

GB Gel Combi

Lido C Sterile Catheter Gel, 12ml

Instructions for Use

Please read the instructions before use

Product Description

GB Gel Combi is a sterile, water soluble, non-irritating lubricant gel with supportive antiseptic and anaesthetic properties used to facilitate the insertion of catheters and other medical instruments (catheterisation, cystoscopy) into the urethra and bladder.

GB Gel Combi helps prevent trauma by lubricating the interface between the urethral mucosa and catheter during catheterisation. The antiseptic property of chlorhexidine reduces the risk of infection and the local anesthetic property of lidocaine reduces perioperative pain associated with the procedure. It minimises patient discomfort during the catheterisation procedure.

Ingredients

100g of GB Gel Combi contains:

Deionized Water, Hydroxyethyl Cellulose (lubricative), Mono Propylene Glycol (moisturiser), 2g Lidocaine (local anaesthetic), 0.05g Chlorhexidine Gluconate (antiseptic), Methyl Hydroxybenzoate (preservative), Propyl Hydroxybenzoate (preservative).

Instructions for Use - Application

- Wash your hands and prepare an area that is as aseptic as possible to perform the operation. Prepare a clean serving tray and place required materials
- Remove the syringe from its sterile package.
- Lightly press on the plunger before removing the cap to provide more even and gentle application. Remove cap
- Carefully insert the cone of the syringe into the urethral opening and slowly inject the gel by applying gentle and even pressure
- Apply the remaining gel to the surface of the catheter
- GB Gel Combi shows lubricative effect straight after application. The anaesthetic effect starts 3-5 minutes later
- If more gel has to be used, condition of the applied tissue, age of the patient and any adverse condition of the patient which may be related to sensitivity of chlorhexidine must be taken into consideration by the physician
- When the whole product is not used, the syringe and the remaining gel should be evaluated and discarded like other medical wastes
- GB Gel Combi should only be used under the supervision of specialist health personnel

Contra-indications

GB Gel Combi should not be used in patients with hypersensitivity to any of the components or patients with marked bradycardial rhythm disorders.

GB Gel Combi should not be used in patients with severe cardiac insufficiency, severe hepatic and renal dysfunction, traumatic mucosa, inflammation, sepsis at the application site, and in patients with a tendency to convulsion (epilepsy, severe shocks). Do not use in children under 2 years.

Warnings and Precautions for Use

- Under anaesthesia, lubricant without lidocaine should be used
- Instillation should only be performed by a physician or by qualified medical personnel
- Patients with glucose-6-phosphate dehydrogenase deficiency or congenital or idiopathic methaemoglobinaemia are more susceptible to drug induced methaemiglobinaemia.
- When applying GB Gel Combi, a temporary burning sensation may occur, patients should be warned in this regard. In this case, a cold compress to the applied region can alleviate the burning sensation

- Allergic reactions to lidocaine and/or chlorhexidine may rarely occur. Please consult your doctor if redness, burning and stinging occurs in the applied site
- Irritates eyes and/or skin in cases of direct contact. Wash with plenty of water in the case of exposure
- If swallowed, seek medical advice
- Keep away from children
- Store in dry and cool places
- Keep away from direct sunlight
- For single use only
- Do not re-sterilise
- Do not use products with damaged packaging because of the risk of sterilisation deterioration

Pregnancy and Lactation

GB Gel Combi can be used during pregnancy and lactation. The risk/benefit assessment should be performed by the physician. Lidocaine passes to placenta and enters breast milk in small quantities, however, therapeutic dose used in GB Gel Combi does not generally pose a risk to the fetus and infants.

Drug Interaction

Interaction due to absorption of **lidocaine** may occur when used in combination with the following drugs;

- Propranolol: Reduction in plasma clearance of lidocaine
- Cimetidine: Reduction in plasma clearance of lidocaine
- Antiarrhythmic products: Increase in toxicity of lidocaine
- Phenytoin or barbiturates: Reduction in plasma levels of lidocaine

The specified interactions can be seen in long-term use and repeated high doses. No clinically significant interactions have been reported when administered at the recommended doses.

Due to the risk of interaction depending on **chlorhexidine**, use with the following is not recommended;

- Chlorhexidine Gluconate (CHX) + Sodium Hypochlorite (NaOCl)
- Chlorhexidine Gluconate (CHX) + Hydrogen Peroxide (H₂O₂)
- Chlorhexidine Gluconate (CHX) + Povidone-Iodine (BTD)

According to scientific literatures, CHX + NaOCl interaction is known to produce toxic by-products for humans.

Side Effects

Allergic reactions to lidocaine and chlorhexidine are extremely rare. In the case of hypersensitivity, skin reactions are possible. Skin reactions depending on anaphylaxis (hypersensitivity) may occur due to the use of lidocaine in the damaged mucosa. Systemic adverse reactions to lidocaine are rare and may result from hypersensitivity or diminished tolerance.

Sterilisation

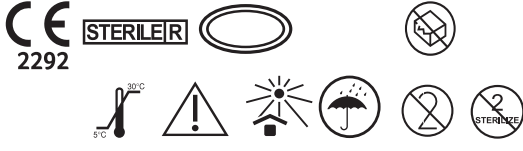
GB Gel Combi is sterilised with radiation after packaging. In the case that the packaging is damaged, do not use as sterility may be compromised.

Cautions

- Use of any medical device carries associated risks. Device failures are rare, however in the event of a device failure of this product, you should contact Great Bear Healthcare using the details provided within this leaflet
- If a failure has resulted in a serious incident, such as significant deterioration of health or death, you should contact Great Bear Healthcare and your local Competent Authority can be found on your local government website

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