Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Lidocaine Hydrochloride 1% w/v Solution for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml of solution for injection contains 10 mg lidocaine hydrochloride (as monohydrate) corresponding to 8.11 mg lidocaine.
Each 5 ml of solution for injection contains 50 mg lidocaine hydrochloride.
Each 10 ml of solution for injection contains 100 mg lidocaine hydrochloride.
Each 20 ml of solution for injection contains 200 mg lidocaine hydrochloride.

Excipient(s) with known effect
Each ml of solution for injection contains approximately 0.124 mmol sodium.
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection.
A clear, colourless aqueous solution, practically free of visible particles.
pH of solution 5.0 - 7.0.
Osmolality of solution 280 – 340 mOsm.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Local anaesthesia by surface infiltration, regional (minor and major nerve block), epidural and caudal routes, dental anaesthesia, either alone or in combination with adrenaline.

4.2 Posology and method of administration

Posology

The dosage should be adjusted according to the response of the patient and the site of administration. The lowest concentration and smallest dose producing the required effect should be given. The maximum dose for healthy adults should not exceed 200 mg.

The volume of the solution used plays a role in the size of the area of spread of anaesthesia. In case it is desirable to administer a larger volume with a lower concentration, than the standard solution has to be diluted with a saline solution (NaCl 0.9 %). This dilution should take place just before administration.

Adults and adolescents (12 - 18 years of age)
Single doses of Lidocaine (for anaesthesia other than spinal) should not exceed 4.5 mg/kg (with a maximum of 200 mg) in adults or in adolescents.

For spinal anaesthesia, up to 100 mg of the drug may be given. For continuous epidural or caudal anaesthesia, the maximum dose should not be repeated at intervals of less than 1.5 hours. For paracervical block for obstetric analgesia (including abortion) the maximum recommended dosage (200 mg) should not be repeated at intervals of less than 1.5 hours. For IV regional anaesthesia in adults using a 5 mg/ml solution, the dose administered should not exceed 4 mg/kg.

Solutions of 10 mg/ml lidocaine hydrochloride (without preservative) are used for epidural or caudal anaesthesia. To prevent intravascular or subarachnoid injection of a large epidural dose of lidocaine, a test dose of 2-5 ml should be injected at least 5 minutes prior to administering the total dose.

In epidural anaesthesia 2-3 ml of 10 mg/ml solution is usually required for each dermatome to be anaesthetised.

In caudal block for production of obstetric analgesia or in epidural thoracic block, 20-30 ml of a 10 mg/ml solution (200-300 mg) of the drug may be used. For epidural lumbar anaesthesia, the dose is 25-30 ml (250-300 mg) of a 10 mg/ml solution.

For intercostal nerve block: 3 ml of a 10 mg/ml solution (30 mg).

For paravertebral nerve block: 3-5 ml of a 10 mg/ml solution (30-50 mg).

For pudendal nerve block (each side): 10 ml of a 10 mg/ml solution (100 mg).

For paracervical nerve block (each side) for obstetric analgesia: 10 ml of a 10 mg/ml solution (100 mg).

For sympathetic nerve blocks: Cervical (stellate ganglion) nerve block: 5 ml of a 10 mg/ml solution (50 mg).

Lumbar nerve block: 5-10 ml of a 10 mg/ml solution (50-100 mg).

For percutaneous infiltration anaesthesia: 1-60 ml of a 5 mg/ml solution or 0.5 to 30 ml of a 10 mg/ml solution (5-300 mg).

For IV regional anaesthesia: 10-60 ml of 5 mg/ml solution (50-300 mg).

Paediatric population
The dose should generally be reduced in children. To minimise the possibility of toxic reactions, children should be given lidocaine hydrochloride solutions in concentrations of 5 mg/ml or 10 mg/ml. Lidocaine by local infiltration for children under the age of 12 years should not exceed 3 mg/kg, repeated not more often than every 4 hours.

Special patient populations
The dose should be reduced in elderly or debilitated patients.

Method of administration

Lidocaine Hydrochloride may be administered by intravenous, intramuscular, subcutaneous or epidural injection. Not intended for use in the eye.

The method of administration of lidocaine varies according to the procedure (intravenous regional anaesthesia, infiltration anaesthesia, nerve blocks or epidural anaesthesia).

For dilution of Lidocaine Hydrochloride solution for injection see section 6.6.

4.3 Contraindications

Hypersensitivity to the active substance, to anaesthetics of the amide type or to any of the excipients listed in section 6.1.

Lidocaine Hydrochloride is contraindicated in patients with:
- complete heart block
- hypovolaemia

4.4 Special warnings and precautions for use

Lidocaine should be administered by persons with resuscitative skills and equipment and facilities for resuscitation should be available when administering local anaesthetics.

As with all local anaesthetic agents, lidocaine can cause acute central nervous and cardiovascular toxic effects when its use causes high concentrations in the blood, particularly after extensive intravascular administration.

Lidocaine should be used cautiously:
- in patients with cardiac disorders of impulse generation and conduction disturbances as local anaesthetic can decrease myocardial conductivity (see also section 4.3).
- in patients treated with anti-arrhythmic drugs class III (e.g. amiodarone). These patients should be under close surveillance and ECG monitoring considered, since cardiac effects may be additive (see section 4.5).

- in patients with congestive heart failure or, bradycardia or following cardiac surgery.
- in patients with severe shock.
- in patients with impaired respiratory function.
- in patients with cerebral seizure disorders.
- in patients with myasthenia gravis.
- In patients with coagulopathy. Treatment with anticoagulants (eg. heparin), NSAIDs or plasma substitutes causes increased bleeding tendency. Accidental injury of blood vessels may lead to serious bleedings. If necessary, bleeding time and activated partial thromboplastin time (aPTT), quicktest and platelet count should be checked.
- in the elderly and generally debilitated persons.
- in patients with impaired hepatic function as it is metabolised in the liver.
- in patients of impaired renal function with a creatinine clearance of less than 10 ml/min.

Hypokalaemia, hypoxia and disorders of acid-base balance should be corrected before treatment with intravenous lidocaine.

Blood pressure should be monitored during spinal anaesthesia. Epidural anaesthesia may lead to hypotension and bradycardia. This risk can be reduced by preloading the circulation with crystalloidal or colloidal solutions. Hypotension should be treated promptly. Caution should always be exercised in patients with impaired cardiovascular function.

Paracervical block can sometimes cause foetal bradycardia or tachycardia and careful monitoring of the foetal heart rate is necessary (see section 4.6).

Injections in the head and neck regions may be made inadvertently into an artery causing cerebral symptoms even at low doses.

Retrobulbar injections may rarely reach the cranial subarachnoid space, causing serious/severe reactions, including cardiovascular collapse, apnoea, convulsions and temporary blindness.

Retro- and peribulbar injections of local anaesthetics carry a low risk of persistent ocular motor dysfunction. The primary causes include trauma and/or local toxic effects on muscles and/or nerves.

The severity of such tissue reactions is related to the degree of trauma, the concentration of the local anaesthetic and the duration of exposure of the tissue to the local anaesthetic. For this reason, the lowest effective concentration and dose of the local anaesthetic should be used.

The effect may be reduced if the injection is made into an inflamed or infected area.

Intramuscular lidocaine may increase creatinine phosphokinase concentrations which can interfere with the diagnosis of acute myocardial infarction. Lidocaine has been shown to be porphyrinogenic in animals and should be avoided in persons suffering from porphyria.

There have been post-marketing reports of chondrolysis in patients receiving post-operative intra-articular continuous infusion of local anaesthetics. The majority of reported cases of chondrolysis have involved the shoulder joint. Due to multiple contributing factors and inconsistency in the scientific literature regarding mechanism of action, causality has not been established. Intra-articular continuous infusion is not an approved indication for lidocaine.

Lidocaine solution for injection is not recommended for use in neonates. The optimum serum concentration of lidocaine required to avoid toxicity, such as convulsions and cardiac arrhythmias, in this age group is not known.

Patients on sodium diet

This medicinal product contains 85 mg (approximately 3.72 mmol) sodium per dose. This is equivalent to 4.25 % of the WHO recommended maximum daily intake of 2 g sodium for an adult. To be taken into consideration by patients on a controlled sodium diet.

4.5 Interaction with other medicinal products and other forms of interaction

Effects of lidocaine on other medicinal products
Lidocaine should be used with caution in patients receiving other local anaesthetics or agents structurally related to amide-type local anaesthetics (e.g. anti-arrhythmics, such as mexiletine and tocaïnide), since the systemic effects are additive.

Specific interaction studies with lidocaine and class III anti-arrhythmic drugs (e.g. amiodarone) have not been performed, but caution is advised.
There may be an increased risk of enhanced and prolonged neuromuscular blockade in patients treated concurrently with muscle relaxants (e.g. suxamethonium).

Effects of other medicinal products on lidocaine
Drugs which inhibit the metabolism of lidocaine (e.g. cimetidine, fluvoxamine, propranolol) may cause potentially toxic plasma concentrations when lidocaine is given repeatedly in high doses over long periods of time. Because lidocaine possesses a narrow therapeutic window, doses of lidocaine may need to be adjusted accordingly.
An increase in serum levels of lidocaine may also occur with anti-viral agents (e.g. amprenavir, atazanavir, darunavir, lopinavir).
Conversely, reduced serum lidocaine concentrations may result from drugs that may stimulate the hepatic metabolism of lidocaine (e.g. phenytoin, oral hormone replacement therapy). Higher lidocaine doses may be required.

Co-administration of antiarrhythmic drugs, beta-blockers and calcium antagonists may cause an additive inhibitory effect on AV conduction, intraventricular conduction and contractility.

There may be an increased risk of ventricular arrhythmia in patients treated concurrently with antipsychotics which prolong or may prolong the QT interval (e.g. pimozide, sertindole, olanzapine, quetiapine, zotepine), prenylamine, adrenaline (if accidently injected intravenously), or 5HT3 antagonists (e.g. tropisetron, dolasetron).

Co-administration of vasoconstrictive drugs leads to a longer duration of action of lidocaine.

While adrenaline (epinephrine) when used in conjunction with lidocaine might decrease vascular absorption, it greatly increases the danger of ventricular tachycardia and fibrillation if accidentally injected intravenously.

Concomitant administration of lidocaine and secale alkaloids (e.g. ergotamine) may cause a severe decrease in blood pressure.

Intravenous administration of phenytoin may increase the cardiodepressive effect of lidocaine.

Cardiovascular collapse has been reported following the use of bupivacaine in patients on treatment with verapamil and timolol; Lidocaine is closely related to bupivacaine.

Concomitant use of quinupristin/dalfopristin should be avoided since the use of this antibiotic with lidocaine may lead to an increased concentration of lidocaine

Hypokalaemia caused by diuretics may antagonise the action of lidocaine if administered concomitantly (see section 4.4).

Caution should be taken in the use of sedatives that also affect the function of the central nervous system and may alter the effect of local anaesthetics.

Dopamine and 5 hydroxytryptamine reduce the convulsant threshold to lidocaine.

Narcotics are probably proconvulsants and this would support the evidence that lidocaine reduces the seizure threshold to fentanyl in man.

Opioid-antiemetic combination sometimes used for sedation in children could reduce the convulsant threshold to lidocaine and increase the CNS depressant effect.

The analgesic effect of local anaesthetics may be potentiated by opioids and clonidine.

Ethyl alcohol, especially chronic abuse, can decrease the effect of local anaesthetics.

Lidocaine is markedly bound to alpha-l-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 hormone replacement therapy.

4.6 Fertility, pregnancy and lactation

Pregnancy

Lidocaine crosses the placenta. There is no evidence that lidocaine causes disturbances in the reproductice process such as increased incidence of malformations or has any direct or indirect effect on the foetus. Animals studies have revealed no evidence of harm to the foetus.

However, it should not administered during pregnancy unless the benefits are considered to outweight the risks.

Lidocaine given by epidural or paracervical block, especially in large doses, or by local perineal infiltration prior to delivery crosses rapidly into the foetal circulation. Elevated lidocaine levels may persist in the newborn for at least 48 hours after delivery. Foetal bradycardia or neonatal bradycardia, hypotonia or respiratory depression may occur.

Breast-feeding
Lidocaine is excreted into breast milk in small amounts. Therefore, caution is advised when Lidocaine Hydrochloride is used in recommended doses to nursing women however there is no need of discontinuation of breastfeeding.

Fertility
There are no human data regarding potential effects of lidocaine on fertility.

4.7 Effects on ability to drive and use machines

Due to the effects of lidocaine on the central nervous system, Lidocaine Hydrochloride has a temporary influence on the ability to drive and use machines.

Thus, when outpatient anaesthesia affects areas of the body involved in driving or operating machinery, patients should be advised to avoid these activities until normal function is fully restored.

4.8 Undesirable effects

Frequencies of undesirable effects are defined using the following convention:

Very common (≥1/10),
Common (≥1/100 to <1/10),
Uncommon (≥1/1,000 to <1/100),
Rare (≥1/10,000 to <1/1,000),
Very rare (<1/10,000),
Not known (cannot be estimated from the available data).

In common with other local anaesthetics, adverse reactions to lidocaine are rare and are usually the result of raised plasma concentrations due to accidental intravascular injection, excessive dosage or rapid absorption from highly vascularised areas, or may result from a hypersensitivity, idiosyncrasy or diminished tolerance on the part of the patient. Systemic toxicity mainly involves the central nervous system and/or the cardiovascular system (see also 4.9).

Following regional blockade as when lidocaine is injected intrathecally or extradurally, hypotension, hypoventilation, Horner's Syndrome and hypoglycaemia may be seen. The degree of these effects will depend on the dose and the height of the block. Urinary retention may occur following sacral or lumbar epidural block. It should not outlast the duration of the block. Apnoea and hemiparesis may occur following stellate ganglion block. The probable cause is a direct injection of lidocaine into the vertebral or carotid arteries.

System Organ Class	**Very common ≥ 1/10**	**Common ≥ 1/100 to < 1/10**	**Uncommon ≥ 1/1,000 to < 1/100**	**Rare ≥ 1/10,000 to < 1/1,000**	**Frequency not known (cannot be estimated from available data)**
Blood and lymphatic system disorders					methaemoglobinaemia
Immune system				hypersensitivity reactions°,	

disorders				urticaria, rash, angioedema, bronchospasm, in severe cases anaphylactic shock	
Nervous system disorders[#]		paraesthesia, dizziness	symptoms of CNS toxicity (convulsions, circumoral paresthesia, numbness of tongue, hyperacusis, visual disturbances, loss of consciousness, tremor, drowsiness, light-headedness, tinnitus, feeling of intoxication, dysarthria)	neuropathy, peripheral nerve injuries, arachnoiditis	nervousness, coma
Eye disorders				blurred vision, diplopia and transient amaurosis, bilateral amaurosis*	
Ear and labyrinth disorders					tinnitus, hyperacusis
Cardiac disorders		bradycardia		cardiac arrest, arrhythmias	
Vascular disorders	hypotension	hypertension			
Respiratory, thoracic and mediastinal disorders				respiratory depression	dyspnoea, respiratory arrest
Gastrointestinal disorders	nausea	vomiting			

° Skin testing for allergy to lidocaine is not considered to be reliable.
* Bilateral amaurosis may also be a consequence of accidental injection of the optic nerve sheath during ocular procedures. Orbital inflammation and diplopia have been reported following retro- or peribulbar anaesthesia.
[#] Neurological complications of spinal anaesthesia include transient neurological symptoms such as pain of the lower back, buttock and legs. These symptoms usually develop within twenty-four hours of anaesthesia and resolve within a few days. Isolated cases of arachnoiditis or cauda equina syndrome, with persistent paraesthesia, bowel and urinary dysfunction, or lower limb paralysis have been reported following spinal anaesthesia with lidocaine and other similar agents. The majority of cases have been associated with hyperbaric concentrations of lidocaine or prolonged spinal infusion.

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517.Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

4.9 Overdose

Symptoms of acute systemic toxicity
Central nervous system toxicity presents with symptoms of increasing severity. Patients may present initially with circumoral paraesthesia, numbness of the tongue, light-headedness, hyperacusis and tinnitus. Visual disturbance and muscular tremors or muscle twitching are more serious and precede the onset of generalised convulsions. These signs must not be mistaken for

neurotic behaviour. Unconsciousness and grand mal convulsions may follow, which may last from a few seconds to several minutes. Hypoxia and hypercapnia occur rapidly following convulsions due to increased muscular activity, together with the interference with normal respiration and loss of the airway. In severe cases, apnoea may occur. Acidosis increases the toxic effects of local anaesthetics.

Effects on the cardiovascular system may be seen in severe cases. Hypotension, bradycardia, arrhythmia and cardiac arrest may occur as a result of high systemic concentrations, with potentially fatal outcome.

Recovery occurs as a consequence of redistribution of the local anaesthetic drug from the central nervous system, and metabolism and may be rapid unless large amounts of the drug have been injected.

Treatment of acute toxicity
If signs of acute systemic toxicity appear, injection of the anaesthetic should be stopped immediately.

Treatment will be required if convulsions and CNS depression and cardiotoxicity occurs. The objectives of treatment are to maintain oxygenation, stop the convulsions and support the circulation. A patent airway should be established and oxygen should be administered, together with assisted ventilation (mask and bag) if necessary. The circulation should be maintained with infusions of plasma or intravenous fluids. Where further supportive treatment of circulatory depression is required, use of a vasopressor agent may be considered although this involves a risk of central nervous system excitation. If the convulsions do not stop spontaneously in 15-20 seconds, they may be controlled by the intravenous administration of diazepam (0.1 mg/kg b.w. i.v.) or thiopentone sodium
(1-3 mg/kg b.w. i.v.), bearing in mind that anti-convulsant drugs may also depress respiration and the circulation.

Prolonged convulsions may jeopardise the patient's ventilation and oxygenation and early endotracheal intubation should be considered. If cardiac arrest should occur, standard cardiopulmonary resuscitation procedures should be instituted. Continual optimal oxygenation and ventilation and circulatory support as well as treatment of acidosis are of vital importance.

Dialysis is of negligible value in the treatment of acute overdose with lidocaine.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Anaesthetics, local, Amides, ATC code: N01BB02

Lidocaine is a short-acting local anaesthetic of the amide type. It is used to provide local anaesthesia by nerve blockade at various sites in the body and in the ionic control of dysrhythmias. It acts by inhibiting the ionic refluxes required for the initiation and conduction of impulses, thereby stabilising the neuronal membrane. In addition to blocking conduction in nerve axons in the peripheral nervous system, Lidocaine has important effects on the central nervous system and cardiovascular system. After absorption Lidocaine may cause stimulation of the CNS followed by depression, and in the cardiovascular system it acts primarily on the myocardium where it may produce decreases in electrical excitability, conduction rate and force of contraction. It has a rapid onset of action (about one minute following intravenous injection and fifteen minutes following intramuscular injection) and rapidly spreads through the surrounding tissues. The effect lasts about ten to twenty minutes and about sixty to ninety minutes following intravenous and intramuscular injection, respectively.

5.2 Pharmacokinetic properties

Absorption
Lidocaine is absorbed from injection sites including muscle and its rate of absorption is determined by factors such as the site of administration and the tissue vascularity. Except for intravascular administration, the highest blood levels occur following intercostal nerve block concentrations (approx. 1.5 µg/ml per 100 mg injected) and the lowest after subcutaneous administration (approx. 0.5 µg/ml per 100 mg injected).

Distribution
Lidocaine is bound to plasma proteins, including alpha-1-acid-glycoprotein (AAG) and albumin. The extent of binding is variable but is about 66 %. The drug crosses the blood-brain and placental barriers probably as a result of passive diffusion. The AAG plasma level is low in neonates and the free biologically active lidocaine fraction is relatively high in neonates. The drug crosses the blood-brain and placental barriers probably as a result of passive diffusion.

Biotransformation
Lidocaine is metabolised in the liver and about 90 % of a given dose undergoes N-dealkylation to form monoethylglycinexylidide (MEGX) and glycinexylidide (GX), both of which may contribute to the therapeutic and toxic effects of lidocaine. The pharmacologic and toxic effects of MEGX and GX are comparable but lesser in strength than those of lidocaine. Glycinexylidide has a longer half-life (about 10 hours) than lidocaine and can accumulate with chronic administration. Further metabolism occurs and metabolites are excreted in the urine with less than 10 % of unchanged lidocaine.

Elimination
Following an intravenous bolus injection the elimination half-life of lidocaine is one to two hours, but this may be prolonged in patients with hepatic dysfunction. The elimination half-life of GX is approximately 10 hours and that of MEGX is 2 hours. Renal function impairment has no effect on the pharmacokinetics of lidocaine but may lead to the accumulation of its metabolites.

Special population groups
The pharmacokinetics of lidocaine can be influenced by conditions affecting the liver function due to its rapid metabolism. The half-life can be increased by a factor of 2 or more in patients with hepatic dysfunction.
Renal function impairment has no effect on the pharmacokinetics of lidocaine but may lead to the accumulation of its metabolites.
In neonates, the α1-acid glycoprotein levels are low and protein binding may be reduced. As the free fraction may be higher, the use of lidocaine in neonates is not recommended.

5.3 Preclinical safety data

Reproductive toxicity
In studies of embryo/foetal development in rats and rabbits with lidocaine given during organogenesis, no teratogenic effects were observed. Embryotoxicity was seen in rabbits at doses toxic to the mother. The young rats treated with doses toxic to the mother during late pregnancy and lactation showed reduced postnatal survival.

Genotoxicity and carcinogenicity
Genotoxicity studies of lidocaine were negative. Carcinogenicity of lidocaine has not been studied. Lidocaine's metabolite, 2,6-xylidine (2,6-dimethylaniline), was shown to have genotoxic potential *in vitro*. In a carcinogenicity study of rats with exposure to 2,6-xylidine *in utero*, postnatally and throughout their lifetime, tumours were seen in the nostrils, subdermally and in the liver. The clinical relevance of these findings for short term/intermittent lidocaine use is not known.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium chloride
Hydrochloric acid (for pH-adjustment)
Sodium hydroxide (for pH-adjustment)
Water for Injection

6.2 Incompatibilities

Lidocaine is incompatible with solutions containing amphotericin B, sulfadiazine sodium, methohexital sodium, cephazolin sodium, phenytoin, glyceryl trinitrate and other alkaline solutions. Therefore, it is not advisable to mix Lidocaine Hydrochloride with other agents.

Acid stable drugs such as adrenaline hydrochloride, noradrenaline acid tartrate, or isoprenaline may deteriorate after mixture with lidocaine hydrochloride and the lidocaine solutions may raise the pH above the maximum pH for their stability.

This medicinal product must not be mixed with other medicinal products except those mentioned in section 6.6.

6.3 Shelf life

Shelf life of the medicinal product in its original package before opening:
3 years

Shelf life after first opening:

Medicinal product must be used immediately after first opening.

Chemical and physical in-use stability has been demonstrated for 24 hours at 25°C.From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8°C, unless dilution has taken place in controlled and validated aseptic conditions.

Shelf life after dilution:
If diluted in sodium chloride 9 mg/ml (0.9 %) solution or 50 mg/ml glucose (5 %) solution to a final lidocaine concentration range of 2 mg/ml to 5 mg/ml under strict aseptic conditions, the solution should also be used immediately.

However, if the diluted solution is not used immediately, do not store for more than 12 hours under strict aseptic conditions below 25°C.

For dilution of Lidocaine Hydrochloride solution for injection see section 6.6.

6.4 Special precautions for storage

This medicinal product does not require any specific storage conditions.

For storage conditions of the opened/diluted medicinal product, see section 6.3.

6.5 Nature and contents of container

Low-density polyethylene ampoules with a twist-off system.

Pack sizes
5 ml ampoules in packs of 5, 10, 20, 50 or 100.
10 ml ampoules in packs of 5, 10, 20, 50 or 100.
20 ml ampoules in packs of 5, 10, 20, 50 or 100.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

Use immediately after opening and only undamaged containers. For single use only.
Do not use if the ampoule is damaged or broken.

Compatibility
Lidocaine Hydrochloride solution for injection can be diluted in sodium chloride 9 mg/ml (0.9 %) solution or 50 mg/ml glucose (5 %).

The diluted solution should be visually inspected and should not be used in the presence of opalescence, visible particles or precipitate.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Fresenius Kabi Deutschland GmbH
Else-Kroener Strasse 1
Bad Homburg v.d.H 61352
Germany

8 MARKETING AUTHORISATION NUMBER

PA2059/003/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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Date of last renewal: 23rd May 2023

10 DATE OF REVISION OF THE TEXT

November 2024