced estrogen production,
- using contraception or other hormonal treatment,
- undergoing onco- or radiotherapy.



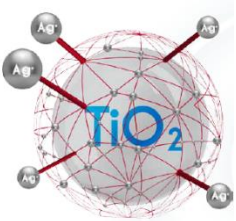
COMPOSITION



Thanks to its hydrating properties, **hyaluronic acid** guarantees adequate **moisturization of the vaginal mucosa**. Vaginal gel with hyaluronic acid has an effective barrier effect that **helps the repairing process of the lesions associated with vaginal dryness** and to restore the physiological condition of the mucous membrane.



Genistein helps to **increase the elasticity of the vaginal mucosa** and complements the effect of hyaluronic acid, thereby **relieving the unpleasant feelings of tension and dryness**.



TIAB® complex has high antimicrobial activity and **helps to reduce the risk of vulvovaginal infections** that can occur due to vaginal atrophy.



**STIMULATION OF VAGINAL
MICROBIAL BALANCE**



**STIMULATES THE NATURAL
VAGINAL IMMUNE DEFENCE**

THE PARAPROBIOTIC CONCEPT BASED ON TYNDALLIZED STRAINS

Tyndallized probiotics have been demonstrated to positively affect human health. They represent a new generation of safer and more stable products.

PROBIOTICS



- According to the FAO/WHO definition (2002), probiotics are defined as „live microorganisms which when administered in adequate amounts confer a health benefit on the host“.
- Probiotic microorganisms must be „live“, and this stipulation is supported by an extensive number of studies suggesting that to for keeping health benefits probiotic microorganisms must be viable.
- However, scientific evidence indicating **that killed or inactivated microbes (dead microbial cells or microbial cell fractions) may also positively affect human health.**

=> **TYNDALLIZATION** = a tailored inactivation treatment used to obtain killed or inactivated microbial cells.

Source: Taverniti V. and Guglielmetti S.: *The immunomodulatory properties of probiotic microorganisms beyond their viability (ghost probiotics: proposal of paraprobiotic concept)*. Genes Nutr. Aug 2011; 6(3): 261-274 [1]

PARAPROBIOTICS

- **Paraprobiotics** are „non-viable microbial cells (intact or broken) or crude cell extracts, which, when administered (orally or topically) in adequate amounts, confer a benefit on the human or animal consumer“.
- Paraprobiotics can be obtained through physical or chemical strategies:
 - Heat treatment, UV ray deactivation, chemical or mechanical disruption, pressure, lyophilisation or acid deactivation.
 - Tyndallized strains are obtained after a heat treatment of the microbial cells.
 - Tyndallization performed at HEATON results in intact non-viable microbial cells – the whole structure of the cell is conserved.

Paraprobiotics:

Non viable microbial cells INTACT

- HEATON TYNDALLIZED STRAINS

Non viable microbial cells BROKEN

Crude cell extracts

CLINICAL EFFECT OF TYNDALLIZED STRAINS

- ✓ **Stimulates the immune response by adhesion to the vaginal wall.**

The process of tyndallization enables the bacteria to retain all of their cell structures and thus to adhere to the vaginal wall.

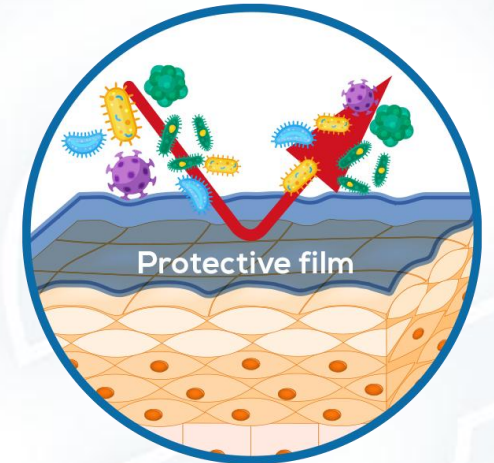
This strengthens the natural defense of the vaginal microflora against bacterial and fungicidal attacks when this is reduced by external factors.

- ✓ **Creates a protective film.**

Adhesion to the vaginal walls stimulates the immune response and creates a protective film.

- ✓ **It supports the natural protective mechanisms of the vaginal microflora.**

Regular (long-term) use can increase the natural immunity of the vaginal epithelium as a result of diseases affecting the vagina (vaginal discharge, inflammation, infection etc.) and thus delay the return of infections.



RESTORATION OF DAMAGED VAGINAL MICROFLORA

- During sufficiently long application of vaginal suppositories with inactivated tyndallized lactobacilli the vaginal mucosa gradually begins to tolerate "foreign" bacteria and to **promote the multiplication of natural lactobacilli** (whether present in insufficient amounts, regardless of the extent of damage).
- This restored vaginal environment **helps the lactobacilli to produce lactic acid** which has a number of benefits to the vaginal microflora (inhibition of remaining pathogens, proper pH, etc.).
- Together **supports natural protective mechanisms of vaginal microflora in time when the defence is reduced due to external factors** (such as usage of antibiotics, often use of tampons, lifestyle, free time activities, contraception, wrong intimate hygiene, pregnancy, birth, etc.).

PERORAL VS. LOCAL THERAPY

- The gut and the vagina are interconnected systems, and all substances we ingest—such as probiotics or antibiotics—can influence the vaginal microbiome

=>we still don't fully understand **to what extent, how quickly, or how predictably** this effect occurs

- **Local application** avoids burdening the gastrointestinal system and delivers probiotics directly to the target site

=>This results in faster action, easier symptom relief, and better control over treatment effectiveness

- **Vaginal suppositories** can be enriched with substances that directly moisturize the vaginal mucosa, offering targeted functional benefits beyond microbiome support



GYNELLA®

Balance



GYNELLA®

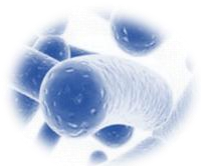
Balance

-Vaginal suppositories based on tyndallized=non **viable** *Lactobacillus acidophilus*, hyaluronic acid, soya isoflavones, and lactic acid

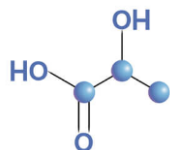
=> thanks to its composition it maintains natural vaginal defences and hydrates the vaginal mucosa when the balance of vaginal microflora altered by physiological conditions of external factors



COMPOSITION



Based on **stable inactivated, non-viable bacteria** - *Lactobacillus acidophilus*.



Lactic acid maintains the natural pH value in the vagina and thus protect it from harmful external influences.



Soy isoflavones help increase elasticity of vaginal mucosa. Thus complement the effect of the hyaluronic acid and relieve unpleasant feelings of tension and dryness.



Hyaluronic acid contributes to the hydration and elasticity of the tissues and thus supports complements the effect of soy isoflavones.

USE

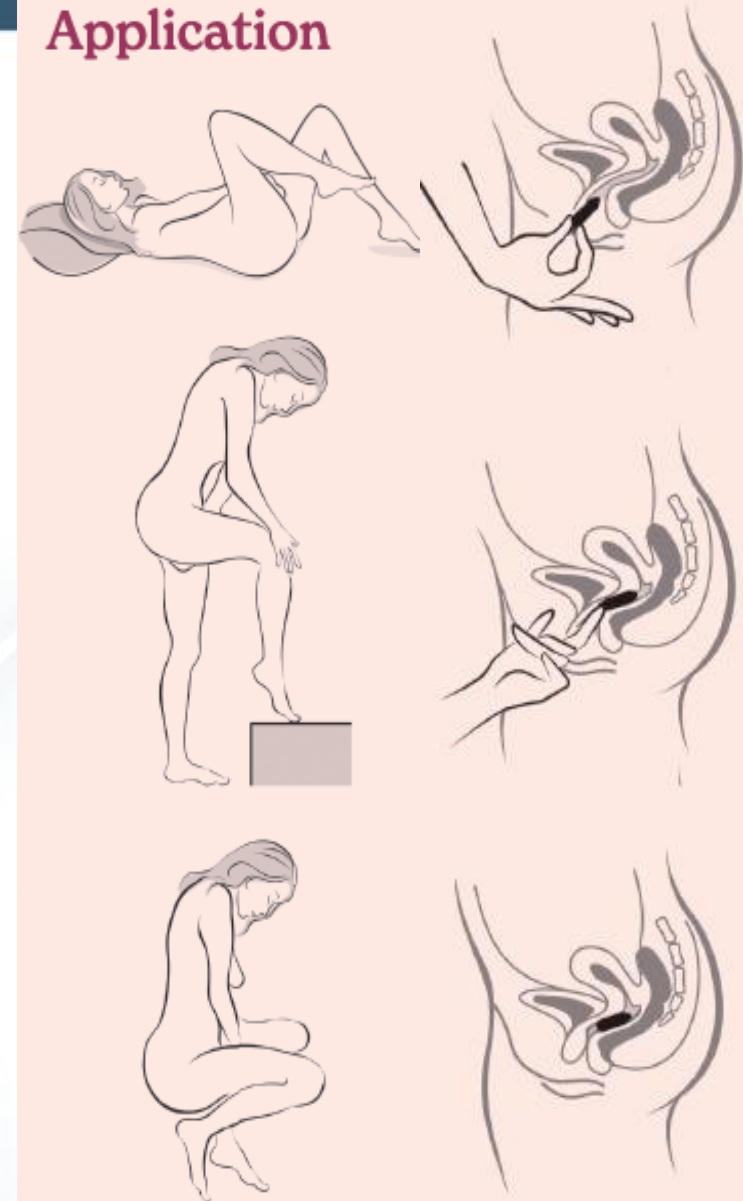
- Start the therapy 10 days before the start or immediately after the end of the menstrual cycle
- According to the assessment of the attending physician, GYNELLA Balance can be used repeatedly
- Insert one suppository gently into the vagina once a day, preferably in the evening before bedtime for 10 days

10 DAYS

1 – 10

PAUSE

Application



GYNELLA[®]
Balance

MAIN BENEFITS

- Maintains natural vaginal defenses by restoring balanced microflora, disrupted by different factors
- Hydrates the vaginal mucosa
- Suppositories ensure good solubility and easy application

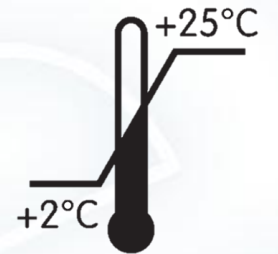


GYNELLA[®]
Balance



PRODUCT ADVANTAGES

- Paraprobiotics which **support increasing vaginal immunity**.
- Does not need to be refrigerated, withstands **temperatures of up to 25 °C**.
- Tyndallized lactobacilli **do not cause resistance to antibiotics**, therefore the treatment is possible to applicate during antibiotic therapy.
- Thanks to complex composition can increase compliance by women 45+.
- Suppositories ensure **good solubility and easy application**.



GYNELLA[®]
Balance

GYNELLA® BALANCE IS SUITABLE FOR WOMEN:

- In menopause, when declining estrogen levels lead to vaginal dryness, burning, itching, and irritation;
- Suffering from vaginal dryness caused by chemical or physical changes in the body;
- Experiencing an imbalance in the vaginal microbiota due to various factors such as menopause, hormonal changes, stress, or the use of antibiotics, contraceptives, tampons, etc.



STUDIES RESULTS

Participant disposition and demographics:

- 30 postmenopausal women, 46 to 59 years (53.8 ± 7.1 years) of Caucasian origin.
- 26 patients were followed for 110 days from the start of treatment, while 4 patients were lost to follow-up at Visit 2 (day 20 ± 3) due to missed appointments.

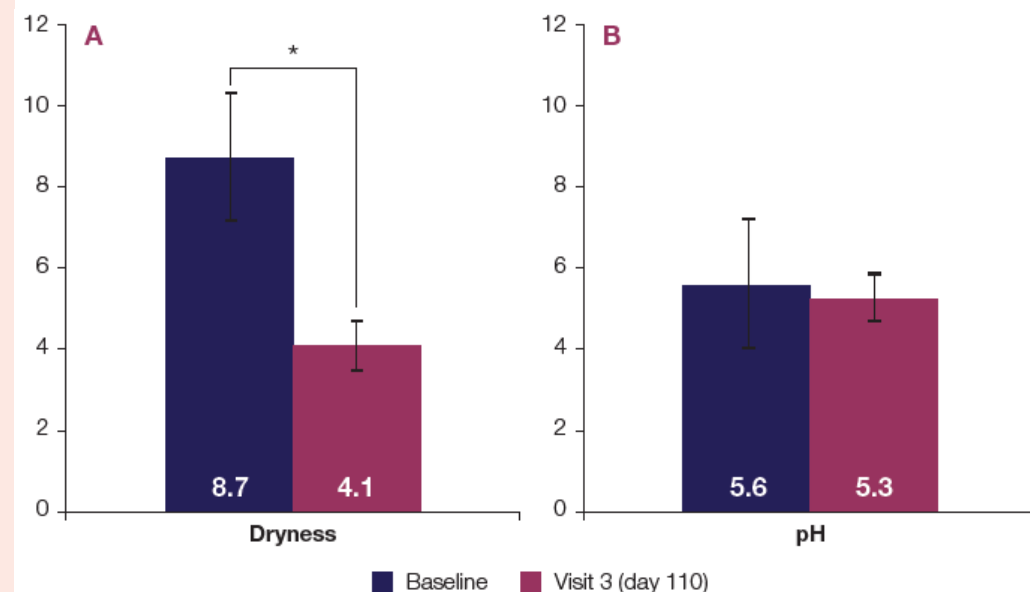
Efficacy outcomes:

Changes in vulvovaginal dryness score:

- The subjective evaluation of vulvovaginal dryness decreased from a mean value of 8.7 to a mean value of 4.1, reaching a statistical significance ($p < 0.05$).

Changes in vaginal pH:

- The mean difference of pH to baseline on Day 110 ± 3 was 0.3 ± 0.2 , with a mean value at baseline of 5.6 ± 0.3 versus a mean value of 5.3 ± 0.2 on Day 110 ± 3 . A decrease of pH value has been observed, without reaching a statistical significance ($p > 0.05$).



The graph illustrates the changes in the severity of vulvovaginal dryness (A) and vaginal pH (B) in postmenopausal women at Visit 1 (baseline) (blue) and at Visit 3, follow-up after 90 days from end of treatment with GYNELLA-Balance vaginal suppositories (magenta). * $p < 0.05$.

GYNELLA[®]
Balance

SUMMARY

GYNELLA[®]

Balance

Composition: Lactic acid, Soy isoflavones, non-viable tyndallized lactic bacteria (*Lactobacillus Acidophilus*) and Hyaluronic acid

Classification: Medical Device class IIA

Presentation: 10 vaginal suppositories

Shelf life: 36 months



GYNELLA®

Flora



GYNELLA[®]

Flora



- Based on **3 types of stable inactivated, non-viable bacteria** - *Lactobacillus acidophilus*, *Lactobacillus casei* and *Lactobacillus reuteri*

=> support natural defenses of vaginal microflora in time when these are reduced due to external factors such as (usage of antibiotics, often use of tampons, lifestyle, free time activities, contraception, wrong intimate hygiene, pregnancy, birth etc.).

- Scientific evidence indicating that these inactivated strains (dead microbial cells or microbial cell fractions) may also **positively affect human health by keeping their immunomodulatory properties.**

INDICATION

- The vaginal system is characterized by various complex of microorganisms that acts physiologically as a natural protection
- The bacterial flora in the vaginal mucosa is mainly formed by lactic acid bacteria
- Combination of tyndallized *Lactobacillus* strains (*Lactobacillus acidophilus*, *Lactobacillus reuteri*, *Lactobacillus casei*) helps to stimulate the natural immune defences, to prevent pathogens adhesion and to maintain the balance of the vaginal flora when it was damaged or destroyed due to pregnancy, by diseases affecting the vagina (vaginal discharge, inflammation, infection)



USE

One suppository into the vagina **once a day**, preferably in the evening before bedtime for 10 days following the last day of the menstrual cycle or according to medical indication

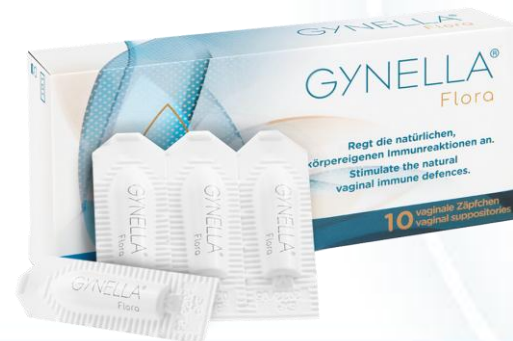
- 1) Wash the private parts thoroughly (preferably with both an external and internal vaginal lavage)
- 1) Open the pack and after washing your hands thoroughly, take a single suppository from the blister.
- 3) Insert gently into vagina trying to get deep, preferably in supine position.

Keep between 2°C and 25°C.

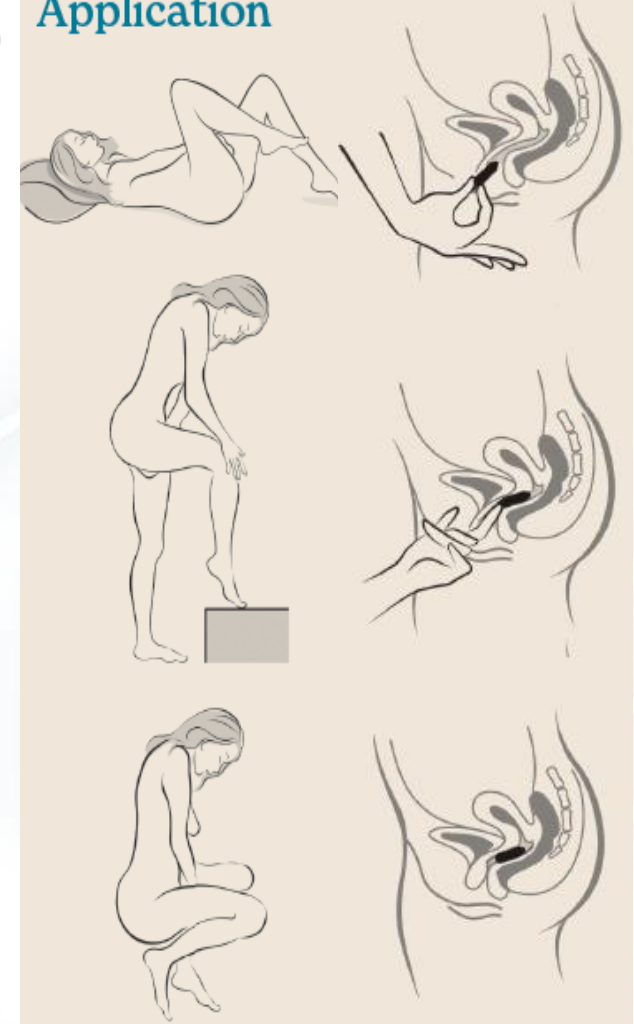
10 DAYS

1 – 10

PAUSE



Application



MAIN BENEFITS

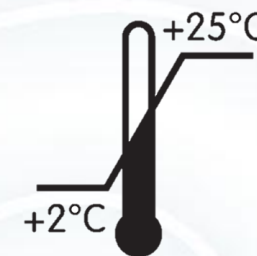
GYNELLA®
Flora

- Maintains balanced microflora, disrupted by different factors
- 3 strains ensure suitability for a wider range of women
- Suppositories ensure good solubility and easy application



PRODUCT ADVANTAGES

- ✓ Paraprobiotics which **support increasing vaginal immunity**.
- ✓ Does not need to be refrigerated, withstands **temperatures of up to 25 °C**.
- ✓ Unlimited target group - **applicable to immunocompromised patients**.
- ✓ Tyndallized lactobacilli **do not cause resistance to antibiotics**, therefore the treatment is possible to applicate during antibiotic therapy.



GYNELLA[®]
Flora

SUMMARY

Composition:	Tyndallized lactic strains (Lactobacillus acidophilus, Lactobacillus reuteri, Lactobacillus casei)
Classification:	Medical Device class IIA
Presentation:	10 vaginal suppositories
Shelf life:	36 months

GYNELLA®
Flora



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HEALTHCARE GROUP

GYNELLA[®]

Meno NRS



SUPPORTS THE MENOPAUSAL TRANSITION

General Information

- For controlled dietary nutrition in premenopause, perimenopause, menopause and postmenopause
- GYNELLA® Meno NRS contains:

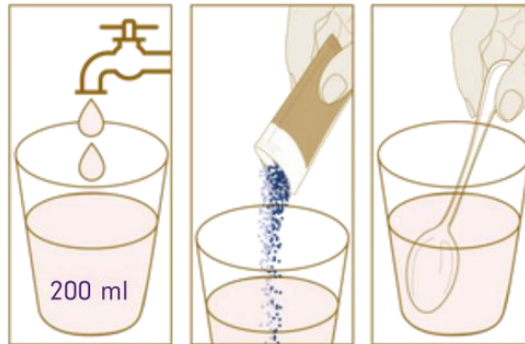


 Myo-inositol	 Soy isoflavones	 Cocoa polyphenols
helps regulating insulin signaling and subsequent its transmission to the cells	resemble estrogens in their structure	are antioxidants that support cardiovascular health and help maintain a positive emotional tone

- **Who GYNELLA® Meno NRS is for:** women experiencing symptoms of the menopausal transition -such as hot flashes, metabolic changes (including weight gain and insulin resistance), and other related symptoms

Instruction for use

- GYNELLA® Meno NRS is intended for oral use only
- The recommended daily intake is 1 sachet per day away from meals
- Dissolve the contents of the sachet in a glass of water (approx. 200 ml)



GYNELLA®
Meno NRS

Clinically proven effect

1) Relief of Menopausal Symptoms

- Significant **reduction** in hot flashes, night sweats, and **improved sleep quality** and **cognitive performance**, improved mood and reduced symptoms of depression.

2) Metabolic Benefits

- **Improved insulin sensitivity (HOMA-IR)**, lower fasting glucose and insulin levels, decrease in **triglycerides and total cholesterol**, with a modest increase in HDL.

3) Cardiovascular Protection

- **Improved vascular function** via increased **nitric oxide (NO) synthesis**, reduction in **arterial stiffness** and **endothelin-1** levels (a potent vasoconstrictor), protection of the **endothelium** and support of **vascular elasticity**.

4) Favorable Safety Profile

- Clinical studies show no increased risk of **breast tissue proliferation** or **endometrial thickening**.
- No significant alterations in **thyroid function**, **breast density**, or **uterine histology** after up to 30 months of supplementation.



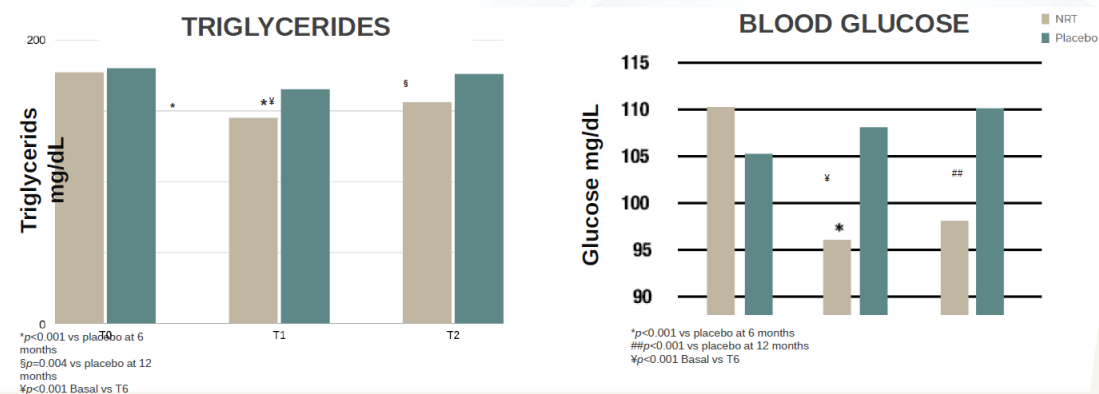
GYNELLA® MENO NRS

- 60 post-menopausal women were divided into two groups:
 - Treatment group (n = 30): GYNELLA MENO NRS (1 sachet/day)
 - Control group (n = 30): placebo
- Treatment period: 6 months
- Study objective: Evaluation of the effects of the treatment on metabolic and cardiovascular parameters at 6 and 12 months.

Metabolic parameters

Study Groups		Glucose (mg/dl)	Triglycerides (mg/dl)
NRT Group	T0	110 ± 10	177 ± 19
	T1	96 ± 7*	145 ± 14*
	T2	98 ± **	156 ± 15 [§]
PLACEBO Group	T0	105 ± 7	180 ± 20
	T1	108 ± 10	165 ± 18
	T2	110 ± 8	176 ± 22

Table 2. Adapted and translated from D'Anna R. et al. *Int J Endocrinol*, 2014. T0: baseline; T1: 6 months; T2: 12 months. *p<0.001 vs placebo 6 months; p=0.004 vs placebo 6 and 12 months; **p<0.001 vs placebo 12 months; §p=0.004 vs placebo 12 months.



=>GYNELLA MENO NRS SIGNIFICANT IMPROVEMENTS IN TRIGLYCERIDES AND BLOOD GLUCOSE LEVELS, EVEN AT THE 12-MONTH FOLLOW-UP

Source: D'Anna R et al. Effects of a new flavonoid and Myo-inositol supplement on some biomarkers of cardiovascular risk in postmenopausal women: a randomized trial. *Int J Endocrinol*. 2014;2014:653561. doi: 10.1155/2014/653561. Epub 2014 Aug 31. PMID: 25254044; PMCID: PMC4164131.

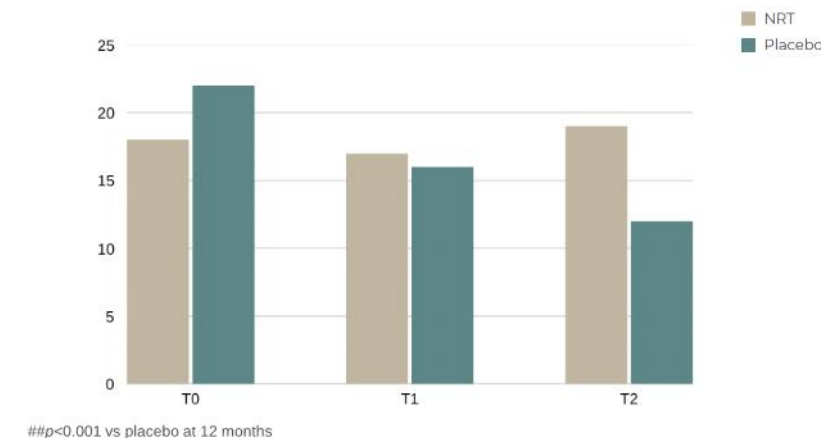
Cardiovascular parameters

ADIPONECTIN is a protein with **ANTI-ATHEROGENIC PROPERTIES** that protects against cardiovascular risk.

- Sensitizes liver and muscle to insulin
- Downregulated in insulin-resistant state
- Strongly correlated with basal insulin and insulin sensitivity
- Low concentrations = increased prevalence of metabolic syndrome, especially in postmenopausal women

=> GYNELLA RESTORED ADIPONECTIN AT 6 MONTHS AND DEMONSTRATED AN INCREASE AT 12 MONTHS

ADIPONECTIN

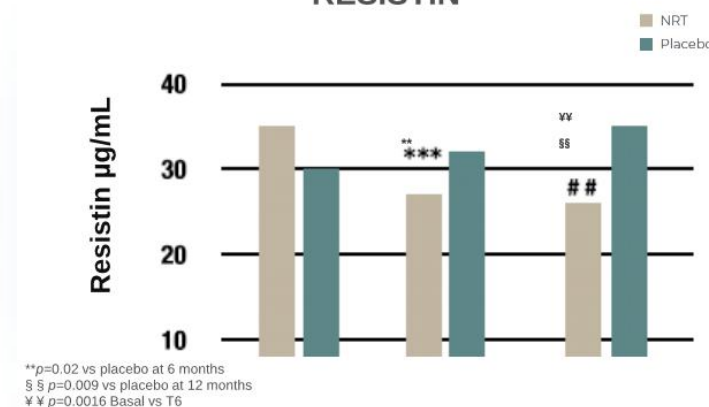


RESISTIN is a protein that lead to **AN INCREASED RISK OF ATHEROSCLEROSIS**

- Highly expressed in abdominal subcutaneous white fat
- In postmenopausal and obese women, resistin levels nearly double
- It links obesity with diabetes
- Close association with metabolic syndrome

=> GYNELLA MENO NRS DEMONSTRATED SIGNIFICANT REDUCTIONS IN RESISTIN AT 6 AND 12 MONTHS

RESISTIN



6-Month, retrospective clinical trial

- Treatment group: 200 menopausal women with metabolic syndrome
- Treatment period: 6 months

Parameters	T0	T1	p Value
Hot flushes, No. (%)			
None	12 (6)	22 (11)	0.07
2-to-3	56 (28)	130 (65)	<0.001 *
4-to-9	108 (54)	36 (18)	<0.001 *
>10	24 (12)	12 (6)	0.055
Severity of hot flushes, No. (%)			
None	16 (8)	24 (12)	0.22
Mild	62 (31)	124 (62)	<0.001 *
Moderate	118 (59)	54 (27)	<0.001 *
Severe	4 (2)	0 (0)	0.04 *
Sweats, No. (%)			
None	8 (4)	18 (9)	0.057
2-to-3	26 (13)	66 (33)	<0.001 *
4-to-9	156 (78)	116 (58)	0.06
>10	10 (5)	0 (0)	<0.001 *
Severity of sweats, No. (%)			
None	0 (0)	28 (14)	<0.001 *
Mild	10 (5)	112 (56)	<0.001 *
Moderate	186 (87)	60 (30)	<0.001 *
Severe	4 (4)	0 (0)	0.04 *

=> GYNELLA MENO NRS DEMONSTRATED SIGNIFICANT IMPROVEMENTS IN VASOMOTOR SYMPTOMS

Source: Mainini G et al. Dietary supplementation of myo-inositol, cocoa polyphenols, and soy isoflavones improves vasomotor symptoms and metabolic profile in menopausal women with metabolic syndrome: a retrospective clinical study. *Medicina*. 2024;60(4):598.

Depressive symptoms			
None	0 (0)	24 (12)	<0.001 *
Mild	18 (9)	64 (32)	<0.001 *
Moderate	174 (87)	112 (56)	<0.001 *
Severe	8 (4)	0 (0)	0.005 *
BMI, No. (%)			
Underweight	6 (3)	14 (7)	0.08
Normal weight	14 (7)	66 (33)	<0.001 *
Overweight	154 (88)	102 (51)	0.01 *
Obesity	28 (14)	18 (9)	0.04 *
Waist circumference			
Lower than 88 cm	78 (39)	96 (48)	0.25
Greater than or equal to 88 cm	122 (61)	104 (52)	0.33
Blood pressure, No. (%)			
Low	6 (3)	3 (1.5)	0.32
Normal	175 (87.5)	190 (95)	0.57
Elevated	18 (9)	7 (3.5)	0.03 *
High	1 (0.5)	0 (0)	0.31

=> GYNELLA MENO NRS DEMONSTRATED SIGNIFICANT IMPROVEMENTS IN DEPRESSION SYMPTOMS AND METABOLIC DYSFUNCTIONS

Source: Mainini G et al. Dietary supplementation of myo-inositol, cocoa polyphenols, and soy isoflavones improves vasomotor symptoms and metabolic profile in menopausal women with metabolic syndrome: a retrospective clinical study. *Medicina*. 2024;60(4):598.

GYNELLA®

Intense



General Information

- Cosmetic product
 - Stimulating intimate gel that helps **support arousal** and contributes to a more **intense intimate experience**
 - **100% oil-based gel**
 - Innovative oleogel formulation based on a water-free composition, which minimizes the need for the use of conventional preservatives
 - Free from hormones and estrogens
 - Contains **maca root extract (*Lepidium meyenii*)**, **myrcene**, **visnadine**, and is **enriched with ylang-ylang oil (*Cananga odorata*)**
- ➔ These ingredients help moisturize, soothe, and protect the skin of the external intimate area
- **SPEEDERM® technology** significantly improves the availability of active ingredients when applied to the skin

GYNELLA®
Intense



- Gentle, safe, and well-tolerated cosmetic product that helps maintain the natural balance of the skin barrier in intimate areas
- Highly bioadhesive, allowing it to adhere effectively at the site of application

Application

- Apply to the intimate area (from the clitoris to below the vaginal opening) a few minutes before sexual intercourse
- For body weight **up to 59 kg** apply **4 doses**, **from 60 kg** apply **5 doses** (the package contains approximately 45 doses)

Patient Profiles

- Women in perimenopause experiencing changes in intimate comfort and sensitivity
- Women experiencing reduced sensitivity or dryness of external intimate areas
- Women preferring non-hormonal, on demand intimate care

Maca (*Lepidium meyenii*)

- A plant native to the Andes
- Traditionally used to support fertility and sexual health¹
- Aphrodisiac effects²
- Maca may help improve sexual difficulties associated with menopause and antidepressant-induced sexual dysfunction in women²

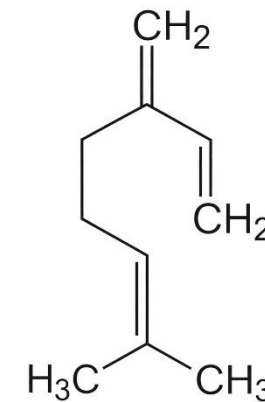


1) Shin BC, Lee MS, Yang EJ, Lim HS, Ernst E. Maca (*Lepidium meyenii*) for improving sexual function: a systematic review. BMC Complement Altern Med. 2010;10:44. doi:10.1186/1472-6882-10-44

2) Zheng, B. L., He, K., Kim, C. H., Rogers, L., Shao, Y., Huang, Z. Y., ... & Zheng, Q. Y. (2000). Effect of a lipidic extract from *Lepidium meyenii* on sexual behavior in mice and rats. *Urology*, 55(4), 598-602.

Myrcene

- A monoterpene (a natural aromatic compound) found in many essential oils (e.g. from hops, bay leaves, and cannabis)
- Associated with calming effects and may contribute to relaxation
- With demonstrated analgesic and sedative properties¹²
- Also has antioxidant and potentially anti-inflammatory effects³



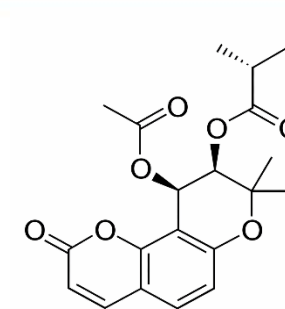
1) Surendran S, Qassadi F, Surendran G, Lilley D, Heinrich M. Myrcene—What Are the Potential Health Benefits of This Flavouring and Aroma Agent? Front Nutr. 2021;8:699666. doi:10.3389/fnut.2021.699666.

2) Animal studies only

3) Xanthis, V.; Fitsiou, E.; Voulgaridou, G.-P.; Bogadakis, A.; Chlichlia, K.; Galanis, A.; Pappa, A. Antioxidant and Cytoprotective Potential of the Essential Oil Pistacia lentiscus var. chia and Its Major Components Myrcene and a-Pinene. Antioxidants 2021, 10, 127. <https://doi.org/10.3390/antiox10010127>

Visnadin

- Visnadin is a natural compound derived from the plant *Ammi visnaga*
- It may be a potentially effective and safe option for alleviating certain clinical symptoms of sexual dysfunction¹
- It is known to dilate small blood vessels and improve tissue blood circulation²
- When applied to the genital area, it supports blood flow to the vulva, lubrication, arousal, orgasm, and sexual satisfaction¹



1) Caira-Chuquineyra, B., Fernandez-Guzmán, D., Garayar-Peceros, H., Benites-Zapata, V. A., Pérez-López, F. R., Blümel, J. E., & Mezones-Holguín, E. (2024). Efficacy and safety of visnadine in the treatment of symptoms of sexual dysfunction in heterosexual women: a systematic review of randomized clinical trials. *Gynecological Endocrinology*, 40(1), 2328619.

2) Elanjian, A. I., Kammo, S., Braman, L., & Liaw, A. (2025). Advancing women's health: a scoping review of pharmaceutical therapies for female sexual dysfunction. *Sexes*, 6(3), 38.

Ylang-Ylang Flower Oil

- Known for its relaxing and calming effects¹
- In Gynella Intense, ylang-ylang therefore helps promote relaxation, enhances sensory perception, and may contribute to increased sexual desire and a more intimate experience



Zhang, N., Zhang, L., Feng, L., & Yao, L. (2016). The anxiolytic effect of essential oil of *Cananga odorata* exposure on mice and determination of its major active constituents. *Phytomedicine*, 23(14), 1727-1734.

Take Home Message

- GYNELLA® Intense is a stimulating intimate gel that helps support arousal and contributes to a more intense intimate experience
- Enhanced delivery of active ingredients through patented SPEEDERM® technology
- Visnadine supports local microcirculation, arousal and sexual satisfaction

GYNELLA®



**SUPPORTS THE PROPER FUNCTION
OF URINARY TRACT AND
PHYSIOLOGICAL IMMUNITY***

GYNELLA® Cystilab

Unique food supplement combines substances for maximal synergic effect. It contains **cranberry juice powder** and **dry extract from Echinacea purpurea**, moreover symbiotic bacteria (**Lactobacillus reuteri**) and **D-mannose**. It supports the proper function of urinary tract and physiological immunity*.

Composition: Dried cranberry juice, extract from Echinacea purpurea, Lactobacillus reuteri, D-mannose, dried blueberry juice

Classification: Food supplements with sweeteners

Presentation: 10 Sachets

Shelf life: 24 months

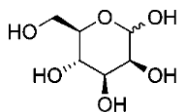


*The Echinacea extract has a positive effect on the health and normal function of the urinary tract.

COMBINES SUBSTANCES FOR MAXIMAL SYNERGIC EFFECT



Contains **Lactobacilli** in high concentrations of 3 billion CFU in 3 doses. Lactobacilli are physiological bacteria settling the healthy tissue (such as the intestines, vagina, etc.).



D-mannose is practically not metabolized, but excreted by the kidneys into the bladder and from there into the urinary tract.



Cranberry juice supports natural immunity. In addition, it synergistically complements the effects of other substances.



Blueberry juice acts as a powerful antioxidant. It protects the cells from free radicals.



The **Echinacea** extract has a positive effect on the health and normal function of the urinary tract. It also helps support the body's natural defenses.

COMPOSITION OF THE PRODUCT

Quantitative composition in daily dose:

	D-mannose	<i>Lactobacillus reuteri</i>	Dried blueberry juice	Dried cranberry juice (<i>Vaccinium macrocarpon</i>)	Extract from <i>Echinacea purpurea</i>
Content in one dose (sachet A+B)	1000 mg	1 billion CFU	90 mg	360 mg (proanthocyanidin 103 mg)	25 mg
Content in 3 doses (sachet A+B)	3000 mg	3 billions CFU	270 mg	1080 mg (proanthocyanidin 309 mg)	75 mg



How to use

- Take 1 sachet A together with 1 sachet B once a day (up to a maximum of 3 sachets A+B/day) preferably in the evening before going to bed or in the morning on an empty stomach and bladder.
- A maximum of 3 doses A+B per day.

To maintain a healthy urinary tract

- Use 1 sachet A+B a day for 10 days per month (for at least 3 consecutive months).

After antibiotic treatment

- Supports immunity after taking antibiotics.

Use in urgent situations

- On days when you suffer discomfort in the urinary tract, take 3 sachets A+B a day for the first two days, then 2 sachets A+B a day on the third and fourth days, one in the morning on an empty stomach and one in the evening before going to bed.

GYNELLA®



VAGINAL GEL FOR COUPLES
WHO ARE TRYING TO CONCEIVE

Vaginal gel for couples who are trying to conceive. It helps not only by affecting the vaginal mucosa and adjusting its pH, but **due to the presence of inositol it can also stimulate sperm**. Increases the pH to values convenient for natural motility of sperm, thus it can increase the probability of natural conception

Composition: Inositol, Sodium hyaluronate, Lactic acid, Glucose, Fructose, Magnesium citrate, Calcium pyruvate, Sorbitol, Citric acid, Potassium citrate, Sodium bicarbonate, Zinc gluconate, Carnitine, Creatine, Sodium chloride

Classification: Medical device IIa.

Presentation: 6 single dose applicators of 5 ml for vaginal use

Shelf life: 24 months

GYNELLA®

Natal Ferti Gel



GYNELLA[®]

Natal Ferti Gel



- Forms optimal environment for sperm.
- Increases the pH to values convenient for natural motility of sperm, thus it can increase the probability of natural conception.
- Is characterized by osmolality similar to ejaculate.
- Hydrates the vaginal environment, thus it can help to provide suitable consistency of ejaculate favorable for sperm motility.

COMPOSITION



FOR SPERM

Inositol - can prevent sperm cells from metabolic changes induced by oxidative stress.

Mg, Zn ions - positively influence the quality parameters of sperm in the ejaculate.

Carnitine, Creatine, Fructose - stimulate the mobility of human sperm, a source of energy.

Ca ions - increase utilization of glucose which serves as one energy source for sperm.

ADJUSTMENT OF VAGINAL ENVIRONMENT

Sodium bicarbonate, Citric acid - adjust and stabilize the pH.

Sodium hyaluronate - moisturizing effect.

COMPARISON OF COMPOSITION OF EJACULATE AND GYNELLA® NATAL FERTI GEL

- Shows many similarities,
- composition as close as possible to the physiological conditions of ejaculate because sperm are susceptible to changing the environment.



	Ingredients	Ejaculate	GYNELLA® Natal Ferti Gel
functional	pH	7,2 - 7,8	7,2 - 7,9
	Osmolality	250-350	300
	Hyaluronic acid		✓
	water	✓	✓
	glucose	✓	✓
	fructose	✓	✓
	sorbitol	✓	✓
	magnesium	✓	✓ (in form of citrate)
	calcium	✓	✓ (in form of pyruate)
	Zink	✓	✓ (in form of gluconate)
physiological and/or usable for quick use by sperms	Inositol		✓
	carnitin	✓	✓
	creatine	✓	✓
	lactic acid	✓	✓
	citric acid	✓	✓
	Sodium	✓	✓ (in form of hyaluronate, chloride, bicarbonate and phosphate + sodium hydroxide)
	Chloride	✓	✓ (in form of sodium salt)
	Potassium	✓	✓ (in form of citrate)
	Citrat	✓	✓ (in form of potassium salt)
Gel preservatives neutral	Hydroxyethylcellulose		✓
	DMDM Hydantion		✓
	Phenoxyethanol		✓
	Ethylhexylglycerin		✓

ADMINISTRATION

Sperm are able to fertilize an egg only 48 hours after ejaculation and the egg can absorb sperm 12 – 24 hours after ovulation.



VAGINAL GEL FOR COUPLES WHO ARE TRYING TO CONCEIVE

GYNELLA®
Natal Ferti Gel

Composition: Inositol, Sodium hyaluronate, Lactic acid, Glucose, Fructose, Magnesium citrate, Calcium pyruvate, Sorbitol, Citric acid, Potassium citrate, Sodium bicarbonate, Zinc gluconate, Carnitine, Creatine, Sodium chloride

Classification: Medical device II.

Shelf life: 24 months

Presentation: 6 single dose applicators of 5 ml for vaginal use



GYNELLA®



INTIMATE HYGIENE FOR WOMEN
IN EVERY STAGE OF LIFE
(COSMETICS)

GYNELLA[®]

Intimate Wash

The intimate gel is suitable **for daily intimate care thanks to its balanced pH and enriched lactic acid**. The intimate gel can also be used to shave intimate parts. Represents the right thing to do when it comes to solving unpleasant feelings in the intimate area (itching, burning, redness, feeling of tension, unpleasant smell). Dermatologically tested.

Composition: Lactic Acid, Pinus Sylvestris Twig Leaf Oil

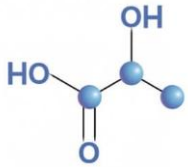
Classification: Cosmetics (dermatologically tested)

Presentation: 200 ml

Shelf life: 30M



Active ingredients:



Lactic Acid: helps to create an acidic environment in the vagina and thus also promotes the growth of lactobacilli



Pinus Sylvestris Twig Leaf Oil: it has an antiseptic effect, blood circulation and cleanses the skin. Thanks to its deodorizing effect, it also removes unpleasant odors from the skin.

GYNELLA[®]
Intimate Wash



GYNELLA®

Intimate Foam

A gentle foam designed for **hygiene** and **shaving of intimate parts**. At the same time, **prevents from genital discomfort after intercourse**, swimming, running, traveling and many other activities in which the intimate parts are exposed to higher levels of irritation. Dermatologically tested.

Composition: Lactic Acid, Panthenol, Salvia Officinalis Oil, Aloe Barbadensis extract

Classification: Cosmetics (dermatologically tested)

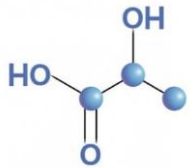
Presentation: 150 ml

Shelf life: 30M



GYNELLA[®] Intimate Foam

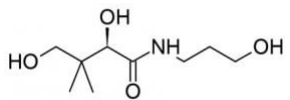
Active ingredients:



Lactic Acid: Lactic acid helps to create an acidic environment in the vagina and thus also promotes the growth of lactobacilli



Aloe Vera: It adds softness to the intimate parts and at the same time has a calming effect and thus alleviates the symptoms of irritation. Therefore it is suitable for use while shaving intimate parts.



Panthenol: Panthenol reduces skin itching, accelerates healing and improves hydration.



GYNELLA®

Girl Intimate Wash

Especially developed **for girls from 2 years of age to first menstruation**. Very gentle on young girls' skin and intimate parts. Developed specifically for this period of age when the ovaries do not produce the female hormone (estrogen) and the vaginal defenses are insufficient. Dermatologically tested.

Composition: Bisabolol, Allantoin, Salvia Officinalis Leaf extract

Classification: Cosmetics (dermatologically tested)

Presentation: 100 ml

Shelf life: 30M



Active ingredients:



Bisabolol: Bisabolol is a major component of the etheric oil of the chamomile. It helps to absorb other substances into the skin. Softens, smoothes, soothes and reduces skin's sensitivity.



Salvia Officinalis Leaf Extract Acid: The effect of sage is very important, with antiseptic, antiviral and anti-inflammatory activity. In the cosmetics, its astringent and disinfecting properties are used.



Allantoin: Protects, soothes and restores skin. It supports the growth of new skin cells, regenerates skin tissue and relieves irritation.

GYNELLA®
Girl Intimate Wash



Heaton

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