# SUMMARY OF PRODUCT CHARACTERISTICS

## 1 NAME OF THE MEDICINAL PRODUCT

Lidocaine Hydrochloride 0.4 % and Glucose 5% Solution for Infusion.

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Lidocaine Hydrochloride 0.4 % and Glucose 5% Solution for Infusion has the following composition:

| Name | Specification Reference | %w/v |
|---|---|---|
| Lidocaine hydrochloride BP | EP | 0.4 |
| Glucose Monohydrate for Parenteral use BP | EP | 5.5 |
| *(Equivalent to Anhydrous Glucose BP* | | *5.0)* |

## 3 PHARMACEUTICAL FORM

Solution for Infusion

## 4. CLINICAL PARTICULARS

### 4.1 Therapeutic indications

Lidocaine reduces cardiac irritability and is given as an intravenous infusion to control ventricular arrhythmias during cardiac surgery or following myocardial infarction.

Usually, the lidocaine containing solutions are used to maintain the suppression of ectopic activity provided by a bolus injection of lidocaine.

### 4.2 Posology and method of administration

Adults
The volume and rate of infusion will depend upon the requirements of the individual patient and the judgement of the physician.

Following a loading dose, lidocaine containing infusions are administered at a rate of 1-4 mg of lidocaine per minute for 12-48 hours.

Children and Elderly
Doses should generally be reduced in the elderly and children. Although dosage will be dictated by clinical response as judged by ECG changes.

For Solution for Infusion.

Fluid balance, serum glucose, serum sodium and other electrolytes may need to be monitored before and during administration, especially in patients with increased non-osmotic vasopressin release (syndrome of inappropriate antidiuretic hormone secretion, SIADH) and in patients co-medicated with vasopressin agonist drugs due to the risk of hyponatraemia.

Monitoring of serum sodium is particularly important for physiologically hypotonic fluids. Lidocaine Hydrochloride 0.4 % and Glucose 5% Solution for Infusion may become extremely hypotonic after administration due to glucose metabolization in the body (see sections 4.4, 4.5 and 4.8).

## 4.3 Contraindications

Patients with hypovolaemia, heart block or other conduction disturbances, bradycardia, or cardiac decompensation or hypertension not due to treatable tachyarrhythmias. Hypersensitivity to local anaesthetics.

## 4.4 Special warnings and precautions for use

The continuous infusion of lidocaine requires careful monitoring by electrocardiograph.

Should be given cautiously to patients with epilepsy, impaired cardiac condition or respiratory function, or with liver damage or myasthenia gravis. Because lidocaine is metabolised in the liver, it should be used with caution in any other conditions which reduce hepatic blood flow such as cardiac and circulatory failure.

The label states: Do not use unless the solution is clear and free from particles.

Contains lidocaine hydrochloride.

Glucose Solution for Infusions are usually isotonic solutions. In the body, however, glucose containing fluids can become extremely physiologically hypotonic due to rapid glucose metabolization (see section 4.2).

Depending on the tonicity of the solution, the volume and rate of infusion and depending on a patient's underlying clinical condition and capability to metabolize glucose, intravenous administration of glucose can cause electrolyte disturbances most importantly hypo- or hyperosmotic hyponatraemia.

Hyponatraemia:

Patients with non-osmotic vasopressin release (e.g. in acute illness, pain, post-operative stress,infections, burns, and CNS diseases), patients with heart-, liver- and kidney diseases and patients exposed to vasopressin agonists (see section 4.5) are at particular risk of acute hyponatraemia upon infusion of hypotonic fluids.

Acute hyponatraemia can lead to acute hyponatraemic encephalopathy (brain oedema) characterized by headache, nausea, seizures, lethargy and vomiting.

Patients with brain oedema are at particular risk of severe, irreversible and life-threatening brain injury.

Children, women in the fertile age and patients with reduced cerebral compliance (e.g. meningitis, intracranial bleeding, and cerebral contusion) are at particular risk of the severe and life-threatening brain swelling caused by acute hyponatraemia.

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

Interactions or moderate clinical significance include those between lidocaine and beta-adrenergic blockers, cimetidine and phenytoin.

Drugs leading to an increased vasopressin effect
The below listed drugs increase the vasopressin effect, leading to reduced renal electrolyte free water excretion and increase the risk of hospital acquired hyponatraemia following inappropriately balanced treatment with i.v. fluids (see sections 4.2, 4.4 and 4.8).

- Drugs stimulating vasopressin release, e.g.:
  Chlorpropamide, clofibrate, carbamazepine, vincristine, selective serotonin reuptake inhibitors, 3.4-methylenedioxy-N-methamphetamine, ifosfamide, antipsychotics, narcotics

- Drugs potentiating vasopressin action e.g.:
  Chlorpropamide, NSAIDs, cyclophosphamide

- Vasopressin analogues, e.g.:
  Desmopressin, oxytocin, vasopressin, terlipressin

Other medicinal products increasing the risk of hyponatraemia also include diuretics in general and antiepileptics such as oxcarbazepine.

## 4.6 Fertility, pregnancy and lactation

The safety of this product during pregnancy and lactation has not been assessed. The benefit to the patient should be balanced against the potential risk.

Lidocaine Hydrochloride 0.2 % and Glucose 5% Solution for Infusion should be administrated with special caution for pregnant women during labour particularly if administered in combination with oxytocin due to the risk of hyponatraemia (see section 4.4, 4.5 and 4.8).

## 4.7 Effects on ability to drive and use machines

Not applicable.

## 4.8 Undesirable effects

Rarely, allergic reactions may occur.

Systemic toxicity mainly involves the CNS and cardiovascular system, although early signs include numbness or the tongue and perioral region. Excitation of the CNS may be manifested by yawning, restlessness, excitement, nervousness, dizziness, tinnitus, nystagmus, blurred vision, nausea and vomiting, muscle twitching, tremors and convulsions. Excitation may be transient and be followed by CNS depression manifested by drowsiness, respiratory failure and coma.

Effects on the cardiovascular system include myocardial depression and peripheral vasodilation resulting in hypertension and bradycardia, arrhythmias and cardiac arrest may also occur.

| **Tabulated list of adverse reactions** | | |
|---|---|---|
| System Organ Class | Adverse reaction (MedDRA term) | Frequency |
| Metabolism and nutrition disorders | Hospital Acquired Hyponatraemia** | Not known |
| Nervous system disorders | Hyponatraemic encephalopathy** | Not known |

** Hospital acquired hyponatraemia may cause irreversible brain injury and death due to development of acute hyponatraemic encephalopathy (see sections 4.2 and 4.4).

Methaemoglobinaemia may also occur especially after higher dosages (see 4.9)

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 Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

## 4.9 Overdose

Symptoms of overdosage would be manifested by adverse effects on the CNS and cardiovascular system (see 4.8).

Following discontinuation of lidocaine infusion treatment should consist in general terms of maintaining circulation and respiration and controlling convulsions. Respiration should be maintained by establishing an airway and administering oxygen. The circulation should be maintained by infusion of plasma or suitable electrolyte solution. Vasopressor agents such as metaraminol, dopamine or dobutamine may be used to maintain blood pressure. Convulsions may be controlled by the intravenous administration of diazepam.

Overdosage with a lidocaine containing infusion may produce methaemoglobinaemia which is treated by the intravenous administration of a 1% solution of methylene blue 1-4 mg/Kg bodyweight.

# 5 PHARMACOLOGICAL PROPERTIES

## 5.1 Pharmacodynamic properties

Lidocaine hydrochloride is a class 1 anti-arrhythmic agent, reducing cardiac irritability. It reduces membrane responsiveness, decreases conduction velocity and prolongs the action potential.

## 5.2 Pharmacokinetic properties

Following the intravenous injection, plasma concentrations decline rapidly with a half-life of about 10 minutes; the elimination half-life is about two hours. Antiarrhythmic concentrations are reported to range from 1.5 to 6 mg/ml. Lidocaine is rapidly distributed into the heart, brain, kidneys and other tissues. It diffuses across the placenta a few minutes after injection.

Lidocaine is rapidly de-ethylated in the liver to the active metabolite monoethylglycinexylidide which has a reduced activity but a longer elimination half-life. The products of metabolism are excreted via the urine together with less than 10 % of unchanged lidocaine.

### 5.3 Preclinical safety data

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

| Name | Specification Reference | %w/v |
|---|---|---|
| Water for Injections in bulk BP | EP | To 100 |
| Hydrochloric Acid BP | EP | QS |
| Sodium Hydroxide BP | BP | QS |

### 6.2 Incompatibilities

Solutions containing lidocaine hydrochloride are incompatible with amphotericin, methohexitone sodium, sulphadiazine sodium and occasionally incompatible with ampicillin depending upon the pH of the lidocaine containing solution.

Because of the nature of the plastic material of the Steriflex bag (PVC), this solution should not be used as a vehicle for the administration of drugs which maybe sorbed to the surface of the bag to varying and significant degrees.

### 6.3 Shelf life

500ml PVC Bags - 24 months.
500ml Polyolefin Bags - 36 months.

### 6.4 Special precautions for storage

Store at 2° to 25°C.

### 6.5 Nature and contents of container

The container is a flexible 500ml bag made of medical grade PVC.

a) A hermetically sealed polythene bag.
b) A rectangular pouch consisting of polyamide/polythene composite
c) Polyamide/Polyethylene-Propylene composite laminate welded to polypropylene ethylene propylene composite, plugged with a polycarbonate plug with either a bromobutyl (West 4481/45) or gum (West 7006/45) stopper.

Or

A flexible 500ml polyolefine bag sealed in a polyolefine overwrap.

Pack size: 1 x 500 ml, 15 x 500 ml and 20 x 500 ml.

Not all pack sizes may be marketed.

### 6.6 Special precautions for disposal and other handling

Opening the overwrap:
Locate the corner tabs at the end of the bag. Grip the two tabs and pull the two halves of the overwrap apart, releasing the bag onto a clean surface.
Setting up the solution:
Position the roller clamp of the giving-set to just below the drip chamber and close.
Hold the base of the giving set port firmly and grip the wings of the twist of tab. Twist to remove the protective cover. Still holding the base of the giving-set port push the set spike fully into the port to ensure a leak proof connection.
Prime the set in accordance with the manufacturer's instructions.

## 7 MARKETING AUTHORISATION HOLDER

Fresenius Kabi Limited
Cestrian Court
Eastgate Way
Manor Park
Runcorn
Cheshire
WA7 1NT

## 8. MARKETING AUTHORISATION NUMBER

PL 8828/0082.

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

06.89/09.99

## 10 DATE OF REVISION OF THE TEXT

04/11/2024