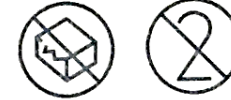


# optiLube active™

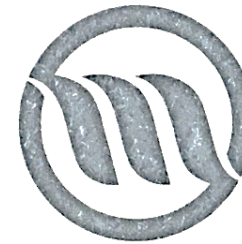
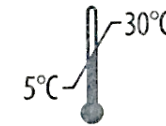
sterile lubricating jelly  
with local anaesthetic & antiseptic  
for urethral application

INSTRUCTIONS FOR USE  
INSTRUCTIONS D'EMPLOI  
ISTRUZIONI PER L'USO  
INSTRUCCIONES DE USO  
INSTRUÇÕES DE USO  
GEBRAUCHSANWEISUNG  
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ИНСТРУКЦИЯ ПО ПРИМЕНЕНИЮ  
تعليمات الاستخدام

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## DESCRIPTION

**OptiLube Active** is a sterile water soluble jelly used for lubrication of the urethra prior to insertion of urethral catheters, cystoscopes and other medical devices.

It helps to prevent trauma being caused to the patient during catheterisation procedures or other urethral procedures by effective lubrication.

Additionally, **OptiLube Active** contains antiseptic and local anaesthetic properties to reduce the risk of infection and pain for the patient.

This instruction for use applies only to **OptiLube Active**.

## INGREDIENTS

100g gel contains:

- Hydroxyethylcellulose, Propylene Glycol (Lubricants)
- Purified Water
- 0.025g Propyl Hydroxybenzoate
- 0.060g Methyl Hydroxybenzoate
- 0.250g **Chlorhexidine** Gluconate [20% concentrate]
- 2g **Lidocaine** Hydrochloride (Local anaesthetic)

## CONTRAINDICATIONS

- **OptiLube Active** must not be used in patients with known hypersensitivity to any of the ingredients
- **OptiLube Active** should not be used in patients who have damaged or bleeding mucous membranes because of the risk of systemic absorption of the **Lidocaine** Hydrochloride

## WARNINGS

**OptiLube Active must only be used under the supervision of health professionals.**

You are not suitable for the gel;

- If you have ever had a reaction to a local anaesthetic
- If you know that you are allergic or hypersensitive to any of the ingredients
- If the gel will be in contact with damaged mucous membranes

Care should be taken when using the gel;

- If you have heart problems or are taking medication for treating irregular heartbeat
- If you have liver problems
- If you are epileptic
- If you are pregnant or breast feeding

You might feel a slight stinging just after the gel is used, but this stops as soon as the anaesthetic starts to work. If you feel that you have had any reaction to the gel, you should tell your doctor as soon as possible.

If any side effects become serious or if you notice any side effects not mentioned in this leaflet, please tell your doctor, pharmacist or manufacturer.

If you feel drowsy after using **OptiLube Active**, do not drive or use machinery.

**Do not use orally.** If the gel has been used orally (inserted into your mouth) care should be taken when chewing or swallowing. Numbness of the tongue or mouth can lead to a bite injury.

**Not for use in the eye. Do not use if the packaging is damaged.**

**Do not use after expiry date. Do not use in children below 2 years of age.**

**For single use only.** Any remaining jelly in the syringe must be disposed of according to hospital procedures.

**Not to be used for i/v and i/m injections. Keep away from children.**

## PREGNANCY AND LACTATION

Tell your doctor if you are pregnant or think you may be pregnant. Only use during pregnancy or when breast feeding under the direction of a doctor.

## EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

The ability to drive and operate machinery may be slightly impaired after the use of lubricant gel with **Lidocaine**. If affected, patients should be advised not to drive or use machinery.

## SIDE EFFECTS

Like any medication, lubricant gel with **Lidocaine** and **Chlorhexidine** may cause side effects in some people.

Local hypersensitivity reactions occur in rare cases such as redness, stinging, or itching and/ or systemic reactions to **Lidocaine** and/or **Chlorhexidine**. There is also a risk of severe reactions including drop in blood pressure, dizziness, nausea, shortness of breath, bradycardia, convulsions and anaphylactic shock.

## DRUG INTERACTIONS

Depending on the absorption of **Lidocaine**, these interactions can be seen when used with the following medications;

Propranolol: Reduction in plasma clearance of **Lidocaine**

Cimetidine: Reduction in plasma clearance of **Lidocaine**

Antiarrhythmic products: Increase in the toxicity of **Lidocaine**

Phenytoin or barbiturates: Reduction in plasma levels of **Lidocaine**

Specified interactions can be seen in the long-term use and repeated high doses.

When administered as recommended, there is no clinically significant interactions reported.



**OptiLube Active** must not be used at the same time as other medical devices or medicines containing local anaesthetic.

## OVERDOSE

This gel must not be used at the same time as any other medical device or medicines containing a local anaesthetic agent. In the event of excessive absorption of **Lidocaine** into the bloodstream, symptoms may include CNS effects and cardiovascular reactions.

## HOW TO USE

**Dosage recommendations:** For adults max. 16g gel ( $\cong$  0.3g **Lidocaine**). For children (between 2 and 15 years); max. 0.3g gel/kg B.W ( $\cong$  6mg **Lidocaine**/kg). No more than four doses may be administered within 24 hours. In children below 2 years of age lubricating gel with **Lidocaine** must not be used.

**Adult maximum dosage:** No more than 600mg of **Lidocaine** Hydrochloride should be given in any 12 hour period.

Excessive dosage or short intervals between doses can result in high Plasma levels and serious adverse effects.

The decision as to which size of **OptiLube Active** sterile lubricating jelly pre-filled syringe to be used is taken by the healthcare professional.

- Remove the syringe from its sterile package by tearing away the backing paper.
- Remove the cap from the end of syringe.
- Apply a drop of gel to urethral opening to make initial insertion easier.
- Insert the nozzle into the urethral opening and press the plunger of the syringe slowly to release the necessary amount of **OptiLube Active**. NOTE: **OptiLube Active** should be applied to the desired area, not directly on the device.
- The lubrication characteristics of the gel start to take effect at the time of application. The onset of anaesthetic effect is 3-5 minutes.

## NOTES & STORAGE

Scale on the syringe is for the orientation of the user. It does not have a measurement function. Store at 5-30°C until expiry date.

## STERILISATION

Sterilised with gamma radiation after the packaging process.

**Do not use if packaging is damaged.**

## PACKAGING

The gel is supplied sterile in disposable pre-filled syringes of 6ml ( $\approx$  6g) and 11ml ( $\approx$  11g).