Voferon

Crosslinked HA hydrogel system for sustained-release drug delivery

INSTRUCTIONS FOR USE

Document No.: IFU-VW-EN (Rev.0)
Date of Revision: 2026. 04. 01

1. Product Name (Item Name) and Model Name:

Voferon (Voferon-WI030 / Voferon-WI060)

2. Manufacturing Number:

Refer to the product packaging

3. Shelf Life

2 years from the date of manufacture (Refer to the product packaging)

4. Components:

Name	Q'ty
Pre-filled Syringe (filled with crosslinked HA)	1ea
Manual drug mixing device	1ea
General-purpose catheter cannula	1ea
Sterile needle	1ea
10 mL syringe	1ea

5. Packaging Unit:

1 set (1 Pre-filled Syringe / 1 Blister)

6. Storage Method:

Store at room temperature (1-25°C), protect from light, and do not freeze.

7. Intended Use:

A sustained-release drug delivery medical device intended for pain control at the surgical site after surgery, used by mixing with ropivacaine hydrochloride 0.75% and applying to the surgical site to release the drug.

8. Principle of Operation:

This product consists of a prefilled syringe (glass syringe) filled with a transparent and viscoelastic gel produced by crosslinking stabilization of non-animal-derived hyaluronic acid, which is a biocompatible absorbable material. When this product is mixed at a specified ratio with ropivacaine hydrochloride 0.75% and applied to the relevant surgical site (such as the skin tissue and fascia of the incision site), ropivacaine hydrochloride 0.75% is released, thereby controlling pain. Ropivacaine hydrochloride 0.75%, which is a medicinal product, is not included as a component of this product.

9. How to Use

1) Preparations Before Use

❶ Before use, check whether the packaging container of the product is damaged.

❷ Check the shelf life of the product and whether it is damaged.

❸ As this product is supplied in a sterile condition, only a sterile product with no damage to the packaging material and within the expiry date shall be used.

❹ Clean your hands before using the product.

❺ Read the instructions for use carefully before use.

2) Method of Use and Operating Procedure

❶ In a sterile environment, remove the product packaging and connect the sterile syringe and sterile needle.

❷ Insert the sterile needle into the vial of ropivacaine hydrochloride 0.75% provided on site and fill the sterile syringe with ropivacaine hydrochloride 0.75% according to the gel volume as shown in the table below.

Gel Volume (Model Name)	Amount of Ropivacaine Hydrochloride 0.75%
3 mL (Voferon-WI030)	1.5 mL
6 mL (Voferon-WI060)	3.0 mL

❸ Remove the sterile needle connected to the sterile syringe filled ropivacaine hydrochloride 0.75%.

❹ Connect the manual drug mixing device to the prefilled syringe and connect the sterile syringe filled with ropivacaine hydrochloride 0.75%.

❺ By repeatedly pushing the plungers of the two connected syringes left and right, mix ropivacaine hydrochloride 0.75% uniformly with the gel in the prefilled syringe. (It is recommended to repeat this at least 10 times.)

❻ Fully depress the plunger of the sterile syringe so that the mixed solution is completely transferred to the prefilled syringe.

❼ Separate and remove the manual drug mixing device from the prefilled syringe.

❽ For application of the drug-mixed solution, connect a general-purpose catheter cannula to the prefilled syringe containing the mixed solution.

❾ Apply enough of the drug-mixed solution so that it can be completely spread over the surgical site (such as the skin tissue and fascia of the incision site). Use the general-purpose catheter cannula so that the solution can be injected deeper than the incision site. (However, care shall be taken not to damage blood vessels and nerves.) The general-purpose catheter cannula is used when applying the drug-mixed solution in the 90-degree direction (horizontal direction) of the cannula.

❿ The amount to be used according to the incision length at the application site is as follows.

Incision Length	Voferon Gel Volume	Ropivacaine Hydrochloride 0.75% Volume	Mixed Volume with Ropivacaine Hydrochloride 0.75% Volume
~8 cm	6 mL	3 mL	9 mL

3) Storage and Maintenance After Use

As this product is for single use only, discard the prefilled syringe and any remaining contents after one use.

10. Precautions for Use

1) Contraindications

❶ In persons with hypersensitivity to the component (hyaluronic acid), use according to the physician's instructions.

❷ Do not use in patients with severe multiple allergies or allergy to hyaluronic acid, patients with a history of hypersensitivity (anaphylaxis) to this drug or other amide-type local anesthetics, or patients with lymphatic fluid- or blood coagulation-related disorders.

❸ Do not use in blood vessels.

2) Adverse Reactions

❶ Hypersensitivity reactions to hyaluronic acid.

❷ If itching, rash, fever, allergic reactions, or signs of infection occur during use of this product, discontinue use and follow the physician's or pharmacist's instructions.

❸ If an adverse reaction occurs when used after mixing with ropivacaine, it shall be reported to the distributor.

* Adverse reactions

① 5% or more: Hypotension, nausea, vomiting, bradycardia, pyrexia, pain, postoperative complications, anemia, paresthesia, headache, pruritus, and back pain.

② 1% or more and less than 5%: Urinary retention, dizziness, rigidity, hypertension, tachycardia, anxiety, oliguria, hypoesthesia, chest pain, dyspnea, convulsion, urinary tract infection, elevated body temperature, and chills.

③ Less than 1%:

- Cardiovascular system: Vasovagal response, syncope, orthostatic hypotension, unspecified ECG abnormalities, extrasystole, unspecified arrhythmia, ventricular fibrillation, ST-segment changes, myocardial infarction, venous thrombosis, phlebitis, pulmonary embolism, and, very rarely, cardiac arrest and arrhythmia.
- Reproductive system: Slow progress of labor and uterine atony.
- Gastrointestinal system: Fecal incontinence, tenesmus, and neonatal vomiting.
- Sensory organs: Tinnitus, hearing impairment, and visual abnormalities.
- Hepatobiliary system: Jaundice.
- Metabolic disorders: Hypomagnesemia and hypercapnia.
- Musculoskeletal system: Myalgia, muscle rigidity, and muscle spasm.
- Neuropsychiatric system: Tremor, Horner syndrome, paralysis, dyskinesia, neuropathy, dizziness, coma, agitation, confusion, somnolence, nervous debility, amnesia, hallucination, emotional instability, insomnia, nightmare, and seizure.
- Respiratory system: Bronchospasm, cough, dyspnea, and hypoxia.
- Skin and appendages: Erythema and urticaria.
- Urinary system: Urinary incontinence, dysuria, and urinary retention.
- Application site reactions: Injection site pain.
- Others: Hypothermia, malaise, asthenia, accident and/or injury, and, very rarely, allergic reactions (anaphylactic shock, angioedema, urticaria).

3) General Precautions

❶ It is recommended to use the product immediately after opening. Any remaining portion not used after opening shall be discarded.

❷ This product may only be used by a qualified professional.

❸ Before use, confirm that the sterile condition has not been compromised.

❹ Check the shelf life indicated on the product label.

❺ This product shall not be reused, and sterility is not guaranteed for products whose packaging is damaged or opened.

❻ Do not re-sterilize the product.

❼ Do not use the product if the packaging is damaged.

❽ Do not use the product after the expiry date indicated on the product packaging box.

❾ Store this product at room temperature (1-25°C).

4) Use in Pregnant Women, Nursing Women, Women of Childbearing Potential, Neonates, Infants, Children, and the Elderly

❶ Use of this product is not recommended during pregnancy.

❷ Use in pregnant women, nursing women, and persons under 18 years of age has not been confirmed in clinical trials.

5) Precautions for Application

❶ Air bubbles may be generated during the mixing process, but this does not affect product performance.

❷ No one other than a qualified professional under the relevant laws and regulations shall use this product.

❸ The amount to be used according to the incision length of the application site recommended in the directions for use shall be observed, and caution is required because use in excess of the presented amount has not been confirmed.

6) Cases Requiring Prevention of Safety Accidents

Take care to avoid needlestick injury when handling sharp instruments such as needles.

7) Precautions for Concomitant Use with Medicinal Products

❶ Avoid additional use of other local anesthetics while administering this product.

❷ When this product is mixed and used with medicinal products other than ropivacaine 0.75% (ropivacaine hydrochloride), its safety and effectiveness have not been confirmed in clinical trials.

❸ This item was evaluated in clinical trials involving patients undergoing laparoscopic surgery.

❹ Before use, the dosage and administration information of the concomitant medicinal product shall be thoroughly read and confirmed, and care shall be taken not to exceed the maximum allowable daily dose.

❺ Before mixing, confirm that the syringe filled with the drug and the prefilled syringe filled with gel are properly connected to the connecting device.

❻ During mixing, do not apply excessive force in an attempt to mix too quickly.

❼ Do not use the mixed solution if foreign matter is observed.

* Note: Please refer to the table below to identify various symbols.

Symbol	Title
	Manufacturer
	Authorized representative in the European Community / European Union
	Date of manufacture
	Use-by date
	Batch code
	Model number
	Sterilized using steam and dry heat
	Do not resterilize
	Do not use if package is damaged and consult instruction for use
	Fragile, handle with care
	Keep away from sunlight
	Keep dry
	Temperature limit
	Do not reuse
	Consult instruction for use or consult electronic instruction for use
	Caution
	Medical device
	Unique device identifier
	CE mark

JP cares Co.,Ltd.
708, 52, Sagimakgol-ro, Jungwon-gu, Seongnam-si,
Gyeonggi-do, Republic of Korea 13210

SOAR & PARTNERS Sp.z o.o.
Address: ul. Zlota 59, 00-120 Warsaw, Poland

*** This product is a sterile single-use medical device; do not reuse.**