Liberty® Hydro-Caine®
Lubricating Gel

STERILE R

INSTRUCTIONS FOR USE

PLEASE READ CAREFULLY

Liberty® Hydro-Caine® Lubricating Gel
with 2% Lidocaine HCl (11ml and 6ml)

DESCRIPTION

Liberty® Hydro-Caine® Lubricating Gel with 2% Lidocaine HCl is a sterile medical device that contains a local anaesthetic and antiseptic agent which is used for instillation into the urethra before the insertion of a catheter or instruments. The insertion of urinary catheters after the administration of **Liberty® Hydro-Caine®** Lubricating Gel with 2% Lidocaine HCl (11ml and 6ml) by health professionals minimises associated trauma, pain and catheter-associated infections before transurethral resection (TUR), and intermittent catheterisation and urethral diagnostic procedures. The anaesthetic takes about 5 minutes to work after the gel has been administrated.

Liberty® Hydro-Caine® Lubricating Gel with 2% Lidocaine HCl is provided in gamma-sterilised form and offers variety of sizes including 11ml and 6ml.

INGREDIENTS

Lidocaine Hydrochloride 2%, Chlorhexidine Digluconate 0.05%, Methyl Hydroxybenzoate, Propyl Hydroxybenzoate, Propylene Glycol, Hydroxyethyl cellulose , Purified Water.

THERAPEUTIC INDICATIONS

Instillation into the urethra prior to the instillation of a catheter or other instruments (catheterisation, cystoscopy) and manipulations which require the use of a local anaesthetic.

CONTRAINDICATIONS

Liberty® Hydro-Caine® Lubricating Gel with 2% Lidocaine HCl should not be used in patients with hypersensitivity to any of the components or patients with marked bradycardial rhythm disorders.

Do not press into the urethra after a failed catheterisation (possibly apply the gel to the instrument or aspirate urine suprapubically).
Liberty® Hydro-Caine® Lubricating Gel with Lidocaine should be used with caution in patients with severe cardiac insufficiency, seriously impaired hepatic and renal function, traumatised mucosa and/or inflammation/sepsis in the region of the proposed application and in patients with tendency to convulsions (epilepsy, severe shocks).

ADVANTAGES OF USE

- The anaesthetic allows the procedure to be as pain free as possible
- Reduced risk of urethral trauma, necrosis or catheter-induced urethritis
- Reduced risk of urinary tract infection as urethral defense mechanisms are not compromised

WARNINGS

Instillation should only be performed by a physician or by a qualified healthcare professional.

Do not use in infants younger than 2 years.

Do not use after expiry date.

Liberty® Hydro-Caine® Lubricating Gel with 2% Lidocaine HCl should not be used if patient has a known reaction to a local anaesthetic, allergic or hypersensitive to parabens or any of the other ingredients, and if the gel will be in contact with damaged membranes.

SPECIAL CARE

Lidocaine should be used cautiously in patients taking antiarrhythmic medication. Products with local anaesthetic properties should also be used with caution on patients with impaired cardiac conditions, hepatic insufficiency and epilepsy.

PREGNANCY AND BREASTFEEDING

Liberty® Hydro-Caine® Lubricating Gel with 2% Lidocaine HCl can be used during pregnancy and lactation, the risk and benefit assessment should be decided by the physician. Lidocaine passes the placenta and enters breast milk in small quantities; however there is generally no risk to the foetus and infants at the therapeutic dose level used in **Liberty® Hydro-Caine®** Lubricating Gel with 2% Lidocaine HCl. Breast-feeding can be continued.

USE

The gel is available in 11ml and 6ml.

Usually the complete contents of the size suitable for the procedure will be used. The syringe is removed from its sterile package by tearing off the backing paper. Before removing the cap from the end of the syringe (11ml and 6ml), free the plunger by gently pressing it. Remove the cap. Insert the nozzle into the opening of the area to be anaesthetised and

press the plunger or plastic syringe container's base slowly to push out the gel. The anaesthetic takes about 5 minutes to work after the gel has been used.

AFTER USE

In case any drowsiness has been felt after the administration of **Liberty® Hydro-Caine® Lubricating Gel** with 2% Lidocaine HCl, driving or machine utilisation is restricted, until symptoms improve.

SIDE EFFECTS

No serious side effects are likely to occur when **Liberty® Hydro-Caine® Lubricating Gel** with 2% Lidocaine HCl is used as intended.

Allergic reactions to lidocaine and chlorhexidine are extremely rare.

In the case of hypersensitivity skin reactions are possible.

Systemic adverse reactions to lidocaine are rare and may result from hypersensitivity or diminished tolerance.

From the technique and duration of the application and from the lidocaine concentration systemic adverse reactions generally are not expected.

Application of more than one tube where jelly enters into the bladder or severe inflammation of the urethra resulting in an increase of lidocaine absorption may lead to an overdose with systemic central nervous and cardiovascular reactions.

Central nervous system reactions are excitatory and/or depressant and may be manifested by prodromal symptoms such as nervousness, dizziness, vertigo, somnolence and tremor.

Cardiovascular reactions, characterised by bradycardia, myocardial depression and increase of ventricular activation time usually only occur at very high blood concentrations of lidocaine.

OVERDOSE

Symptoms of an intoxication with lidocaine (blood concentration: >5µg/ml) are characterised by beginning prodromal symptoms such as nervousness, dizziness, vertigo, somnolence and in more serious cases loss of consciousness, respiratory depression and cardiac arrest. More symptoms are: visual disorders, tinnitus, vomiting. Therapy of an intoxication: In common with other anaesthetic/antiseptic gels, treatment of a patient with systemic toxicity consists of ensuring adequate ventilation with oxygen, if necessary by assisted or controlled ventilation. If convulsions do occur, they could be treated rapidly by intravenous injections of Diazepam 5 to 15mg. Necessity of circulation assisting manipulations depends on the clinical symptoms. If bradycardia or cardiac arrest occur, Atropine or sympathomimetica (adrenalin) should be given intravenously as soon as possible and cardiovascular resuscitation performed.

SHELF LIFE

Three years after date of manufacture.

Each container is for single use only. Any unused gel remaining in the container should be disposed.

STORAGE

Do not use after expiration date

Do not use if package is damaged

Do not resterilise

Store at 5°-30°C until expiry date within the original carton. Keep away from moisture, keep away from sunlight and heat. Keep away from children.

For single use only, remove the residual gel from application area. If the content is not used completely, the container and unused gel must be discarded.

DISPOSAL METHOD

Disposal of **Liberty® Hydro-Caine® Lubricating Gel** with 2% Lidocaine HCl should be carried out in accordance with local regulations.

STERILE R	Sterilized using irradiation		Caution
2	Do not re-use		Do not use if package is damaged
2 max	Do not resterilize		Contains a medicinal substance
LOT	Batch code	MD	Medical device
	Date of manufacture		Distributor
	Use by date		Country of manufacture
	Consult instructions for use	UDI	Unique device identifier
	This device is free from natural latex		Single sterile barrier system
	Keep dry		Single sterile barrier system with protective packaging outside
	Keep away from sunlight	CE	European conformity mark
30°C 5°C	Temperature limit 5°- 30°C		

Liberty® Hydro-Caine® Lubricating Gel
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CE 2292

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