PEROVIAL 0.8%

Hyaluronic acid sodium salt 8 mg/1 ml

Hyaluronic acid sodium salt 16 mg/2ml

Medical device for intralesional penile injection

Sterile - Single-use

DESCRIPTION

Peyronie's disease, or *induratio penis plastica (IPP)* is a fibrotic disease acquired with an unknown pathophysiology, characterized by the deposition of collagen and fibrin in the form of a scar (plaque) on the tunica albuginea of the penis, which gradually reduces elasticity with consequent penis deformity and pain. The healing process is believed to be hindered by the presence of traumas or micro traumas responsible for the formation of fibrous-scar tissue. The pathophysiological bases of IPP refer to the inflammation observed in the acute phase caused by free radicals; at this stage of the disease, the plaque on the tunica albuginea of the penis has not yet been calcified.

PEROVIAL® is composed of a buffered saline solution of hyaluronic acid sodium salt. PEROVIAL® contains 0.8% highly purified hyaluronic acid sodium salt with a molecular weight between 800 and 1.200 kDalton.

Hyaluronic acid is a predominant GAG - glycosaminoglycan of the connective tissue - and is present at high concentrations in the tunica albuginea. Hyaluronic acid is composed of glucuronic acid and N-acetylglucosamine, held together by β-glycosidic bonds. At physiological pH, hyaluronic acid is highly polarized and maintains hydration, turgor, plasticity and viscosity in the amorphous connective matrix.

Thanks to its antioxidant and antifibrotic effects, there is a reduction in plaque-related symptoms and a limitation of growth.

INTENDED USE

PEROVIAL®, thanks to the ability of hyaluronic acid (HA) to retain an extremely high amount of water, allows softening the plaque on the tunica albuginea of the penis and facilitates the correct healing process, combating the progression of the scar. Furthermore, due to the antioxidant effect of HA, the pro-inflammatory action of free radicals is reduced.

INDICATIONS

PEROVIAL® is indicated for the treatment of acute Peyronie's disease.

INTENDED POPULATION AND USERS

PEROVIAL® is indicated for adults and is to be administered by intrapenile injection by qualified personnel only.

PEROVIAL® IS TO BE SOLD ON MEDICAL PRESCRIPTION ONLY.

COMPOSITION

PEROVIAL® has consisted by the prefilled syringe with 1 or 2 ml of solution, which contains:

SYRINGE VOLUME	1 ml	2 ml
FUNCTIONAL COMPONENT		
SODIUM HYALURONATE	8.000 mg	16.000 mg
OTHER COMPONENTS		
SODIUM CHLORIDE	8.500 mg	17.000 mg
SODIUM PHOSPHATE	0.205 mg	0.410 mg
WATER FOR INJECTION	q.s. 1.0 ml	q.s. 2.0 ml

POSOLOGY

Intrapenile treatment with PEROVIAL® is to be performed weekly for 10-12 weeks according to the doctor's judgment. The volume of the injections depends on the size of the plaque.

AVAILABLE KITS

MARCHIO® is available in kits of 1syringe with 1 needle of 27G x ½ in the following volumes:

- 1ml prefilled syringe: 8 mg hyaluronic acid sodium salt in 1 ml sodium chloride buffered saline solution
- 2ml prefilled syringe: 16 mg hyaluronic acid sodium salt in 2 ml sodium chloride buffered saline solution

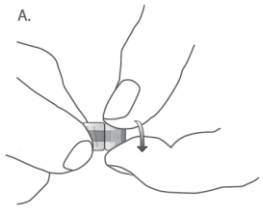
The content of the syringe is sterile and pyrogen-free.
Prefilled syringe sterilized by moist heat.

CE 0197 **Manufacturer:** Terumo Europe N.V. - Interleuvenlaan 40 - 3001 Leuven, Belgium

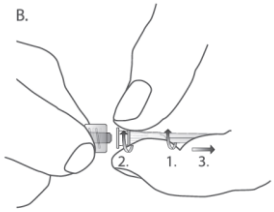
Needle sterilized by ethylene oxide.

INSTRUCTIONS FOR USE

- Carefully unscrew the syringe cap, firmly holding the Luer-lock closing neck between your fingers and being particularly careful to avoid contact with the opening (Figure A).



- Firmly holding the Luer-lock closing neck between your fingers, screw the 27G needle tightly onto the closing neck of the syringe until you feel slight pressure so as to ensure an airtight seal and prevent liquid leakage during administration (Figure B).



- Inject PEROVIAL® at ambient temperature and on a thoroughly disinfected genital skin
- The injection site should be on healthy skin and away from subcutaneous veins.
- Identify plaque by palpation
- After anaesthetising the base of the penis, infiltrate the plaque firmly with the needle and inject the device.
- Due to the viscous nature of the device, it may be necessary to apply pressure to the syringe handpiece during the procedure.
- If there is strong resistance, slowly change the position of the needle, taking care not to bend it.
- Do not inject via the vascular route, but into the tunica albuginea. In case of intravascular injection, see section “Side Effetct” of this Instruction For Use

- Do not inject outside the shaft
- Do not inject into the glans or urethra
- Massage after injection
- Do not use ice on the penis before or after the treatment.

- After injection, advise the patient to avoid any sexual and intense physical activity for 24-48 hours
- After use, the empty syringe and needle must be disposed of in accordance with the regulations in force for disposal of medical waste.

After the treatment:

After the treatment, the implant card must be filled in and provided to the patient; the implant card can be found in the first page of the instruction for use containing in the pack.

Instruction for completing the Implant card

Fill in the fields marked with the following symbols with the information indicated:

	Patient Name or patient ID
	Date of treatment
	Name and address of the implanting healthcare institution Name of medical practioner**.**

WARNINGS

- The content of the prefilled syringe is sterile.
- The syringe is packed in a sealed blister pack.
- The outer surface of the syringe is not sterile.
- Do not use PEROVIAL® after the expiry date indicated on the package.
- Do not use PEROVIAL® if the packaging is open or damaged, because the sterility of the product could be compromised
- Do not resterilize. The device is intended for single use only.
- Do not reuse in order to prevent any risk of contamination.

- Store at ambient temperature below 25°C and away from heat sources.
- Do not freeze.
- Once opened, PEROVIAL® must immediately be used and discarded after use.
- Any air bubble present does not compromise the characteristics of the product.
- The injection site must be on healthy skin.
- Do not administer if there is a skin infection, foreskin infection or urethritis
- Do not inject intravascularly.
- In case of intravascular injection, see section “Side Effetct” of this Instruction For Use
- Do not inject PEROVIAL® in patients with calcified plaque (chronic phase of IPP) or with hourglass deformity found by duplex Doppler ultrasound.
- Do not use PEROVIAL® in case of known hypersensitivity or allergies to the components of the product.
- Avoid intense physical activity and any sexual activity for at least 24-48 hours, after injection
- PEROVIAL® is indicated for adult patients.
- Keep out of the reach and sight of children.

PRECAUTIONS FOR USE

Do not mix PEROVIAL® with disinfectants such as quaternary ammonium salts or chlorhexidine as a precipitate may form.

INTERACTIONS

To date, there are no known interactions between PEROVIAL® and other drugs/treatments.

Nonetheless, in case of therapies and/or taking medications in conjunction with the treatment, consult your doctor for more information.

SIDE EFFECTS

Intrapenile infiltration of PEROVIAL® may locally cause undesirable effects.

During use of PEROVIAL®, symptoms such as pain, sensation of heat, reddening, swelling, ecchymosis or haematoma may occur at the injection site. They generally disappear after a short period of time. Physicians must ensure that patients notify them of any undesirable effects that occur after the treatment.

In case of intravascular injection apply a local vigorous massage to stimulate vasodilatation and facilitate the diffusion and the subsequent degradation of the product.

In the event of an incident, inform the Manufacturer or the competent authority.

OVERDOSE

Follow the posology indicated and if you experience any side effects related to an overdose, contact your doctor or nearest hospital.

CONTRAINDICATIONS

PEROVIAL® should not be injected if the patient has an infection in the area of the injection site.

Shelf-life: 36 months.

The expiry date indicates the maximum shelf-life of the medical device referring to the product properly stored in an intact package.

DATE OF LAST REVISION OF PACKAGE LEAFLET

January 2025

DISPOSAL

Do not dispose of the product in the environment after use. Follow local regulations for disposal of the product.

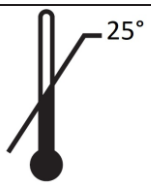
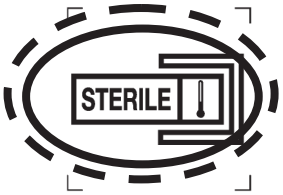
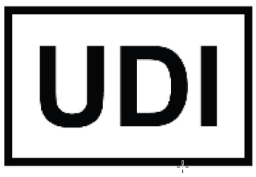
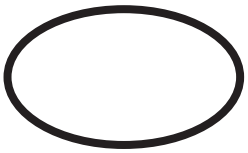
To the following link it's possible to download the Summary of Safety and Clinical Performance:
https://www.ibsa.it/en/chi-siamo/summary-of-safety-and-clinical-performance.html
https://www.ibsa.it/en/chi-siamo/sscp-area-riservata.html

Manufacturer:

IBSA Farmaceutici Italia srl
Via Martiri di Cefalonia, 2 – 26900 Lodi – Italy
E-mail: info@ibsa.it

Distributor:

(Name and address of distributor)

CE 0477			
	See the instructions for use	Carefully read the warnings	Use by...
			
Single-use	Storage temperature	Sterilized by moist heat	Batch
 Do not use if the package is damaged	 Date of manufacture	 The medical device contains a sterile fluid path that has been sterilized by moist heat. Moreover indicates a single *sterile* barrier system with protective packaging outside	 **Manufacturer**
 Do not resterilize	 Unique device identifier	 Medical Device	 Sterilized by ethylene oxide
Exp. Expiry			
	Single sterile barrier system		