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HEALTH DIVISION

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DH Circular No 64/2007

20th March 2007

Attention all Consultants
Medical Officers
Pharmacists
Nurses

Re: Properties of the Lidocaine 1% injection currently and temporarily available

A different preparation of Lidocaine 1% injections is being procured temporarily to avoid an out of stock situation.

In contrast to the Lidocaine 1% injections previously procured, the preparation which is now available contains a preservative. Thus, the properties of the lidocaine 1% injection currently available, differ from those of the previous one.

The lidocaine 1% injection with preservative is used as a local anaesthetic when injected subcutaneously. It is not intended for intravenous use. As it contains a preservative, it should not be used for spinal, epidural, caudal or intravenous regional anaesthesia.

The Summary of Product Characteristics (SPCs) and Patient Information Leaflet are being annexed for your reference and information.

For your attention please,

Dr Ray Busuttil
Director General Health

hameln pharmaceuticals ltd

injecting solutions to healthcare

PATIENT INFORMATION LEAFLET

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

In this leaflet:

LIDOCAINE INJECTION BP WITH PRESERVATIVE 1%

The active ingredient in this medicine is lidocaine hydrochloride. This is the new name for lignocaine hydrochloride. The ingredient itself has not changed.

This injection contains the active ingredient lidocaine hydrochloride 1%. Each ml contains 10 mg of lidocaine hydrochloride.

This injection also contains the following inactive ingredients:

Sodium chloride, methylhydroxybenzoate (E218), propylhydroxybenzoate (E216) and water for Injections.

Holder of the Marketing Authorisation:	hameln pharmaceuticals ltd Gloucester UK
Manufacturer:	hameln pharmaceuticals gmbh Langes Feld 13, 31789 Hameln Germany

1. What your medicine is and what it is used for

Lidocaine Injection with Preservative 1% is a clear, colourless, sterile and isotonic solution supplied in 20 and 50 ml clear glass vials, only intended to be given by injection under your skin (subcutaneously or SC).

Lidocaine is a local anaesthetic of the amide group. When injected into the skin, it causes loss of feeling before or during surgery. Lidocaine allows doctors to sew up cuts in the skin and to undertake operations without any pain even though the patient is awake.

2. Before you receive your medicine

You should tell your doctor if:

- you think you are allergic to either lidocaine or the preservatives used in this injection. The
- preservatives are often known just as benzoates or hydroxy-benzoates. (See also section 4. Possible side effects for further information).

- you suffer from epilepsy or have fits
- you suffer from heart, lung or breathing disorders
- you have kidney or liver disease
- you suffer from myasthenia gravis (loss of muscle function and weakness)
- you are pregnant, likely to become pregnant or breast-feeding
- you have inflammation or infection in the area to be injected
- you are taking cimetidine (for stomach ulcer or heartburn) or beta-blockers, for example, propranolol (for angina, high blood pressure or other heart problems)

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, even those not prescribed.

Driving and operating machinery: Depending on where and how lidocaine is used, it may affect your ability to drive or operate machinery. Ask your doctor about when it would be safe to drive or operate machines.

3. How your medicine is administered

The dose of a local anaesthetic will be different for different patients. Your healthcare professional will decide on the right amount for you, depending on:

Your age; your general physical condition; the reason the local anaesthetic is being given and other medicines you are taking or will receive before or after the local anaesthetic is given.

Adults: As a guide, 20 ml (equivalent to 200 mg) of Lidocaine Injection with Preservative 1% is the usual maximum dose. Your doctor will decide on the most appropriate dose for you. A smaller dose may be used if you are elderly or weak.

Children: A smaller dose is usually used for children depending on their age, physical condition and the procedure to be performed.

4. Possible side effects

Like all medicines, Lidocaine Injection with Preservative 1% can have side effects:

Lidocaine is generally well tolerated, but along with its needed effects, all medicine can cause unwanted effects. Lidocaine may occasionally cause the following side effects:

- pain, inflammation or numbness at the site of injection after the effects of the injection should have worn off
- nervousness
- tremor
- blurred or double vision
- dizziness or drowsiness
- convulsions (seizures)
- nausea or vomiting
- breathing problems
- slowed heart beat or low blood pressure

Allergic reactions to lidocaine hydrochloride are rare, but tell your doctor immediately if you get any difficulty with your breathing, a rash or itchy skin.

Methylhydroxybenzoate (E218) and propylhydroxybenzoate (E216) may cause allergic reactions (possibly delayed), and exceptionally, bronchospasm.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

For patients going home before the numbness or loss of feeling caused by a local anaesthetic wears off:

During the time that the injected area feels numb, serious injury can occur without your knowing about it. Be especially careful to avoid injury until the anaesthetic wears off or feeling returns to the area.

5. Storing your medicine

Your doctor will store the vials in the outer carton in order to protect from light, between 10 °C and 25 °C and out of reach and sight of children.

6. Use by date

Your doctor will not use the drug after the expiry date shown on the vial and carton.

This leaflet was last updated on July 13th 2004.

PL 1502/0035

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SUMMARY OF PRODUCT CHARACTERISTICS

PRODUCT SUMMARY

NAME OF THE MEDICINAL PRODUCT

Lidocaine Injection BP with Preservative 1 %

QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml contains 10.0 mg of lidocaine hydrochloride, corresponding to 8.1 mg lidocaine.

PHARMACEUTICAL FORM

Solution for injection

4. Clinical Particulars

4.1 Therapeutic indications

Lidocaine Injection is used as a local anaesthetic.

4.2 Posology and method of administration

Lidocaine Injection is used as a local anaesthetic when injected subcutaneously.

This solution is not intended for use intravenously. Solutions of lidocaine, which contain preservatives, should not be used for spinal, epidural, caudal or intravenous regional anaesthesia.

The dosage should be adjusted according to the response of the patient and the site of administration. The lowest concentration and the smallest dose producing the required effect should be given. The maximum dose for healthy adults should not exceed 200 mg corresponding to 20 mls.

Children and elderly or debilitated patients require smaller doses, commensurate with age and physical status.

The injection maybe used for infiltration in volumes of 1 ml to 60 ml.

4.3 Contra-indications

Know hypersensitivity to hydroxybenzoates and to anaesthetics of the amide type.

4.4 Special warnings and precautions for use

As with other local anaesthetics, lidocaine should be used with caution in patients with epilepsy, cardiac conduction disturbances, congestive cardiac failure, bradycardia or impaired respiratory function. Lidocaine is metabolised in the liver and it should be used with caution in patients with impaired hepatic function. Lidocaine should not be used in cases of acute porphyrias.

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Patients with myasthenia gravis are particularly susceptible to the effects of local anaesthetics.

Facilities for resuscitation should be available when administering local anaesthetics.

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

4.5 Interactions with other medicinal products and other forms of interactions

The clearance of lidocaine may be reduced by beta-adrenoceptor blocking agents and by cimetidine, requiring a reduction in the dosage of lidocaine.

4.6 Pregnancy and lactation

Although animal studies have revealed no evidence of harm to the foetus, lidocaine crosses the placenta and should not be administered during early pregnancy unless the benefits are considered to outweigh the risks.

Small amounts of lidocaine are secreted into breast milk and the possibility of an allergic reaction in the infant, albeit remote, should be borne in mind when using lidocaine in nursing mothers.

4.7 Effects on ability to drive and use machines

Where 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

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 vascular 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.

CNS reactions may be excitatory and/or depressant and may manifest as nervousness, tremor, blurred vision, nausea and vomiting, followed by drowsiness, convulsions, coma and possible respiratory arrest. The excitatory reactions may be brief or may not occur at all, so that the first signs of toxicity may be drowsiness, followed by coma and respiratory failure. Cardiovascular reactions are depressant and may manifest as hypotension, bradycardia, myocardial depression and possible cardiac arrest.

Allergic reactions are rare. They may be characterised by cutaneous lesions, urticaria, oedema or anaphylactoid reactions. Skin testing for allergy to lidocaine is not considered to be reliable.

Solutions of lidocaine, which contain preservatives, are not suitable for spinal, epidural or caudal anaesthesia. Adverse effects reported following unpreserved lidocaine solutions administered by this route include hypotension and isolated cases of bradycardia and cardiac arrest.

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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 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.

4.9 Overdose

The effects of overdosage involve the central nervous system, where reactions may be excitatory and/or depressant and the cardiovascular system where the effects are depressant.

In the event of overdosage, immediate steps should be taken to maintain the circulation and respiration and to control convulsions.

A patent airway should be established and oxygen should be administered, together with assisted ventilation 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 CNS excitation. Convulsions may be controlled by the intravenous administration of diazepam or thiopentone sodium, bearing in mind that anti-convulsant drugs may also depress respiration and the circulation. If cardiac arrest should occur, standard cardiopulmonary resuscitation procedures should be instituted.

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

5. Pharmacological Properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Local anaesthetic, ATC code: N01BB02.

Lidocaine is a local anaesthetic of the amide group. It is used to provide local anaesthesia at various sites in the body and 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. In the cardiovascular system, it acts primarily on the myocardium where it may produce decreases in electrical excitability, conduction rate and force of contraction.

5.2 Pharmacokinetic properties

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 and the lowest after subcutaneous administration. Lidocaine is bound to plasma proteins, including alpha-1-acid-glycoprotein. The drug crosses the blood-brain and placental barriers.

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Lidocaine is metabolised in the liver and about 90 % of a given dose undergoes N-dealkylation to form monoethylglycinexylidide and glycinexylidide, both of which may contribute to the therapeutic and toxic effects of lidocaine. Further metabolism occurs and metabolites are excreted in the urine with less than 10 % of unchanged lidocaine. The elimination half-life of lidocaine following an intravenous bolus injection is one to two hours, but this may be prolonged in patients with hepatic dysfunction.

5.3 Preclinical safety data

No further information other than that which is included in the Summary of Product Characteristics.

6. Pharmaceutical Particulars

6.1 List of excipients

Sodium Chloride Ph. Eur.
Methylhydroxybenzoate Ph. Eur. (1.7 mg/ml)
Propylhydroxybenzoate Ph. Eur. (0.3 mg/ml)
Water for Injections Ph. Eur.

6.2 Incompatibilities

Lidocaine causes precipitation of amphotericin, methohexitone sodium and sulphadiazine sodium in glucose injection. It is recommended that admixtures of lidocaine and glyceryltrinitrate should be avoided.

6.3 Shelf life

24 months.

6.4 Special precautions for storage

Keep container in the outer carton in order to protect from light.
Store between 10C and 25C.

6.5 Nature and contents of container

Type II clear glass vial, 20 ml and 50 ml, with chlorbutyl rubber stopper, plastic outer cap and inner aluminium ring. Packed in cardboard cartons to contain 10 vials.

6.6 Instructions for use, handling and disposal

Use as directed by a physician.

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ADMINISTRATIVE DATA

MARKETING AUTHORISATION HOLDER

hameln pharmaceuticals ltd
Gloucester
UK

MARKETING AUTHORISATION NUMBER

01502/0035

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1st October 2004

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