

# BOHUS

SCANDINAVIAN<sup>HA</sup>

## Lubravisc<sup>®</sup> Bio

Sodium hyaluronate 20 mg/ml, 2 ml



CE<sub>0483</sub>

CE Marked as per  
MDD 93/42/EEC



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VER 2024-04

# INSTRUCTIONS FOR USE

## Lubravisc® Bio

### Composition

Each ml contains:	<b>Lubravisc® Bio 1.0%</b>
Sodium hyaluronate	20.0 mg
Disodium phosphate dihydrate	2.8 mg
Sodium chloride	16.8 mg
Potassium dihydrogen phosphate	0.52 mg
Water for injection	q.s

### Description

Lubravisc® Bio is a non-surgical, non-pharmacological, preservative-free, pain-relieving viscosupplement based on highly purified, high molecular weight sodium hyaluronate (by fermentation) dissolved in a physiological buffer. It is a clear solution supplied in sterile disposable glass syringes, containing 2.0 ml of liquid. The filled syringes are sterilized and packed in single blisters.

Lubravisc® Bio (sodium hyaluronate) is a 1.0 % viscoelastic, sterile and clear single dose solution for injection into the joint cavity. The highly purified sodium hyaluronate is dissolved in a physiological buffer at pH 6.8–7.6.

### Characteristics

The most important properties of HA are to protect, lubricate and support delicate cells and tissues. Lubravisc® Bio is free from avian protein and may ameliorate the viscoelastic properties of synovial fluid, thus improving its lubrication and shock absorbing properties, hence reducing the mechanic overload of the joints. Lubravisc® Bio is to be injected into the affected joint only once. Several joints may be treated at the same time. Repeated treatment cycles may be administered as required at intervals not less than 6 months. The prefilled syringe shall be taken out of the blister and cap removed by twisting and immediately attach a suitable needle (e.g. 18 or 22G). Work shall be performed aseptically to open the needle and to remove the cap on the syringe.

### Intended use

Treatment of mild to moderate osteoarthritis in the knee, hip, shoulder, ankle and temporomandibular joints.

### Contraindications and precautions

- Lubravisc® Bio must be used when patients have septic arthritis. It's not indicated for use in other types of arthritis not related to osteoarthritis.
- Lubravisc® Bio must only be injected by qualified personnel (orthopedist, rheumatologist or equivalent). The dosage shall be prescribed by the physician, who will adjust the dosage specifically for the individual patient.
- The syringe is intended for single use only. The syringe shall be used immediately after the packaging has been opened. Strict aseptic technique is applicable. Remove superfluous synovial fluid before injecting in the knee joint. Do not use the product if the package or the single dose syringe is damaged.
- Limited experience of usage during pregnancy is available. Consult your doctor when using Lubravisc® Bio during pregnancy.
- Breast-feeding. Lubravisc® Bio is transmitted into the mother's milk, but most probably doesn't affect babies being breast-fed. Consult your doctor when using Lubravisc® Bio during breast-feeding.
- Don't inject anesthetics or other pharmaceutical preparations in the knee joint during the period of time the patient is treated with Lubravisc® Bio. In rare cases allergic reaction can occur.

### Interactions

Do not inject anaesthetics or other pharmaceutical preparations in the knee joint during the period of time the patient is treated with Lubravisc® Bio.

### How Supplied

Lubravisc® Bio is supplied in sterile disposable glass syringes, containing 2.0 ml of liquid. The filled syringes are sterilized and packed in single blisters.























### Instruction for use

Work aseptically to remove the grey tip cap on the syringe. Also open the cannula aseptically. To prevent product leakage from the syringe, twist off the tip cap. Inject the product into the joint using an 18-22 gauge cannula.

Before use allow the preparation to equilibrate to room temperature for 20 minutes. Remove the tip cap. Mount the cannula by using the thumb and forefinger to hold firmly around both the glass syringe barrel and the luer-lock adapter. Grasp the cannula shield with the other hand. To facilitate proper assembly, both push and rotate firmly."

**Shelf life** is 3 years from manufacturing date.

### SYMBOLS

	Consult instructions for use		Non-pyrogenic
	Caution		Medical device name
	Single-use only		Unique device identifier
	Do not resterilize		Readable unique device identifier
	Steam sterilized		Lot number/batch number
	Single sterile barrier system with protective packaging outside		Version number
	Store at 2-25° C. Protect from light and freezing		Expiry date (year-month)
	Humidity limitation 60%-75%		Manufacturer
	Keep away from sunlight		Date of manufacture (year-month)
	Keep dry		Syringe
	Do not use if package material is damaged		CE-mark of conformity (0483)