

## PATIENT INFORMATION LEAFLET

### SCHEDULING STATUS:

S4

### ENDOSTIL 6 ml (Gel – pre-filled syringe)

### ENDOSTIL 11 ml (Gel – pre-filled syringe)

Lidocaine hydrochloride & Chlorhexidine digluconate

Sugar free

### Read all of this leaflet carefully before you receive ENDOSTIL

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- ENDOSTIL has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

### What is in this leaflet

1. What ENDOSTIL is and what it is used for
2. What you need to know before you receive ENDOSTIL
3. How to receive ENDOSTIL
4. Possible side effects
5. How to store ENDOSTIL
6. Contents of the pack and other information

## **1. What ENDOSTIL is and what it is used for**

ENDOSTIL is used when putting a tube or instrument into the urethra (tube that drains the bladder). It contains a local anaesthetic to prevent pain and antiseptics to reduce the risk of infection.

## **2. What you need to know before you receive ENDOSTIL**

### **ENDOSTIL should not be administered to you**

- If you are hypersensitive (allergic) to lidocaine (lignocaine) and chlorhexidine digluconate or any of the other ingredients of ENDOSTIL (listed in section 6).
- If you have very slow heartbeat or other problems with your heart rhythm.
- If you have lost a lot of fluid (for example, after vomiting or diarrhoea).
- If ENDOSTIL is going to be in contact with damaged membranes.
- If you have inflammation of the urethra (tube that drains the bladder).
- If you are under 18 years of age.

### **Warnings and precautions**

Tell your doctor or health care provider before being administered ENDOSTIL:

- If you have heart and lung problems.
- If you have open or bleeding wounds.
- If you have epilepsy.
- If you are being treated for irregular heartbeats.
- If you have liver problems.

### **Children and adolescents**

ENDOSTIL should not be given to children under the age of 18 years.

### **Other medicines and ENDOSTIL**

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines).

You should tell your doctor if you are taking or have recently taken medicines used for treatment of heart rhythm problems.

### **Pregnancy and breastfeeding**

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before ENDOSTIL is administered to you.

ENDOSTIL should not be used if you are pregnant.

ENDOSTIL may be excreted into the breastmilk, therefore breastfeeding should be suspended for 12 hours.

### **Driving and using machines**

It is not always possible to predict to what extent ENDOSTIL may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which ENDOSTIL affects them.

ENDOSTIL contains Methylhydroxybenzoate and Propylhydroxybenzoate. This may cause allergic reactions (possibly delayed).

### **3. How to receive ENDOSTIL ~~[WILL BE ADMINISTERED TO YOU]~~**

Do not share medicines prescribed for you with any other person.

You will not be expected to give yourself ENDOSTIL. It will be given to you by a person who is qualified to do so.

Your doctor will insert the required amount of gel for the procedure. The anaesthetic takes

about 10 minutes to work after the gel has been used.

### **If you receive more ENDOSTIL than you should**

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact your nearest hospital or poison centre.

Since a healthcare provider will administer ENDOSTIL, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

### **If you forget to receive ENDOSTIL**

Since a healthcare provider will administer ENDOSTIL, it is unlikely that the dose will be missed.

## **4. Possible side effects**

ENDOSTIL can have side effects.

Not all side effects reported for ENDOSTIL are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ENDOSTIL, please consult your health care provider for advice.

The following side effects occur less frequently. If you have any of these, tell your doctor immediately or go to the nearest casualty department:

- A serious allergic reaction (angioedema) which may include breathing problems or swelling of the lips, face, throat and tongue.
- A serious allergic skin reaction (contact dermatitis). You may experience skin rashes, blisters, redness and severe itching.
- Infection of the bladder (painful, frequent and burning urination, cloudy or bloody urine, which may have an odour).
- Skin sensitivity that includes burning, stinging, swelling or tenderness.

The following side effects may occur if you have a damaged mucous membrane and ENDOSTIL is absorbed:

Tell your doctor immediately if you have any of these symptoms:

- Light-headedness, nausea, blurred vision, numbness of the tongue, restlessness, twitching, tremors, nervousness or drowsiness.
- Feeling faint and having a slow or irregular heartbeat.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

**Reporting of side effects**

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (whoumc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of ENDOSTIL.

**5. How to store ENDOSTIL**

Store all medicine out of reach of children.

Store at or below 25 °C.

Keep in outer carton until used.

Do not refrigerate.

**6. Contents of the pack and other information**

**What ENDOSTIL contains**

The active substances are:

|                           | <b>6 ml syringe</b>                | <b>11 ml syringe</b> |
|---------------------------|------------------------------------|----------------------|
| Lidocaine hydrochloride   | 117,6 mg<br>(2,00 g per 100 g gel) | 215,7 mg             |
| Chlorhexidine digluconate | 15,7 mg<br>(0,05 g per 100 g gel)  | 28,8 mg              |

The other ingredients are hydroxymethylcellulose, propylene glycol and purified water.

*Preservatives:*

Methylhydroxybenzoate      0,060 % m/m

Propylhydroxybenzoate      0,025 % m/m

**What ENDOSTIL looks like and contents of the pack**

ENDOSTIL is a clear, practically colourless, viscous liquid.

A pre-filled syringe made of polypropylene with polypropylene plunger and a chlorobutyl rubber stopper piston, containing 6 ml or 11 ml of gel. The syringes are packed in boxes of 10.

**Holder of Certificate of Registration**

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**ENDOSTIL 6 ml:** 42/13.3/0959

**ENDOSTIL 11 ml:** 42/13.3/0960