BIBLIOGRAPHY


Dott. Larry C. Ford del Department of Obstetric and Gynecology, UCLA School of Medicine, USA, in una lettera datata 1 novembre 1988 scrive che le soluzioni di argento hanno proprietà battericide e fungicida per la Candida Albicans e la Candida Globata. Il dott. E.M. Crooks ha dichiarato che l’argento colloidale elimina organismi patogeni in tre o quattro minuti di contatto.
Clinical studies have found that the vaginal mucous membrane is colonised by non-harmful bacterial strains, especially lactobacilli, which can protect the vagina from other bacteria that could be harmful either directly or through the products of their metabolism. The good health of the vaginal mucous membrane largely depends on preserving the prevalence of non-pathogenic bacterial strains identified in the various species of lactobacilli, which, thanks to their actions, prevent the proliferation of other germs. The bacterial populations found in the human vagina represent a complex ecosystem, to which a wide range of "host-derived substances" contribute. There are numerous factors that may alter the composition of the vaginal ecosystem (antibiotic treatment, excessively frequent vaginal douches, hormonal disorders, and diabetes).

The alteration or reduction of the normal vaginal flora leaves the mucous membrane susceptible to microbial infections, with consequent harmful effects. The micro flora of the vaginal tract has been widely studied, through the use of advanced microbiological techniques, in order to understand the composition and characteristics of vaginal secretion.

The "barrier" action at protective effect, carried out by the lysates of lactobacilli towards the alteration of bacterial flora and of possible infective consequences, contributes to maintain the pH of mucosa within physiological values (pH 4-4.5). In fact the increase of pH of vagina, favours the flourishing and growth of pathogenic germs and increases the risk of severe infections.

The range of Floragyn® products, all of them CE certified, was developed as a result of the above observations and consists of: Floragyn® Lavanda, Floragyn® Immo, Floragyn® Gel, Floragyn® Ovuli, Floragyn® Silver.
Vaginal gel with lysates of lactobacilli and vitamin A developed to relieve vaginal dryness signs and symptoms. Moistening action simulant the vaginal physiology. Not greasy product. Topical use.

What is Floragyn® Vaginal Gel
Floragyn® Vaginal Gel is a medical device product certified by European competent authorities with CE mark was developed as unique and particularly effective gel formulation to induce vaginal dryness signs and symptoms' amelioration and improve women's quality of life. Vaginal dryness is present in any woman's age with the highest prevalence in the premenopausal and postmenopausal period and can be originated by different causes and be occasional or chronic and very greatly among individuals. Different causes may induce a decrease or an interruption in vaginal flora production. The more frequent is the menopause, but physiological stress, use of oral contraceptives and other medicines, local medications, vaginopathy inflammatory and/or not suitable vaginal cleaning products. Vaginal dryness is, still nowadays, an underestimated phenomenon which is often kept concealed due to psychological reasons by women themselves to doctors and is often related to the individual psychological sphere of the woman herself such as stress and anxiety and is also related to sexual intercourse.

Floragyn® Vaginal Gel contains:
- Lysates of Lactobacilli present with six strains (Bulgarcus, Acidophilus, Bifidus, Rennomillus, Plantorum, Casei). They all concur actively in creating “barrier effect”, which inhibits the growth of pathogenic bacterial species and adjusts the physiological vaginal mucous pH. Thus, lysates of lactobacilli have a crucial role for the vaginal homeostasis and stops external environmental unpleasantness and stressors.
- Vitamin A carries out a skin protective action. Absence of Vitamin A settings a real risk.
- Glycerine and amphoteric cleanser provide, in the right concentration, the gel with the necessary moisturizing and lubricating properties of the above ingredients concern to guarantee effective protective action against external agents able to develop inflammatory processes. Their role is to carry out moisturizing action simulant the vaginal physiology.

Floragyn® Vaginal Gel is a medical device which resolves definitely the problem of vaginal dryness, keeping the vaginal environment pleasant and scented; thanks to its gel formulation, Floragyn® Vaginal Gel achieves optimal results without the typical problem caused by using oily (greasy) substances. Intravaginal gel for daily treatments in particular during and after the menopause, and during pregnancy.

Relieves rapidly dryness symptoms.
- Optimal product for lubricating also before sexual intercourse to achieve a perfect harmony within the couple.
- Improves vaginal flora.
- Prevents inflammation actions.

Floragyn® Vaginal Gel is a useful product in case of vaginal dryness signs and symptoms caused by menopause, menstrual cycle, use of medicines, actual presence of vaginal inflammatory pathologies and/or use of not suitable vaginal cleansing product which might degenerate bacterial flora.

Floragyn® Vaginal Gel solves vaginal problem re-establishing the physiological characteristics of mucous and by which, eliminates all unsatisfactions associated to sexual sphere.

Floragyn® Vaginal Gel does not substitute medical therapy but represents a useful complementary product.

How to use
Single use small tube with integrate applicator. Topical use.

When should not be used
There are not known contraindications following the use of Floragyn® Vaginal Gel, except eventual and rare individual cases of hypersensitivity to any of the components.

Interactions or incompatibilities are not known.

Warnings and precautions for use
To use the product for long-term therapy, as per all topical products, could originate local sensitivity skin irritation. If any side effects get worse, or if any side effects not listed in this leaflet are noticed, discontinue treatment and please inform your doctor or pharmacist.

Special precautions during pregnancy and lactation
The use of the product is not discouraged in pregnancy and lactation. Ask your doctor before using the product for advice.

Eventual declared toxicity
No declared toxicity.

Maintenance, storage and preparation of the device
No particular precaution is necessary for proper maintenance, storage and preparation of the device. It is important to keep always the information of the product, hence store both the external pack and this leaflet. Do not use the product after the expiry date indicated on the external pack. Such date refers to the product in integral packaging, and correctly stored.

Keep out of the reach and sight of children.

Special precautions for disposal and other handling
No special precautions for disposal and other handling are established.

Floragyn® Vaginal Gel contains:

Retail format
One cardboard sheet containing 6 single dose gels x 5 ml each one and one inner leaflet.

One cardboard sheet containing 8 single dose gels x 3 ml each one and one inner leaflet.

What is Floragyn® Lavanda
Floragyn® Lavanda is a topical use medical device product certified by European competent authorities with CE mark, was developed as unique and particularly effective gel formulation.

Floragyn® Lavanda is a ready-to-use solution with lysates of lactobacilli and chlorhexidine (0.2%) suitable for intimate hygiene purposes. The solution, whilst respecting the delicate balance of vaginal bacterial flora, allows effective cleansing of the mucous membrane and leaves immediate feeling of freshness and cleanliness. Particularly recommended in case of frequent washes because it lubricate and carefully studied components which do not produce irritations. Floragyn® Lavanda eliminates undesired secretions and is a suitable product to be used for intimate hygiene after sexual intercourse. Floragyn® Lavanda, in addition, carries out mechanic action in taking off residuals of organic tissues and clots of blood, so favouring the reduction of unpleasant odours which were caused by presence of ammine developed by several anaerobes bacteria peculiar of vaginal exudate.

Floragyn® Lavanda contains:
- Sodium Cocamphoacetate (Miranol Ultra C32), a suitable cleanser, made from coconut extract, which washes gently.
- Chlorhexidine Diglicionate, as antibacterial additive able to preserve the preparation.
- Lysates of Lactobacilli present with following strains (Thermophilus, Acidophilus, Bifidus, and Bulgaricus). The qualitative and quantitative choice of the aforementioned strains, which are usually present in the healthy vaginal environment, ensures effective protective action preventing the onset of infections that encourages the development of vaginal inflammation and deter the vagina with no alteration of normal physiological barriers.

Why to use
Floragyn® Lavanda is indicated for prophylaxis and for its ability to contribute, in the shortest possible time, to recovery vaginal mucosa flora impoverished by pharmacological treatment against mycotic vulvovaginal induced by Candida vaginis, in other words candidiasis (fungal yeast infections). In particular Floragyn® Lavanda is indicated, after menstrual flow, in order to regeneration and to replenish bacterial flora and to eliminate the unpleasant feeling of freshness. Floragyn® Lavanda is specifically recommended in case that frequent intimate hygiene is considered necessary. Floragyn® Lavanda eliminates undesired secretions and is suitable for intimate hygiene after sexual intercourse. Floragyn® Lavanda does not substitute medical therapy but represents a useful complementary product.

How to use
Lavanda is indicated, after menstrual flow, to prevent and eliminate the presence of lysates of lactobacilli. The shaking the bottle, does not substitute medical therapy but represents a useful complementary product.

Use of Lavanda:
- Shake well the bottle before use, then douche. The cannula can be inserted in various positions: sitting on the bidet or WC, or standing in the show er or in the bath tub. The solution should fluid with regularly, squeezing gently the bottle. Do not wash your vagina with water at the end of lavage. Eventual light splashiness of liquid and sedimentation on the bottom of bottle or in suspension is a natural process which does not affect the quality of the product, it is signal of relevant presence of lysates of lactobacilli. The shaking the bottle, reconstitutes its natural lacticence. Topical use only.

When should not be used
There are not known contraindications following the use of Floragyn® Lavanda, except eventual and rare individual cases of hypersensitivity to any of the components. Interactions or incompatibilities are not known.

Warnings and precautions for use
To use the product for long-term therapy, as per all topical products, could originate local sensitivity skin irritations. If any side effects get worse, or if any side effects not listed in this leaflet are noticed, discontinue treatment and please inform your doctor or pharmacist.

Floragyn® Lavanda should not be used in case of inner lesions. Floragyn® Lavanda contains methyl and propyl parahydroxybenzoates (methylparaben and propylparaben) which cause allergic reactions.

Special precautions during pregnancy and lactation
The use of the product is not discouraged in pregnancy and lactation.

Eventual declared toxicity
No declared toxicity.

Maintenance, storage and preparation of the device
No particular precaution is necessary for proper maintenance, storage and preparation of the device. It is important to keep always the information of the product, hence store both the external pack and this leaflet. Do not use the product after the expiry date indicated on the external pack. Such date refers to the product in integral packaging, and correctly stored.

Keep out of the reach and sight of children.

Special precautions for disposal and other handling
No special precautions for transport. After use, do not throw away the empty containers or residuals of the product. Use the containers for waste sorting of products according to the local legislation.

Compositions
Aqua (Water), Sodium Cocamphoacetate (Miranol Ultra C32), Chlorhexidine Dihydrochloride, Hydrolyzed Elastin, Mix of Lysates of Lactobacilli (Bulgarcus, Acidophilus, Bifidus, Rennomillus, Plantorum, Casei), Emulg. HKE 40, Chlorhexidine Gluconate, Cocem 2/3, Pure-Silicone 2□.

Retail format
One cardboard sheet containing 5 x 140 ml disposable single use plastic bottles with cannula and one inner leaflet. One cardboard sheet containing 4 disposable single use plastic bottle with cannula and one inner leaflet.
Vaginal mousse containing jaluronic acid, extract of grain buds, and metallic silver, useful for treating alterations of vaginal mucous membrane.

What is Floragyn® Silver
Floragyn® Silver medical device product certified by European competent authorities with CE mark, was developed as unique and particularly effective mousse formulation. Its mousse forms a thin layer inside the cervical-vaginal mucous membrane.

Floragyn® Silver contains
Jaluronic acid (as sodium salt); Extract of grain buds; Colloidal metallic silver; Metallic silver. Jaluronic acid is a natural substance, which varies in concentration with the age and stimulates the fibroblasts giving rise to connective tissue. Exploiting this peculiarity and by a topical use, jaluronic acid boosts skin repairation. Jaluronic acid covers with a thin layer the vaginal mucous membrane, forming a natural barrier and boosting the cicatrization process and the disappearance of redness, irritations, and abrasions on the vaginal mucous membrane.

The presence of jaluronic acid rends the device particularly indicated as co-adjuvant after cervical-vaginal physical treatment in diatermocoagulation, laser therapy and cryotherapy. Extract of grain buds, rich of Vitamin E, is a natural hydrating and eutrophic oil, able to develop an emollient and anti-oxidative action and able to cooperate with the protective actions supplied by the jaluronic acid. Metallic silver, in its colloidal form, is known as the most ancient and reliable microbiode. Odourless, tasteless and very gentle on humid and sensitive tissues. Its action, as preservative, guarantees the preparation by microbiocidal contamination.

Why to use
Is a topical product developed for treating alterations in the vaginal mucous membrane (irritations, abrasions, burning) and alterations due to lack of tissue growth.

How to use
1-2 applications a day. Take off the small white plastic cap and shake well the bottle. Introduce the cannula on the proper insert on the bottle and use the product, holding the cylinder upside down.

Choose a comfortable position and introduce the cannula into the genital cavity of vagina for about 5 cm; then press for 4-5 seconds. It is possible to reuse the cannula only after rinse with hot water.

When should not be used
There are not known contraindications following the use of Floragyn® Silver, except eventual and rare individual cases of hypersensitivity to any of the components. Interactions or incompatibilities are not known.

Warnings and precautions for use
To use the product for long-term therapy, as per all topical products, could originate local sensitivity skin irritations. If any side effects get worse, or if any side effects not listed in this leaflet are noticed, discontinue treatment and please inform your doctor or pharmacist.

Special precautions during pregnancy and lactation
The use of the product is not discouraged in pregnancy and lactation. Ask your doctor before using the product for advice.

Eventual declared toxicity
No declared toxicity.

Maintenance, storage and preparation of the device
Container under pressure. Protect from direct sunlight and do not expose to a temperature over 50°C. Do not pierce or do burn even after the use. Keep out from any source of combustion. Do not vapourise on a flame or on an incandescent substance. Avoid smoking. Do not use the product after the expiry date indicated on the external pack. Such date refers to the product in integral packaging, and correctly stored. Keep out of the reach and sight of children.

Intim o Intim o
• Anti-microbic and antibacterial action because of the metallic silver, useful for treating alterations of vaginal mucous membrane, form ing a natural barrier and boosting the cicatrization process and the disappearance of redness, irritations, and abrasions on the vaginal mucous membrane.

• Active interception, thanks the intercepting action of the metallic silver, of microorganisms (bacteria, yeast, viruses) which could originate local sensitivity skin irritations.

• Positive effect of lythrum salicaria.

• Effectiveness and gentle daily cleansing and active pH and bacterial flora prevention against the onset of inflammatory conditions of mucosa by the biological antagonism of lactobacilli.

• Anti-microbial and antibiotics action because of the positive effect of lythrum salicaria.

• Active interception, thanks the intercepting action of jaluronic acid (NH₄⁺) deriving from fermentation and maceration processes caused by urine.

Floragyn® Intimo is a delicate soap which carries out anti-bacterial action and active inflammatory or irritating conditions prevention.

What is Floragyn® Intimo
Floragyn® Intimo is an intimate soap indicated for the daily intimate hygiene of external genitals.

Thanks to the presence of the its active ingredients, Floragyn® Intimo performs a triple action:
• Effective and gentle daily cleansing and active pH and bacterial flora prevention against the onset of inflammatory conditions of mucosa by the biological antagonism of lactobacilli. 
• Anti-microbial and antibiotics action because of the positive effect of lythrum salicaria.
• Active interception, thanks the intercepting action of jaluronic acid (NH₄⁺) deriving from fermentation and maceration processes caused by urine.

Intimate soap indicated for daily intimate hygiene

Ingredients
Aqua, Cocamidopropylbetaine, Sodium dioleamphoacetate, Magnesium laureth sulfate, Cocamidopropylaminomoxide, PEG-200 hydrogenated glycercyl palmitate, PEG-7 glycercyl cocaate, bisabolol, Lactococcus lysetis, Bilifidus lysetis, Lactic acid, lythrum salicaria, PEG-40 hydrogenated castor oil, Propylene glycol, Methylparaben, Proplylparaben, PPG-26 buteth-26, Parfum, disodium edta, Alfaketoglutaric acid, Imidazolidinylurea.

Retail format
One cardboard sheet containing one inner leaflet and 200 ml bottle with metering liquid dispenser.

Intim o
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Thanks to the presence of the its active ingredients, Floragyn® Intimo performs a triple action:
• Effective and gentle daily cleansing and active pH and bacterial flora prevention against the onset of inflammatory conditions of mucosa by the biological antagonism of lactobacilli.

• Anti-microbial and antibiotics action because of the positive effect of lythrum salicaria.

• Active interception, thanks the intercepting action of jaluronic acid (NH₄⁺) deriving from fermentation and maceration processes caused by urine.

Is particularly recommended for daily hygiene in case of small losses of blood and reddening, during the menstrual cycle and after labour. Floragyn® Intimo contains methyl and propyl parahydrobenzoates (methylparaben) which might cause allergic reactions.

Ingredients
Aqua, Cocamidopropylbetaine, Sodium dioleamphoacetate, Magnesium laureth sulfate, Cocamidopropylaminomoxide, PEG-200 hydrogenated glycercyl palmitate, PEG-7 glycercyl cocaate, bisabolol, Lactococcus lysetis, Bilifidus lysetis, Lactic acid, lythrum salicaria, PEG-40 hydrogenated castor oil, Propylene glycol, Methylparaben, Proplylparaben, PPG-26 buteth-26, Parfum, disodium edta, Alfaketoglutaric acid, Imidazolidinylurea.

Retail format
One cardboard sheet containing one inner leaflet and 200 ml bottle with metering liquid dispenser.