PART III: CONSUMER INFORMATION

Instillagel®

Lidocaine and Chlorhexidine Gel BP

This leaflet is part III of a three-part "Prescribing Information" published when Instillagel® was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about Instillagel®. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

Instillagel® is used for adults and children over 2 years old when putting a tube or instrument into your urethra (the canal leading to your bladder). Instillagel® is used:

- During insertion of a medical instrument into your urethra (cystoscopy)
- During insertion of a catheter
- During exploration by sound and other operations in the urethra

What it does:

Instillagel® contains a local anaesthetic (lidocaine) to prevent pain and an antiseptic (chlorhexidine) to reduce the risk of infection getting in, while lubricating to make the process smooth.

When it should not be used:

The gel should not be used if you know that you are allergic or hypersensitive to these or any of the other ingredients, or to any other "-caine" type anaesthetics. Please inform the healthcare professional who is going to use the gel if this applies to you.

What the medicinal ingredients are:

Lidocaine hydrochloride (2% w/w) and chlorhexidine gluconate (0.05% w/w).

What the non-medicinal ingredients are:

Methylparaben, Propylparaben, Hydroxyethylcellulose, Sodium Hydroxide, Propylene Glycol and Purified Water.

What dosage forms it comes in:

The gel is available as a sterile syringe, in two package sizes - 6 mL and 11 mL.

WARNINGS AND PRECAUTIONS

Instillagel® is for topical use only and is not to be injected.

Before using Instillagel®, tell your doctor if:

- you have heart problems
- you have liver problems
- you have kidney problems
- you are epileptic
- you have ever had an unusual or allergic reaction to Instillagel®, to another lidocaine or other medicine ending in "caine", or to chlorhexidine or chlorhexidine-containing medicines or chlorhexidine-coated catheters
- there is an infection, cut or rash at or near the area where you wish to apply Instillagel®
- you are in severe shock
- you have malignant hyperthermia (a hereditary condition)
- you are pregnant or breastfeeding.

The gel should not be used if it is going to be in contact with damaged membranes.

INTERACTIONS WITH THIS MEDICATION

Drugs that may interact with Instillagel® include:

Some other local anaesthetics, medicines used for treating irregular heartbeats, a medicine used for heart problems, an antibiotic and a medicine used for depression or obsessive compulsive disorder**.** These medicines are:

- Amiodarone
- Erythromycin
- Fluvoxamine
- Mexiletine
- Propranolol

PROPER USE OF THIS MEDICATION

The gel is available in two package sizes - 6 mL and 11 mL. Usually the complete contents of the size suitable for the procedure will be used.

Adults: Do not use more Instillagel® than the doctor has recommended. A usual adult dose is one syringe of 11 mL, with possibly an additional syringe of 6 or 11 mL (for men) or one syringe of 6 mL (for women). During procedures, the doctor may use as many as 4 syringes (a total of 39 mL) in one dose. Do not use more than 4 doses in a period of 24 hours.

Children: Your doctor will instruct you on how much to give your child as the amount will vary depending on age and weight.

The product should start to work within 5-10 minutes of using it.

For self-catheterization: Follow these directions carefully. Clean the urethral area before using Instillagel®. The syringe is removed from its sterile package by tearing off the backing paper. Before removing the blue cap from the end of the syringe, free the plunger by gently pressing it. Remove the cap. Insert the nozzle into the opening of the urethra and press the plunger slowly to push out the gel.

The syringe is for single use only. If the complete contents are not used, the syringe and remaining gel must be thrown away.

This medicine has been prescribed for your current medical problem only. Do not give it to other people.

Overdose:

Avoid contact with your eyes or ears. Numbness in the eyes may prevent you from noticing if you get something in the eye.

For symptoms of serious side effects please consult the table entitled "SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM".

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, Instillagel® may have, in addition to its beneficial effects, some unwanted effects. You might feel a slight stinging just after the gel is used, but this stops as soon as the anaesthetic starts to work. Most people find that there are no problems after the gel has been used, but of course there may be some soreness when the effect of the local anaesthetic has worn off.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and seek immediate medical attention
		Only if severe	In all cases	
Rare	**Allergic reaction such as:** Shortness of breath, feeling faint, chest pain, faster than usual heart beat, not present before using this medicine.			**X**
Very rare	**Overdose:** Drowsiness, numbness of your tongue, light-headedness, ringing in your ears, blurred vision, vomiting, dizziness, unusually slow heartbeat, fainting, nervousness, unusual sweating, trembling, or seizures.			**X**

Other side effects not listed above may also occur in some patients. If you notice any other effects, tell your doctor immediately.

If you feel that you have had any reaction to the gel, please tell your doctor as soon as possible

HOW TO STORE IT

The gel should not be used after the expiry date shown on the package. If you are asked to keep a package of gel for use at another time, store it below 25°C.

Keep this medicine out of the reach of children.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
  - Fax toll-free to 1-866-678-6789, or
  - Mail to:
    Canada Vigilance Program
    Health Canada
    Postal Locator 0701E
    Ottawa, Ontario
    K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect

NOTE: Should you require information related to the management of side effects, contact your healthcare professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full prescribing information, prepared for health professionals can be obtained by contacting the sponsor, PENDOPHARM, Division of Pharmascience Inc. at: http://www.pendopharm.com or http://www.instillagel.ca

By telephone: 1-888-550-6060
By post: PENDOPHARM, Division of Pharmascience Inc.
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