1 NAME OF THE MEDICINAL PRODUCT

Lidocaine Hydrochloride BP Laryngojet 4% w/v.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Lidocaine Hydrochloride BP 160mg in 4ml.

3 PHARMACEUTICAL FORM

Sterile aqueous solution for topical application to the oral mucosa.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For topical anaesthesia of the mucous membranes of the oropharynx, trachea, and respiratory tract, e.g. in bronchoscopy, bronchography, laryngoscopy, endotracheal intubation and biopsy in these areas.

4.2 Posology and Method of Administration

The lowest effective dose should be administered. The usual adult dose is 160mg (one pre-filled syringe). If less is required, the excess should be expelled before use to avoid inadvertent overdosage.

Adults: 1-5ml (40-200mg lidocaine).

Elderly: may need reduced dosage depending on physical state.

Children: up to 3mg/kg.

The solution may be sprayed, instilled (if a cavity) or applied with a swab. Anaesthesia usually occurs within 5 minutes.
4.3 **Contraindications**

Lidocaine is contraindicated in patients with known hypersensitivity to local anaesthetics of the amide type or to any of the excipients listed in section 6.1; and in patients with porphyria.

4.4 **Special warnings and precautions for use**

Topical application of lidocaine should be used with caution if the mucosa in the area of application has been traumatised or sepsis is present, as absorption will be high.

Use with caution in patients with epilepsy, liver disease, congestive heart failure, marked hypoxia, severe respiratory depression, hypovolaemia or shock and in patients with any form of heart block, atrioventricular conduction disturbance (in line with Sections 4.5 and 4.8) or sinus bradycardia, or myasthenia gravis. Hypokalaemia, hyperkalaemia, hypoxia and disorders of acid-base balance should be corrected before treatment with lidocaine begins.

It should be kept in mind that absorption of aqueous drugs from the respiratory tract may often be nearly as rapid and complete as that occurring with intravenous injection. If there are likely to be high blood levels, resuscitation equipment should be available.

Anaesthesia around the oral cavity may impair swallowing and thus increase the risk of aspiration.

4.5 **Interaction with other medicinal products and other forms of interaction**

- Propranolol and cimetidine may reduce the renal and hepatic clearance of lidocaine, thus increasing toxicity.
- The cardiac depressant effects of lidocaine are additive to those of other antiarrhythmic agents particularly class I (e.g. kinidine, disopyramide) or class III (e.g.amiodarone or sotalol). Caution should be exercised particularly in patients with cardiac decompensation.
- Inhibition of CYP1A2 by fluvoxamine considerably reduces elimination of lidocaine and increases the risk of lidocaine toxicity. Concomitant use of both fluvoxamine and a CYP3A4 inhibitor such as erythromycin can further increase lidocaine concentrations. Because lidocaine possesses a narrow therapeutic window, doses of lidocaine may need to be adjusted accordingly. Conversely, reduced serum lidocaine concentrations may result from drugs that may stimulate the hepatic metabolism of lidocaine (e.g. phenytoin, oral HRT).
- Hypokalaemia produced by acetazolamide, loop diuretics and thiazides antagonizes the effect of lidocaine.
- Propranolol, metoprolol and nadolol may increase lidocaine levels by 20% to 30%.
- Lidocaine is markedly bound to α1-acid glycoprotein (AAG). AAG concentrations may be reduced by oestrogens leading to a higher free fraction of lidocaine in women than in men and the free fraction is further increased during pregnancy and in women taking oral contraceptives or HRT.
- Lidocaine prolongs the action of neuromuscular blocking agents such as suxamethonium and cisatracurium.

4.6 Pregnancy and lactation

The safe use of lidocaine has not been established with respect to possible adverse effects upon foetal development. Lidocaine crosses the placenta and blood brain barrier. Lidocaine is excreted into breast milk and so should therefore be used with caution in nursing women.

4.7 Effects on Ability to Drive and Use Machines

Not applicable.

4.8 Undesirable effects

Adverse effects are usually due to inadvertent intravenous administration or overdosage. Allergic reactions (including anaphylaxis) have been reported rarely.

The following systemic reactions have been reported in association with lidocaine:

*Central nervous system*: light-headedness, drowsiness, dizziness, apprehension, nervousness, euphoria, tinnitus, blurred or double vision, nystagmus, headache, nausea, vomiting, sensations of heat, cold or numbness, twitching, tremors, paraesthesia, convulsions, unconsciousness, respiratory depression and arrest, transient neurological symptoms i.e. pain and/or dysaesthesia in the buttocks or legs.

*Cardiovascular system*: hypotension, arrhythmia, cardiovascular collapse and bradycardia which may lead to cardiac arrest. AV block and myocardial depression.

*Psychiatric disorders*: confusion and psychosis.

*Blood and the lymphatic system disorders*: methaemoglobinaemia.

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: reactions due to overdose with lidocaine (high plasma levels) are systemic and involve the central nervous and cardiovascular systems. Effects include medullary depression, tonic and clonic convulsions and cardiovascular collapse.

Treatment: institute emergency resuscitative procedures and administer the drugs necessary to manage the severe reaction. For severe convulsions small increments of diazepam or an ultra-short acting barbiturate (thiopentone), or if not available, a short-acting barbiturate (pentobarbitone or quinalbarbitone), or if the patient is under anaesthesia, a short-acting muscle relaxant (suxamethonium) may be given intravenously. Patency of the airway and adequacy of ventilation must be assured.

Should circulatory depression occur vasopressors such as metaraminol may be used.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic Properties

Lidocaine stabilises the neuronal membrane and prevents the initiation and transmission of nerve impulses, thereby effecting local anaesthetic action. The onset of action is rapid and the blockade may last from one to one and a half hours.

5.2. Pharmacokinetic Properties

Lidocaine is rapidly distributed to all body tissues. About 65% is plasma bound. Lidocaine crosses the placenta and the blood brain barrier. The plasma half life is 1.6 hours. About 80% of the dose is metabolised in the liver; less than 10% is found unchanged in the urine.

5.3. Pre-clinical Safety Data

Not applicable since lidocaine has been used in clinical practice for many years and its effects in man are well known.
6. PHARMACEUTICAL PARTICULARS

6.1. List of Excipients

Sodium Hydroxide NF
Water for Injection USP

6.2. Incompatibilities

None known.

6.3. Shelf Life

36 months.

6.4. Special Precautions for Storage

Store below 25°C

6.5. Nature and Contents of Container

The solution is contained in a USP type I glass vial with an elastomeric closure which meets all the relevant USP specifications. The product is available as 4ml.

6.6. Instructions for Use/Handling

The container is specially designed for use with the IMS Laryngojet injector device.

7 MARKETING AUTHORISATION HOLDER
8. MARKETING AUTHORISATION NUMBER(S)

PL 03265/0040.

9. DATE OF FIRST AUTHORISATION/RENEWAL OF AUTHORIZATION

Date first granted: 15 November 1977
Date renewed: 21 November 1997

10 DATE OF REVISION OF THE TEXT

20/09/2016