

Public Assessment Report

**Lidocaine Injection BP with preservative 1%
Lidocaine Injection BP with preservative 2%**

PL 01502/0070

PL 01502/0071

Hameln Pharmaceuticals Limited

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Lay Summary

The MHRA granted Hameln Pharmaceuticals Limited Marketing Authorisations (Licences) for the medicinal products Lidocaine Injection BP with preservative 1% (PL01502/0070) and Lidocaine Injection BP with preservative 2% (PL01502/0071) on 3rd August 2006.

Lidocaine is used as a local anaesthetic

No new or unexpected safety concerns arose from these simple applications and it was judged, therefore that the benefits of Lidocaine Injection BP with preservative 1% or Lidocaine Injection BP with preservative 2% outweigh the risks, hence a Marketing Authorisation was granted.

SCIENTIFIC DISCUSSION

1. INTRODUCTION

This Public Assessment Report is based on the National Assessment Report for the recently granted Market Authorisations for Lidocaine Injection BP with preservative 1% (PL 01502/0070) and Lidocaine Injection BP with preservative 2% (PL 01502/0071). These applications were 'informed consent' applications (Article 10c (2004/27/EC)).

The cross-referenced products (PL 01502/0035-6) were first approved on 09/08/1982 and subsequently renewed with regard to creating the product SPC on 10/12/1998.

The applicant is the same MAH as that for the reference products. Therefore, the applicant will have access to clinical and quality dossiers and no further authorisation would be required. Satisfactory expert statements from pre-clinical, clinical and pharmaceutical experts were provided.

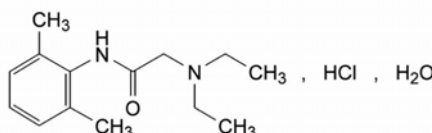
2 DRUG SUBSTANCE

2.1 General Information

Lidocaine hydrochloride BP (*Ph Eur monograph 0227*)

Molecular formula: $C_{14}H_{22}N_2O \cdot HCl \cdot H_2O$; Molecular weight: 288.8

ATC code: N01BB02



The proposed drug substance specification is identical to that approved for the cross reference products.

2.2 Manufacture

The active substance manufacturer is same as previously authorised for the cross-referenced product. The manufacturing site is within the community and has been previously approved and a Certificate of Suitability was included for the drug substance.

3. DOSAGE FORM

3.1 DESCRIPTION AND COMPOSITION OF THE DRUG PRODUCT

Each 20ml and 50 ml vial contains sterile aqueous solution of lidocaine hydrochloride 1% w/v equivalent to 8.1mg lidocaine free base or lidocaine hydrochloride 2% w/v equivalent to 16.2 mg lidocaine free base. Excipients include Methyl hydroxybenzoate (E 218) 1.7 mg/ml, Propylhydroxybenzoate (E 216) 0.3 mg/ml, sodium chloride, hydrochloric acid, sodium hydroxide and water for injection (QS). The composition is identical to previously approved product

3.2 Manufacture

Applicant has provided the details for the manufacturing approvals previously granted to the premises. The manufacturers will be responsible for the quality control and release of the product and has been approved within community. A statement from the pharmaceutical expert indicates that an identical manufacturing process to that for the cross-reference product is used.

3.3 Container Closure System

The MAA and SPC indicate that the finished product will be packed in Type II glass vials with chlorbutyl rubber stopper, plastic outer cap and inner aluminium ring. 10 vials will then be packaged in cardboard cartons. It is identical to that of the cross-referenced products.

4.4 Storage Details

The proposed shelf life for 2 years has been previously approved for the cross-referenced product. Storage conditions are 'Do not store above 25°C; Do not refrigerate or freeze; Keep vials in the outer carton' for both the cross reference product and the subjects of this Public Assessment Report.

5. DATA

5.1 Summary of Product Characteristics

The SPC is essentially similar to the cross reference product with only minor changes in line with amendments in directive.

5.2 Patient Information Leaflet

Patient information leaflet is near identical to that approved for the cross-reference product, and is therefore, acceptable. However, minor changes to bring the SPC in line with the harmonised version have necessitated minor revision of the PIL.

5.3 Labels

Labels are identical to the cross-reference product apart from the necessary change in storage conditions

PRE-CLINICAL ASSESSMENT

No new data were submitted and none are required for an application of this type.

CLINICAL ASSESSMENT

No new data were submitted and none are required for an application of this type.

CONCLUSION

A Market Authorisation was granted

OVERALL CONCLUSION AND RISK/BENEFIT ANALYSIS

Quality

The data for these applications are consistent with that previously assessed for the cross-reference product and as such has been judged to be satisfactory.

Preclinical

No new preclinical data were submitted and none are required for applications of this type.

Efficacy

No new efficacy data for were submitted and none are required for this type of application.

Risk Benefit Assessment

The quality of the product is acceptable and no new preclinical or clinical safety concerns have been identified. The applicant's products are identical to the cross-reference products which, in turn, have been shown to be interchangeable with the innovator products. Extensive clinical experience with lidocaine is considered to have demonstrated the therapeutic value of the compound. The risk benefit is therefore considered to be positive.

STEPS TAKEN DURING ASSESSMENT

1	The MHRA received the application on 16 th January 2006.
2	Following initial assessment of the application the MHRA requested further information from the applicant regarding the quality assessment on 3 rd April 2006.
3	The applicant provided further information in regard to the quality assessment on 4 th July 2006.
4	The application was determined on 3 rd August 2006.

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Lidocaine Injection BP with Preservative 1 %

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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

3 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 may be used for infiltration in volumes of 1 ml to 60 ml.

4.3 CONTRAINDICATIONS

Known 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.

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.

This product contains 2.4-2.9 mmol (or 55-67 mg) sodium per vial. To be taken into consideration by patients on a controlled sodium diet

4.5 INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION

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.

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 reflexes 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.

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

Methylhydroxybenzoate -E218 (1.7 mg/ml)

Propylhydroxybenzoate-E216 (0.3 mg/ml)

Water for Injections

Sodium Hydroxide (pH adjustment)

Hydrochloric Acid (pH adjustment)

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 vials in the outer carton

Store below 25°C. Do not refrigerate or freeze

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 SPECIAL PRECAUTIONS FOR DISPOSAL

No special requirements

7 MARKETING AUTHORISATION HOLDER

hameln pharmaceuticals ltd

Gloucester

UK

8 MARKETING AUTHORISATION NUMBER(S)

01502 / 0070

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

03/08/2006

10 DATE OF REVISION OF THE TEXT

03/08/2006

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Lidocaine Injection BP with Preservative 2 %

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml contains 20.0 mg of lidocaine hydrochloride, corresponding to 16.2 mg lidocaine.

3 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 may be used for infiltration in volumes of 1 ml to 60 ml.

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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.

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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

Methylhydroxybenzoate -E218 (1.7 mg/ml)

Propylhydroxybenzoate-E216 (0.3 mg/ml)

Water for Injections

Sodium Hydroxide (pH adjustment)

Hydrochloric Acid (pH adjustment)

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 vials in the outer carton

Store below 25°C. Do not refrigerate or freeze

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 SPECIAL PRECAUTIONS FOR DISPOSAL

No special requirements

7 MARKETING AUTHORISATION HOLDER

hameln pharmaceuticals ltd

Gloucester

UK

8 MARKETING AUTHORISATION NUMBER(S)

01502 / 0071

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

03/08/2006

10 DATE OF REVISION OF THE TEXT

03/08/2006

LABELS AND LEAFLETS

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:

1. What your medicine is and what it is used for
2. Before you receive it
3. How it is administered
4. Possible side effects
5. Storing it

Lidocaine Injection 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
United Kingdom

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. This product contains 2.4-2.9 mmol (or 55-67 mg) sodium per vial. This should be taken into consideration by patients on a controlled sodium diet.

5. Storing your medicine

Your doctor will store the vials in the outer carton in order to protect from light, below 25°C and out of reach and sight of children. The vials should not be refrigerated or frozen.

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 April 20th, 2006.

PL 01502/0070

43870/16/06



Lidocaine Injection with preservative **1%**

200 mg in 20 ml

10 x 20 ml vials - For s.c. injection.



hameln pharmaceuticals Ltd
Gloucester
UK



200 mg in 20 ml



Lidocaine Injection with preservative **1%**

200 mg in 20 ml

10 x 20 ml vials - For s.c. injection.

1 ml solution for injection contains:

ACTIVE INGREDIENT: Lidocaine hydrochloride 10 mg equivalent to Lidocaine 6.1 mg
PRESERVATIVE: methylhydroxybenzoate (E218) 1.7 mg, propylhydroxybenzoate (E216) 0.3 mg
Excipients: sodium chloride, hydrochloric acid, sodium hydroxide and water for injections.
For multi-dose use. Read package insert before use. Use as directed by a physician.
This product contains 2.4-2.9 mmol (or 55-67 mg) sodium per vial. To be taken into consideration by patients on a controlled sodium diet. Keep out of the reach and sight of children. Keep container in the outer carton in order to protect from light.
Store below 25°C. Do not refrigerate or freeze.

POM

4467416/06

PL 01502/0070

Batch No.:

Exp. date:



200 mg in 20 ml

200 mg in 20 ml



Lidocaine Injection with preservative **1%**

200 mg in 20 ml

For s.c. injection.

POM

PL 01502/0070

hameln pharmaceuticals Ltd
Gloucester, UK

43836/05/04

Batch no.:

Exp. date:



 **Lidocaine Injection**
with preservative **1%**

200 mg in 20 ml

10 x 20 ml vials - For s.c. injection.




hameln pharmaceuticals ltd
Gloucester
UK



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200 mg in 20 ml

 **Lidocaine Injection**
with preservative **1%**

200 mg in 20 ml

10 x 20 ml vials - For s.c. injection.

1 ml solution for injection contains:

ACTIVE INGREDIENT: lidocaine hydrochloride 10 mg equivalent to lidocaine 8.1 mg
PRESERVATIVE: methylhydroxybenzoate (E218) 1.7 mg, propylhydroxybenzoate (E216)
0.3 mg Excipients: sodium chloride, hydrochloric acid, sodium hydroxide and water for
injections. For multi-dose use. Read package insert before use. Use as directed by a
physician. Keep out of the reach and sight of children. Keep container in the outer
carton in order to protect from light.
Store between 10°C and 25°C.



44674015/04
PL 01502/0070

Batch No.:
Exp. date:

200 mg in 20 ml

To open slit here

PATIENT INFORMATION LEAFLET



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- **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:

1. What your medicine is and what it is used for
2. Before you receive it
3. How it is administered
4. Possible side effects
5. Storing it

Lidocaine Injection with Preservative 2%

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

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.

This injection contains the active ingredient lidocaine hydrochloride 2%. Each ml contains 20 mg of lidocaine hydrochloride.

2. Before you receive your medicine

You should tell your doctor if:

This injection also contains the following inactive ingredients:
Sodium chloride, methylhydroxybenzoate (E218), propylhydroxybenzoate (E216) and water for injections.

- 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)

Holder of the Marketing Authorisation:

hameln pharmaceuticals ltd
Gloucester
United Kingdom

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 2% 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





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, 10 ml (equivalent to 200 mg) of Lidocaine Injection with Preservative 2% 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 2% 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. This product contains 1.5-2 mmol (or 35-47 mg) sodium per vial. This should be taken into consideration by patients on a controlled sodium diet.

5. Storing your medicine

Your doctor will store the vials in the outer carton in order to protect from light, below 25°C and out of reach and sight of children. The vials should not be refrigerated or frozen.

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 April 20th, 2006.

PL 01502/0071

44179/16/06


400 mg in 20 ml

Lidocaine Injection
with preservative **2%**

400 mg in 20 ml

For s.c. injection.

POM
PL 01502/0071
hameln pharmaceuticals ltd
Gloucester, UK
438-40/05/04
Batch no.:
Exp. date:



Lidocaine Injection
with preservative **2%**

400 mg in 20 ml

10 x 20 ml vials - For s.c. injection.

hameln pharmaceuticals hameln pharmaceuticals ltd
Gloucester UK

400 mg in 20 ml

Lidocaine Injection
with preservative **2%**

400 mg in 20 ml

10 x 20 ml vials - For s.c. injection.
1 ml solution for injection contains:
ACTIVE INGREDIENT: lidocaine hydrochloride 20 mg equivalent to lidocaine 16.2 mg
PRESERVATIVE: methylhydroxybenzoate (E218) 1.7 mg, propylhydroxybenzoate (E216) 0.3 mg. Excipients: sodium chloride, hydrochloric acid, sodium hydroxide and water for injections.
For multi-dose use. Read package insert before use. Use as directed by a physician.
This product contains 1.5-2 mmol (or 35-47 mg) sodium per vial. To be taken into consideration by patients on a controlled sodium diet. Keep out of the reach and sight of children. Keep container in the outer carton in order to protect from light.
Store below 25°C. Do not refrigerate or freeze.

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PL 01502/0071
Batch No.:
Exp. date:

400 mg in 20 ml

400 mg in 20 ml

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Lidocaine Injection with preservative **2%**

400 mg in 20 ml

10 x 20 ml vials - For s.c. injection.



hameln
pharmaceuticals

hameln pharmaceuticals ltd
Gloucester
UK



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400 mg in 20 ml



Lidocaine Injection with preservative **2%**

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PRESERVATIVE: methylhydroxybenzoate (E218) 1.7 mg, propylhydroxybenzoate (E216) 0.3 mg. Excipients: sodium chloride, hydrochloric acid, sodium hydroxide and water for injections. For multi-dose use. Read package insert before use. Use as directed by a physician. Keep out of the reach and sight of children. Keep container in the outer carton in order to protect from light.
Store between 10°C and 25°C.



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PL 01502/0071

Batch No.:
Exp. date:

400 mg in 20 ml