

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Instillagel®

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

6 ml gel contains:

Lidocaine Hydrochloride	125.40 mg
Chlorhexidine Gluconate	3.14 mg
Methyl Hydroxybenzoate	3.76 mg
Propyl Hydroxybenzoate	1.57 mg

11 ml gel contains:

Lidocaine Hydrochloride	230.00 mg
Chlorhexidine Gluconate	5.75 mg
Methyl Hydroxybenzoate	6.90 mg
Propyl Hydroxybenzoate	2.87 mg

3. PHARMACEUTICAL FORM

Gel

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Catheterisation, cystoscopy. Exploratory and intra-operative investigations, exchange of fistula catheters, protection against iatrogenic damage in the rectum and colon. For use during gynaecological investigation.

4.2 Posology and method of administration

Unless otherwise prescribed by a doctor:

a) Urethral sounding and catheterisation: instill 6-11 ml.

After the usual cleaning of the glans and urethra and orifice, Instillagel® is instilled into the urethra and the glans is pressed for a short time between the thumb and index finger until the anaesthetic effect begins. When narrow gauge catheters are being introduced, any blockage of the eye of the catheter by gel can either be eliminated, if the bladder is full, by light pressure on the hypogastrium producing discharge of urine, or re-opened by means of the sterile disposable syringe and instillation of sterile saline solution.

b) Cystoscopy: with a view to considerate and painless introduction of instruments, the entire urethra including the external sphincter must be coated with a film of lubricant and anaesthetised. With a short penis and correspondingly narrow urethra, a dose of 11 ml is sufficient; in other cases an additional instillation of 6-11 ml of Instillagel® is recommended. A penis clamp is applied in the area of the coronary sulcus. The anaesthetic effect begins after 3.5 minutes. In prograde ureterocystoscopy the external sphincter, which is simultaneously anaesthetised, can distinctly be seen opening up when irrigated.

4.3 Contraindications

Instillagel® must not be used in patients with known hypersensitivity to the active ingredients (amide-type anaesthetics, chlorhexidine and alkyl hydroxybenzoates) or any of the excipients. Instillagel® should not be used in patients who have damaged or bleeding mucous membranes because of the risk of systemic absorption of the lidocaine hydrochloride.

4.4 Special warnings and special precautions for use

Products containing local anaesthetics should also be used with caution in patients with impaired cardiac conditions, hepatic insufficiency and in epileptics.

Oropharyngeal use of Instillagel may cause difficulty in swallowing and therefore an increased risk of aspiration due to its local anaesthetic effect. Numbness of the tongue and buccal mucosa may also increase the chance of biting trauma.

In case of systemic effects from absorption of lidocaine hydrochloride, please see Section 4.9 'Overdose'.

Instillagel contains methyl hydroxybenzoate and propyl hydroxybenzoate, which may cause allergic reactions (possible delayed).

This medicine also contains 3.14 g propylene glycol in each syringe of 6 ml and 5.75 g propylene glycol in each syringe of 11 ml. This is equivalent to 522.5 mg/ml. Propylene glycol may cause skin irritation.

Instillagel must not come into contact with the eye. Serious cases of persistent corneal injury, potentially requiring corneal transplant, were reported following accidental ocular exposure to chlorhexidine containing medicinal products despite taking eye protective measures due to migration of solution beyond the intended surgical preparation area. Extreme care must be taken during application to ensure that Instillagel does not migrate beyond its intended application site into the eyes. Particular care should be taken in anaesthetised patients, who are unable to immediately report ocular exposure. If Instillagel comes into contact with the eyes, wash out promptly and thoroughly with water. An ophthalmologist's advice should be sought.

4.5 Interactions with other medicinal products and other forms of interaction

Lidocaine should be used with caution in patients receiving antiarrhythmic drugs.

4.6 Pregnancy and lactation

During the first 3 months of pregnancy, lidocaine should be used only if absolutely necessary.

The amount of lidocaine excreted in breast milk is too small to be harmful.

4.7 Effects on ability to drive and use machines

The ability to drive and operate machinery may be slightly impaired after the use of Instillagel®. If affected, patients should be advised not to drive or use machinery.

4.8 Undesirable effects

In spite of the proven wide safety range of Instillagel, undesirable effects of the local anaesthetic, lidocaine, are possible where there is severe injury to the mucosa and absorption may occur. Examples are anaphylaxis, fall in blood pressure, bradycardia or convulsions.

Eye Disorder:

Frequency not known: Corneal erosion, epithelium defect/corneal injury, significant permanent visual impairment (see section 4.4).

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

4.9 Overdose

Symptoms

In the event of excessive absorption of lidocaine into the bloodstream, symptoms may include CNS effects (such as convulsions, unconsciousness and possibly respiratory arrest) and cardiovascular reactions (such as hypotension, myocardial depression, bradycardia and possibly cardiac arrest).

Treatment

Treatment of a patient suffering from systemic toxicity of lidocaine consists of arresting the convulsions and ensuring adequate ventilation with oxygen, if necessary by assisted or controlled ventilation (respiration).

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

The anaesthetic ingredient of Instillagel® is lidocaine, which stabilises neuronal membranes and prevents initiation and conduction of nerve impulses, thus effecting local anaesthetic action.

Chlorhexidine and methyl and propyl hydroxybenzoates have antiseptic properties.

5.2 Pharmacokinetic properties

After the product's application to mucous membranes, lidocaine is absorbed, but its blood concentrations after the instillation of doses of up to 800mg into the urethra remain in the low range, below toxic levels. The metabolism of lidocaine takes place in the liver and unchanged drug is excreted renally.

Very small amounts of chlorhexidine may be absorbed. Chlorhexidine is eliminated almost unchanged although it is hardly absorbed even after high oral doses. Although para-hydroxybenzoates can be absorbed from mucous membranes, they are rapidly

eliminated and do not accumulate. The para-hydroxybenzoates are excreted in the form of para-hydroxybenzoic acid.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Propylene Glycol
Hydroxyethylcellulose
Sodium Hydroxide
Purified Water

6.2 Incompatibilities

None

6.3 Shelf life

60 months

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of the container

Disposable 6 ml or 11 ml syringes made of polypropylene with butyl rubber stopper, in pack sizes of 1, 10 and 100 syringes.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

The product is for single use only. The syringe and any unused gel must be discarded.

7. MARKETING AUTHORISATION HOLDER

Farco-Pharma GmbH
Gereonsmühlengasse 1-11
D-50670 Cologne
Germany

8. MARKETING AUTHORISATION NUMBER

PL 03377/0002

**9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE
AUTHORISATION**

30th June 1994 / 15th July 1999

10 DATE OF REVISION OF THE TEXT

18/12/2024