PROmovia
HYDRO BALANCE

Commercial Informations

PROMOVIA® Hydro Balance Injectables
Format: 1 pre-filled syringe per unit
Indication of Use: Available single shot following medical administration advice
Shelf Life: 36 months
Minimum order quantity: 500 units

INNATE S.R.L.

Phone: +39 01432645
Email: info@innate.it

Viale Industria, 11/13 - 15067 Novi Ligure (AL) Italy
Via Celeste Milani, 24/26 - 21040 Origgio (VA) Italy

Download this leaflet here:

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Patented formulation based on sodium hyaluronate and trehalose

- Sterile, biodegradable, and isotonic **injectable gel**
- **Medium-chain** hyaluronic acid and **Low-chain** hyaluronic acid
- With trehalose used as a technological excipient to **enhance the stability of hyaluronic acid**

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HUMAN HEALTH

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Highlights

Number Patent: 102018000010415
Medical Device Class III

CE **Mark 1984**

Intended use: Chondropathy, Arthrosis, Arthritis.
Classification: Implantable, non-active, re-absorbable, long term (>30 days) medical device.

Promovia® Injections

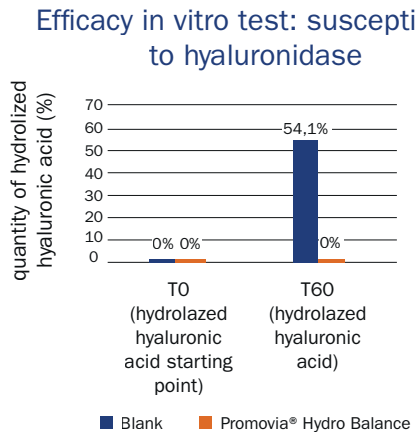
Promovia® Hydro Balance is an **injectable gel designed to replace synovial fluid in the joint**. It provides a **long-lasting viscosupplementation effect** and **immediate relief** for patients with joint disorders. Unlike traditional infiltration products, Promovia® Hydro Balance offers a one-shot injection session, reducing the need for repeated treatments and rest periods.

The gel's formulation **includes hyaluronic acid and trehalose**, which work together to enhance viscosupplementation and protect hyaluronic acid from degradation. Trehalose attracts and retains water, improving the gel's viscoelastic properties. Additionally, it binds to the enzyme hyaluronidase, slowing down the degradation of hyaluronic acid.

Promovia® Hydro Balance **is available in different concentrations** to suit various levels of joint disturbance and sizes. It is sterile, biodegradable, and formulated with medium-chain and low-chain hyaluronic acid obtained from Streptococcus equi bacterium. Trehalose is used as a **technological excipient** to enhance stability and protect hyaluronic acid from hyaluronidase activity.

Formats available: Promovia® Hydro Balance 50mg and Promovia® Hydro Balance 100mg.

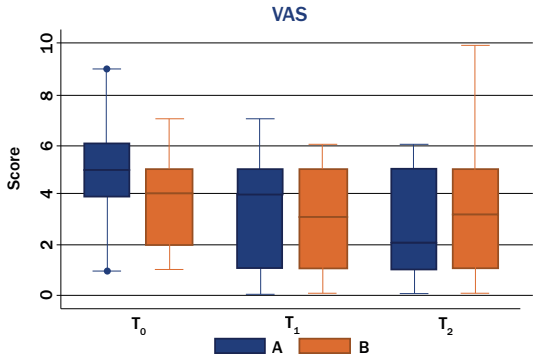
Efficacy in vitro test (E.IT.076 _2018/2116 B dated 31/07/2018)

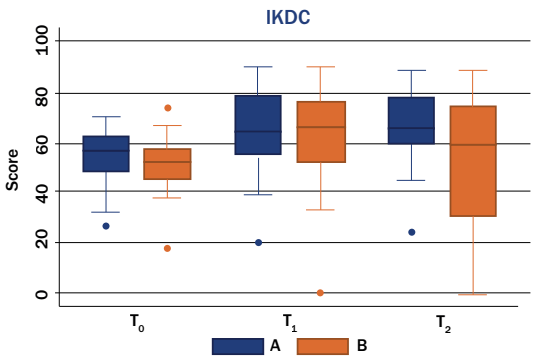


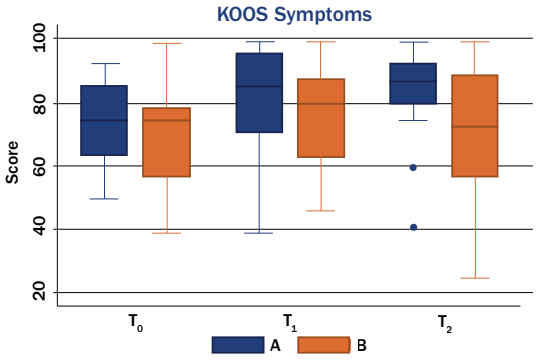
The hyaluronidase susceptibility test follows protocols described by Tolksdorf et al (1949) and Kass and Seatone (1944). The reaction is monitored at 540 nm. Reagents used include a sodium phosphate buffer (pH 5.3) with sodium chloride, a sodium acetate buffer (pH 4.2), an albumin reagent, and hyaluronidase solution. Each tested product is added to the reaction mixture, and the turbidity of the mixture is measured at the **start (T0) and after 60 minutes (T60)**. The data obtained from the measurements are used to quantify hyaluronidase activity. The tests are performed in triplicate, and the reported data represents the average of the results.

Conclusion: As can be seen from the graphs, in Promovia® Hydro Balance the effect of hyaluronidase is al- most nil.

Clinical evaluation







A prospective double-blind controlled study with 60 knee osteoarthritis patients compared the effectiveness of **T-HA** (hyaluronic acid with trehalose) and **NT-HA** (non-trehalose hyaluronic acid) treatments. Patients received three doses and were assessed at three and six months using the **IKDC, KOOS, and VAS scales for pain**. Both groups showed improvement at three months. However, at six months, the T-HA group **continued to improve**, while the NT-HA group's scores declined. The T-HA group had higher IKDC scores at six months, indicating **longer-lasting symptom relief** compared to NT-HA.