

# BOHUS

SCANDINAVIAN HA

## Lubravisc® Bio

Sodium hyaluronate 20 mg/ml, 2 ml



0483

CE Marked as per  
MDD 93/42/EEC



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VER 2024-04

## INSTRUCTIONS FOR USE

## Lubravisc® Bio

**Composition**

Each ml contains:  
 Sodium hyaluronate  
 Disodium phosphate dihydrate  
 Sodium chloride  
 Potassium dihydrogen phosphate  
 Water for injection

**Lubravisc® Bio 1.0%**  
 20.0 mg  
 2.8 mg  
 16.8 mg  
 0.52 mg  
 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, rheumatolo-gist 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



Caution



Single-use only



Do not resterilize



Steam sterilized



Single sterile barrier system with protective packaging outside



Store at 2-25° C. Protect from light and freezing



Humidity limitation 60%-75%



Keep away from sunlight



Keep dry



Do not use if package material is damaged



Non-pyrogenic



Medical device name



Unique device identifier



Readable unique device identifier



Lot number/batch number



Version number



Expiry date (year-month)



Manufacturer



Date of manufacture (year-month)



Syringe



CE-mark of conformity (0483)