

# GIAVAL<sup>®</sup> ovule

Ovules to relieve from dryness

- Vaginal ovules enriched by **Hyaluronic Acid**
- Adjuvant in repairing, **regenerating** and in **epithelialization activity**
- **Helping** the **resolution** or reduction of signs and symptoms of vaginitis at the end of treatment



# GIAVAL® ovule

## Highlights



### Medical Device Class IIb

CE Mark 0477 | Certified under Regulation (EU) MDR 745/2017

**Intended use:** adjuvant in treatment of acute or chronic vulvaginitis, cervicitis, cervical erosion, leucorrhoea and vulvar itching.

## Giaval® Ovules

The vaginal epithelium in women is **highly sensitive to the effects of estrogen**, which can lead to various problems such as vulvaginitis, cervicitis, and vulvar itching. These discomforts affect more than **70% of women from the age of 20 onwards**. During menopause, when estrogen levels drastically decrease, the vaginal epithelium undergoes significant structural changes, resulting in progressive and worsening atrophic changes. Other factors such as contraceptive use, pregnancy and certain medications can also contribute to symptoms and discomfort related to the health of the vaginal epithelium.

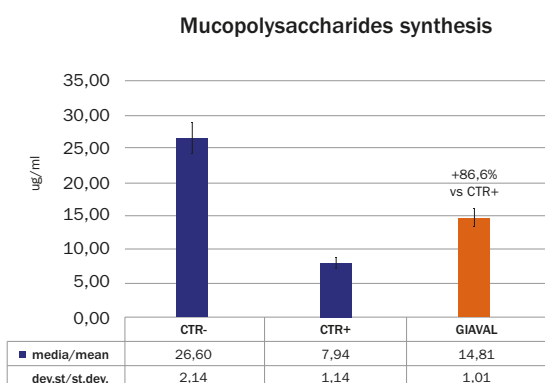
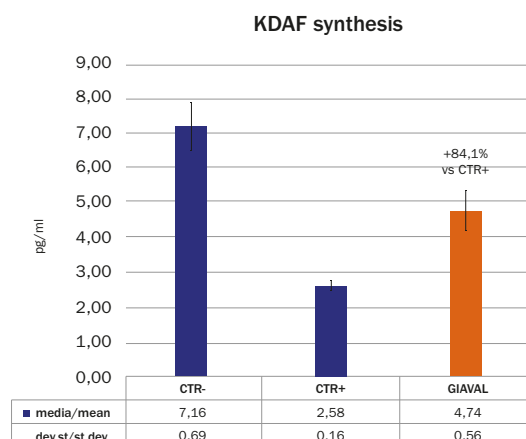
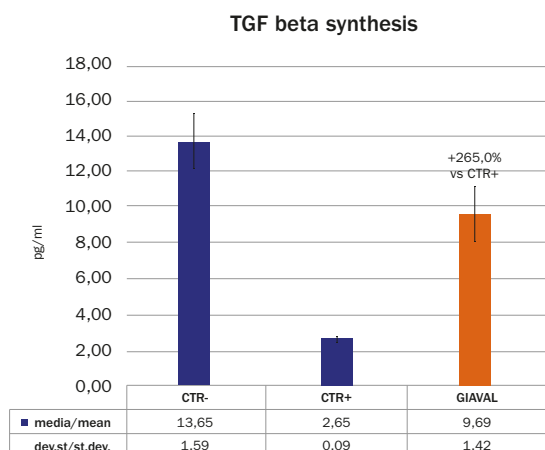
To alleviate these disorders, Innate's R&D team has developed Giaval®, a **vaginal ovule with a unique formulation enriched with Hyaluronic Acid (HA)**. HA is a naturally occurring polysaccharide that has the ability to attract and retain water molecules, maintaining

tissue turgidity, moisturizing the skin during inflammation, and preserving tissue homeostasis. **HA supports cellular migration and tissue regeneration**, making it effective in treating skin diseases.

By doing so, it helps prevent the proliferation of pathogens. Clinical benefits of Giaval® include resolving or reducing symptoms of vaginitis, such as burning, pain, itching, vaginal dryness, dyspareunia, and dysuria.

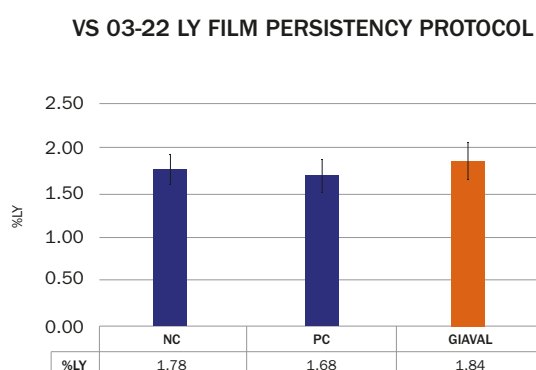
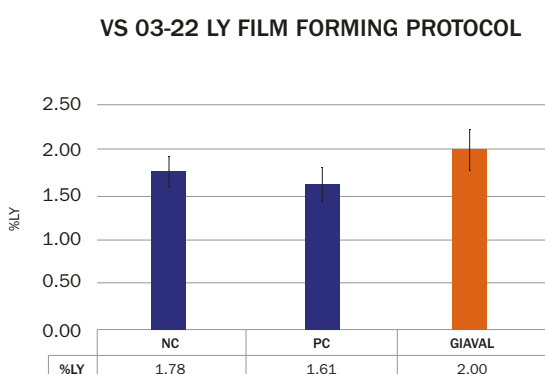
Giaval® offers a solution to address the discomforts and disorders associated with the vaginal epithelium. Its unique formulation enriched with hyaluronic acid provides protective and regenerative properties, aiding in the restoration of vaginal health and reducing symptoms. By targeting both subjective and objective symptoms, Giaval® aims to improve the quality of life for women affected by these conditions.

# Test for efficacy in reepitelization of Giaval®



**Results:** According to the applied experimental protocol, the results obtained and displayed in the figures demonstrate that **the treatment of the vaginal epithelium with Giaval® has significantly and positively helped in modulating all the markers considered. Based on such evidence it being confirmed the contribution of Giaval® to local reepithelization.**

# Test for barrel activity of Giaval®



A test with the intent to evaluate the barrel action of the product was done using a caffeine based solution. The **passage through a barrier** was tested and compared versus the negative control. **Film forming property was evaluated after 1 hour of exposure** and immediate readout while film persistency was evaluated after one hour of exposure and after a gentle washing with 0,9% saline solution In both cases the product significantly reduced the passage of the caffeine compared to the negative control demonstrating therefore the barrier activity of Giaval® . Please note that LY stands for Lucifer Yellow Flux (paracellular).

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## Commercial Informations

### **GIAVAL<sup>®</sup> Ovules**

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

**Indication of Use:** one ovule per day for 10 days -

Package leaflet in each box

**Shelf Life:** 36 months

**Minimum order quantity:** 5000 units

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