STERILISED WATER FOR INJECTIONS

PL 01502/0069

UKPAR

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STERILISED WATER FOR INJECTIONS

PL 01502/0069

LAY SUMMARY

The Medicines and Healthcare products Regulatory Agency (MHRA) granted Hameln Pharmaceuticals Limited a Marketing Authorisation (licence) for the medicinal product Sterilised Water for Injections (PL 01502/0069). This product is only available with a prescription.

Sterilised water for injections is used to dissolve and dilute injectable medicines.

No new or unexpected safety concerns arose from this simple application and it was, therefore, judged that the benefits of taking Sterilised Water for Injections outweigh the risks, hence a Marketing Authorisation has been granted.

STERILISED WATER FOR INJECTIONS

PL 01502/0069

SCIENTIFIC DISCUSSION

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INTRODUCTION

The UK granted a marketing authorisation for the medicinal product Sterilised Water for Injections (PL 01502/0069) to Hameln Pharmaceuticals Limited on 20 October 2006. This product is a prescription only medicine (POM) and is used to make up solutions at a suitable concentration for patients in need of intravenous treatment.

The application was submitted as an abridged informed consent application according to Article 10c of EC Directive 2001/83. The cross reference product is Water for Injection BP (PL 01502/0003), held by Hameln Pharmaceuticals Limited and granted 27 June 1986.

No new data was submitted, nor was it necessary for this simple application, as the data is identical to that of the previously granted cross-reference product. As the cross-reference product was granted prior to the introduction of current legislation, no Public Assessment Report (PAR) was generated for it.

PHARMACEUTICAL ASSESSMENT REPORT

INTRODUCTION

This is an abridged application made under Article 10c of EC Directive 2001/83, as amended, and is considered to be an essentially similar product to that of PL 01502/0003R (Water for Injection BP). The licence is held by Hameln Pharmaceuticals, granted 27th June 1986. The licence was received in December 2005.

A letter of consent has not been supplied by Hameln Pharmaceuticals Limited for cross reference to PL 01502/0003R in conjunction with this application as it is the same marketing authorisation holder, this is acceptable.

A Manufacturer's licence, dated August 2003, has been provided from the German Authorities. The site included is in compliance with the cross reference licence.

The active ingredient supplier has not been specified. The active substance does not have a certificate of suitability or DMF. The active substance is controlled by the European Pharmacopoeia monograph.

EXPERT REPORTS

Satisfactory statements have been provided.

PRODUCT LITERATURE

1. Summary of Product Characteristics

The SPC for this product is satisfactory.

2. Label

The labelling for this product is satisfactory.

3. PIL

The Patient Information Leaflet (PIL) for this product is satisfactory.

4. MAA

The Marketing Authorisation Application (MAA) form submitted with this application is satisfactory.

RECOMMENDATION

Grant of a Marketing Authorisation is acceptable.

CONCLUSION

A marketing Authorisation can be granted.

PRECLINICAL ASSESSMENT

No new preclinical data have been supplied with this application and none is required for an application of this type.

CLINICAL ASSESSMENT

No new clinical data have been supplied with this application and none is required for an application of this type.

OVERALL CONCLUSION AND RISK BENEFIT ASSESSMENT

QUALITY

The data for this application is 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 an application of this type.

EFFICACY

No new or unexpected safety concerns arise from this application.

The SPC, PIL and labelling are satisfactory and consistent with that for the cross-reference product.

RISK BENEFIT ASSESSMENT

The quality of the product is acceptable and no new preclinical or clinical safety concerns have been identified. The applicant's product is identical to the cross-reference product. The risk benefit ratio is considered to be positive.

STERILISED WATER FOR INJECTIONS

PL 01502/0069

STEPS TAKEN FOR ASSESSMENT

1	The MHRA received the marketing authorisation application on 20 December 2005
2	Following assessment of the application the MHRA requested further information relating to the quality dossier on 2 February 2006
3	The applicant responded to the MHRA's requests, providing further information on 31st March 2006
4	Following assessment of the response the MHRA requested further information relating to the quality dossier on 28 April 2006
5	The applicant responded to the MHRA's requests, providing further information on 4th July 2006
6	The application was determined on 20 October 2006

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Sterilised water for injections

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains 100% Water for Injections

3 PHARMACEUTICAL FORM

Solution for injection
Clear glass ampoules containing, 2ml, 5ml, 10ml or 20ml Sterilised water for injections

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Sterilised water for injections is used as a dissolvent and diluent for injectable medicines.

4.2 Posology and method of administration

Sterilised water for injections is administered by Intravenous Injection. Dosage for Adults (including the elderly) and Children:- as required, by intravenous injection.

4.3 Contraindications

None known.

4.4 Special warnings and precautions for use

None known.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Pregnancy and lactation

None known.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

None known.

4.9 Overdose

None known.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC code K4D - Other injection solutions/infusions.
Sterilised water for injections is used as a dissolvent and diluent for injectable medicines

5.2 Pharmacokinetic properties

Not Applicable

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

None

6.2 Incompatibilities

None known

6.3 Shelf life

60 months

6.4 Special precautions for storage

Store below 25° C

6.5 Nature and contents of container

Type I clear glass ampoules, 2ml, 5ml, 10ml and 20ml

6.6 Special precautions for disposal

Only to be used as a diluent

7 MARKETING AUTHORISATION HOLDER

Hameln pharmaceuticals ltd
Gloucester
UK

8 MARKETING AUTHORISATION NUMBER(S)

PL 01502 / 0069

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

20/10/2006

10 DATE OF REVISION OF THE TEXT

20/10/2006

PATIENT INFORMATION LEAFLET

Patient Information Leaflet

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

- Keep this leaflet. You may need to read it again. In some circumstances this may not be possible if you are given this injection in an emergency. This leaflet will be kept in a safe place should you wish to read it again
- If you have any 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.

1. What sterilised water for injections is and what it is used for

This solution for injection contains water that has been very carefully cleaned and purified so there are no chemicals, bacteria or moulds in it. Each ml contains 100% Water for Injections.

The injection is supplied in 2, 5, 10 and 20 ml clear glass ampoules. 10 or 20 ampoules supplied in each carton.

Sterilised water for injections is used to dissolve and dilute other medicines so that they can be given into your blood stream as an intravenous injection (into the vein).

2. Before you are given sterilised water for injections

Tell the person giving you this injection if you know of any reason why you should not receive sterilised water for injections

3. How to use sterilised water for injections

Your doctor will decide the correct dosage for you and when and how the injection will be given to you.

4. Possible side effects

Water is a natural substance in the body and so is unlikely to cause any unwanted effects. However, if you think this injection is causing you any problems or you are at all worried, talk to your doctor, nurse or pharmacist.

5. Storing sterilised water for injections

Your injection should be stored below 25°C. The nurse or doctor will check that the injection is not past its expiry date before giving you the injection.
Keep out of the reach and sight of children

6. Further information

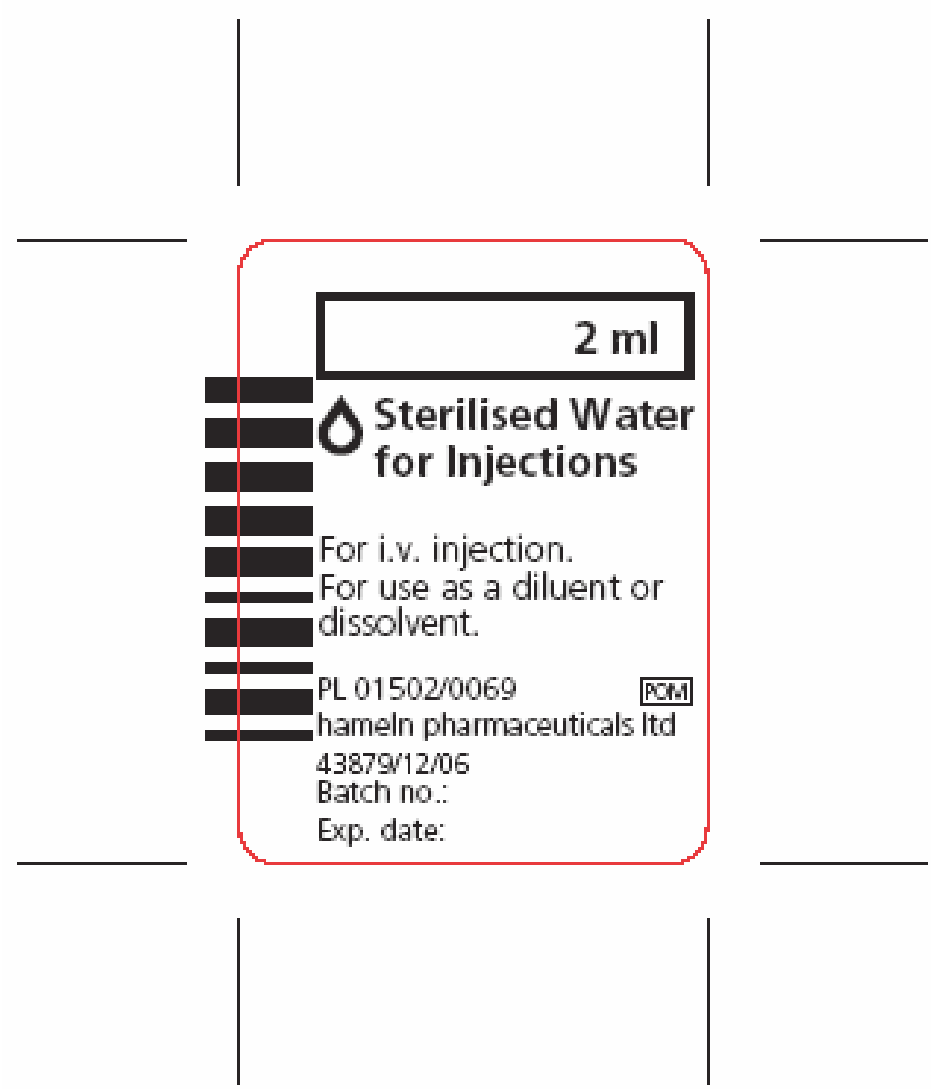
The marketing authorization holder of this medicine is:
hameln pharmaceuticals ltd
Gloucester
UK

The medicine is manufactured by:
hameln pharmaceuticals gmbh
Langes Feld 13 Hameln,
31789 Germany

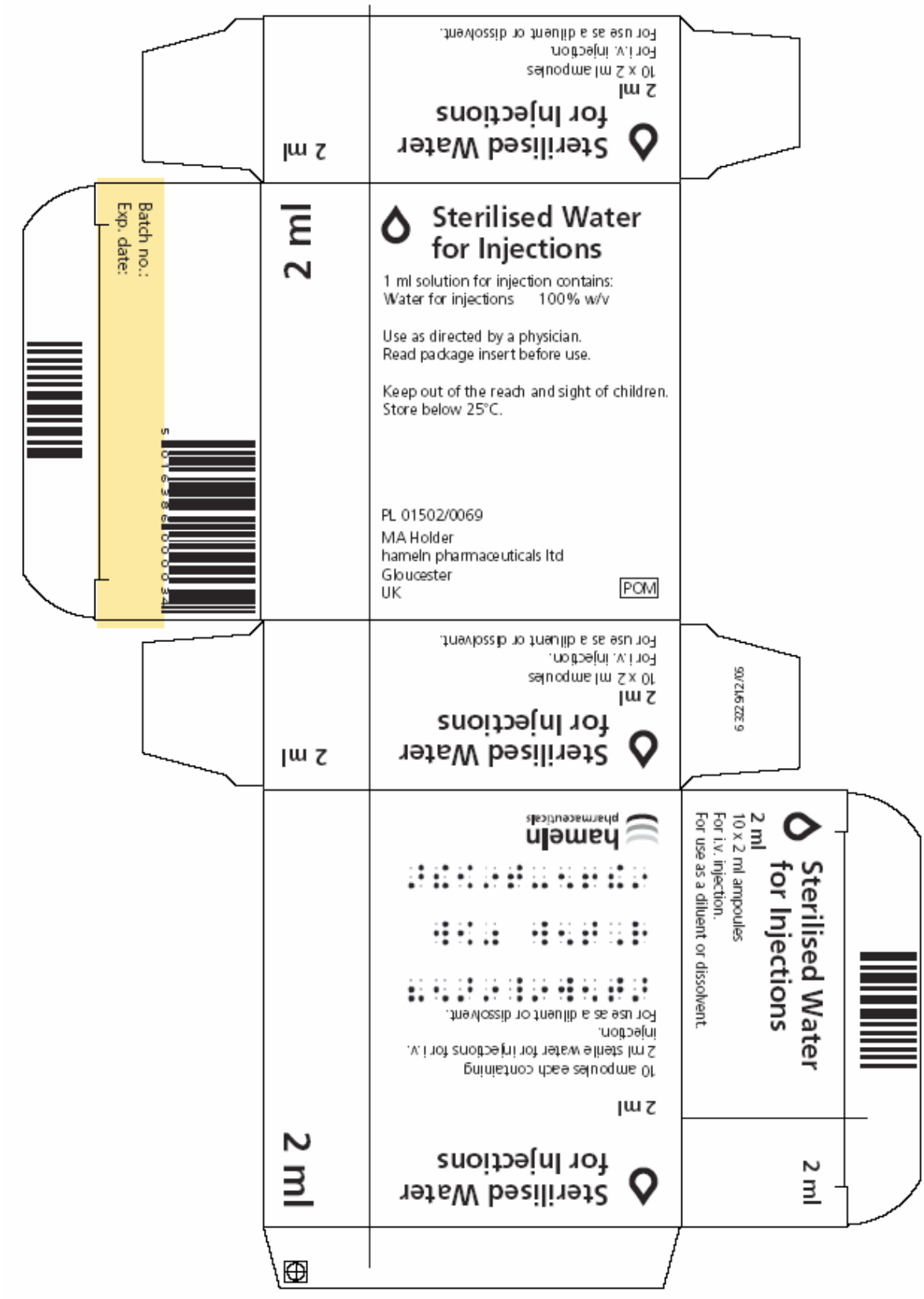
Revised March 2006

LABELLING

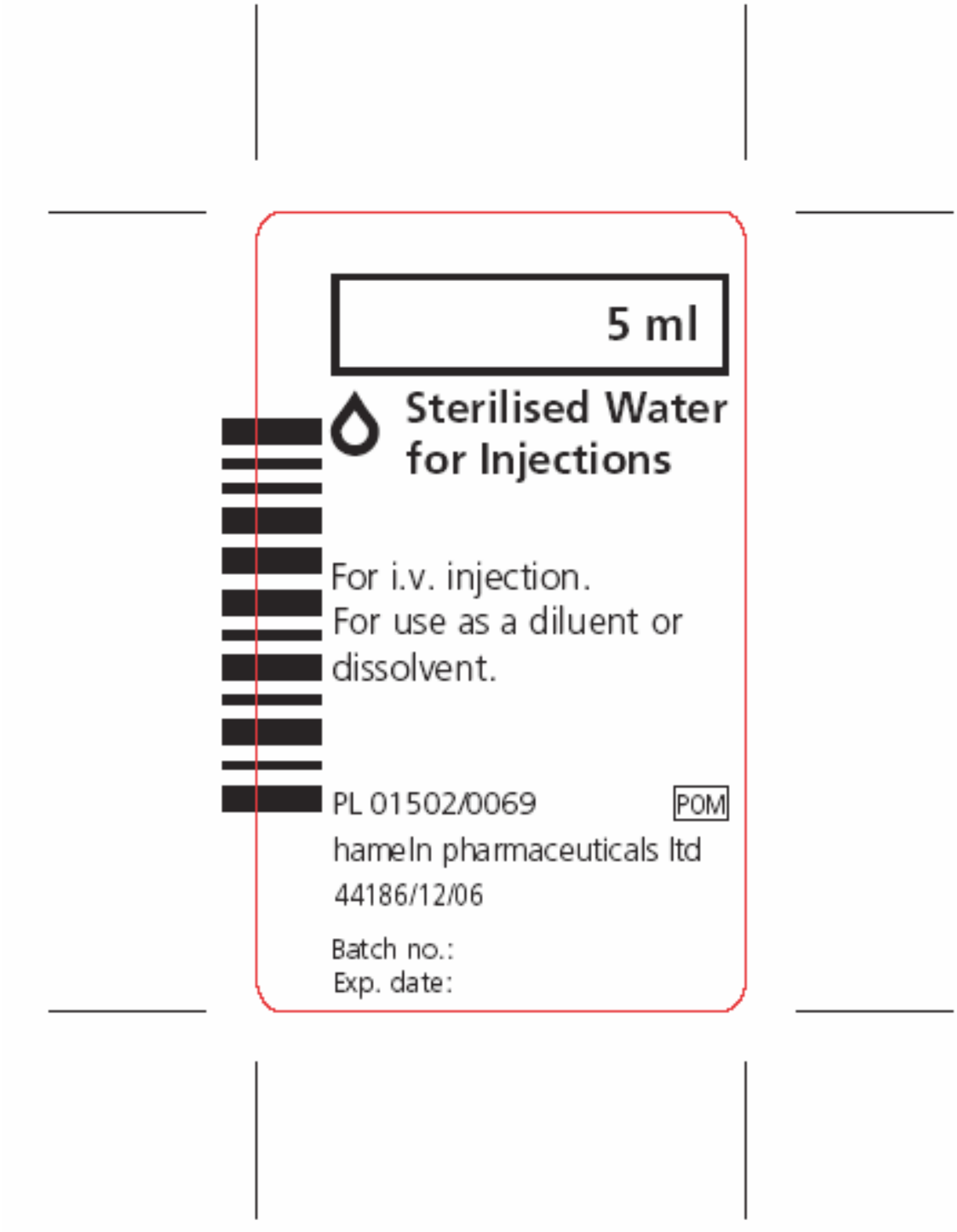
2 ml label:



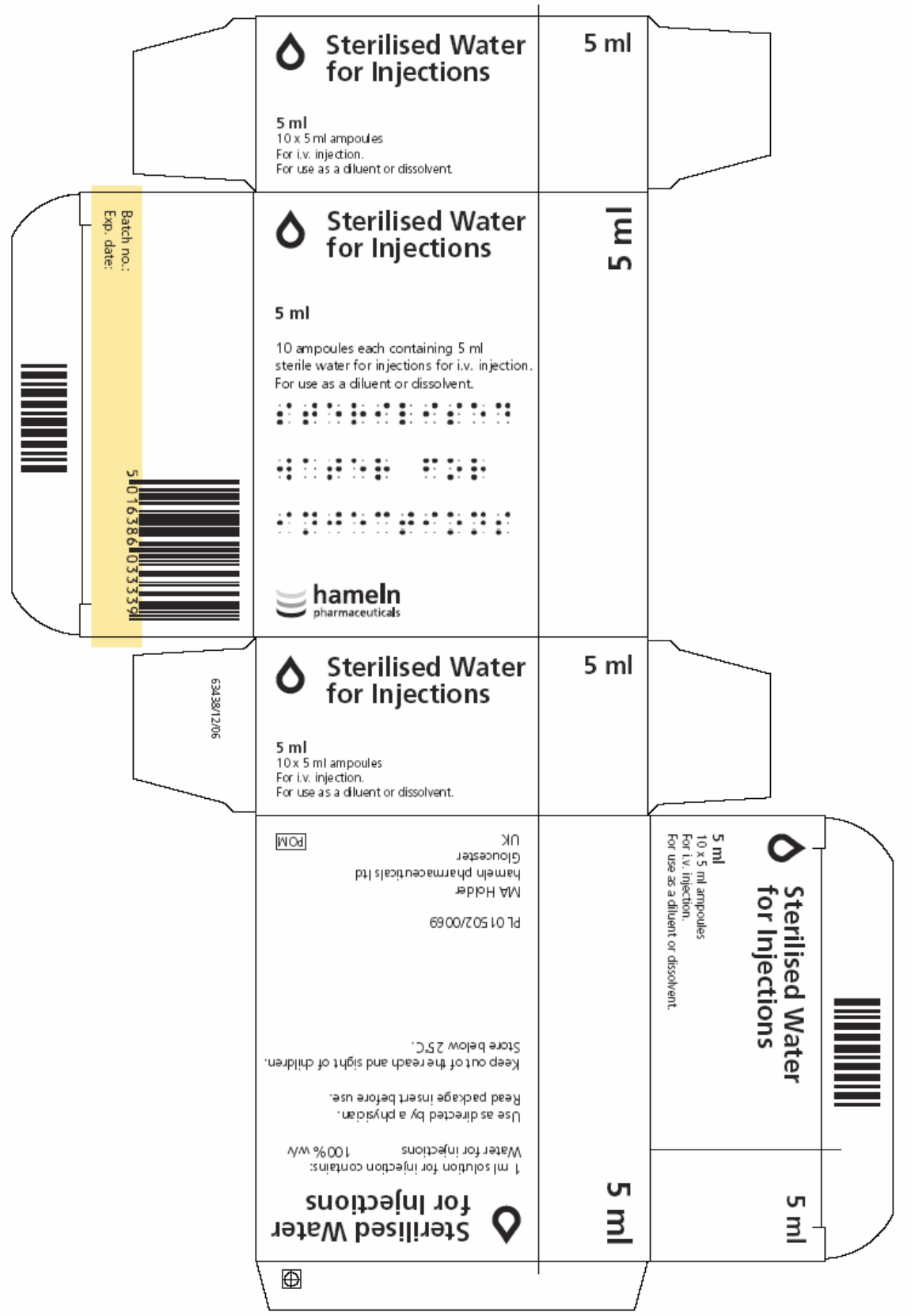
2 ml carton:


Sterilised Water for Injections
2 ml
10 ampoules each containing 2 ml sterile water for injections for i.v. injection.
For use as a diluent or dissolvent.
hameln pharmaceuticals
Sterilised Water for Injections
2 ml
10 x 2 ml ampoules
For i.v. injection.
For use as a diluent or dissolvent.
6 322 9712 /05
Sterilised Water for Injections
2 ml
1 ml solution for injection contains:
Water for injections 100% w/v
Use as directed by a physician.
Read package insert before use.
Keep out of the reach and sight of children.
Store below 25°C.
PL 01502/0069
MA Holder
hameln pharmaceuticals ltd
Gloucester
UK
POM
Batch no.:
Exp. date:
5 016388 000034
2 ml
Sterilised Water for Injections
2 ml
10 x 2 ml ampoules
For i.v. injection.
For use as a diluent or dissolvent.
2 ml
Sterilised Water for Injections
2 ml
10 x 2 ml ampoules
For i.v. injection.
For use as a diluent or dissolvent.
2 ml

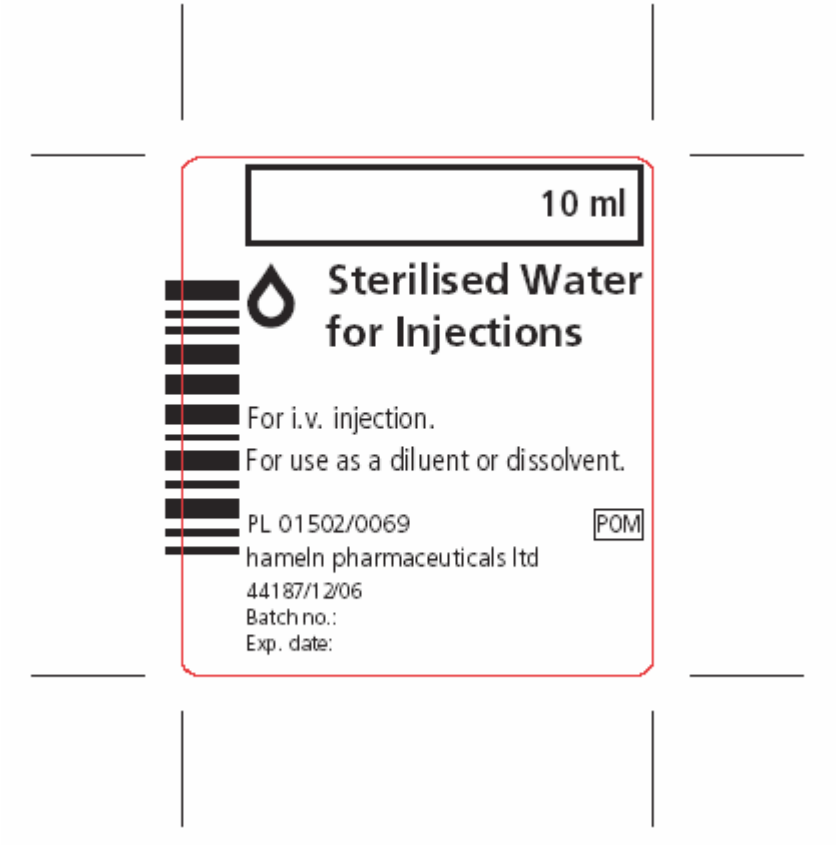
5 ml label:


5 ml
Sterilised Water for Injections
For i.v. injection.
For use as a diluent or dissolvent.
PL 01502/0069
POM
hameln pharmaceuticals ltd
44186/12/06
Batch no.:
Exp. date:

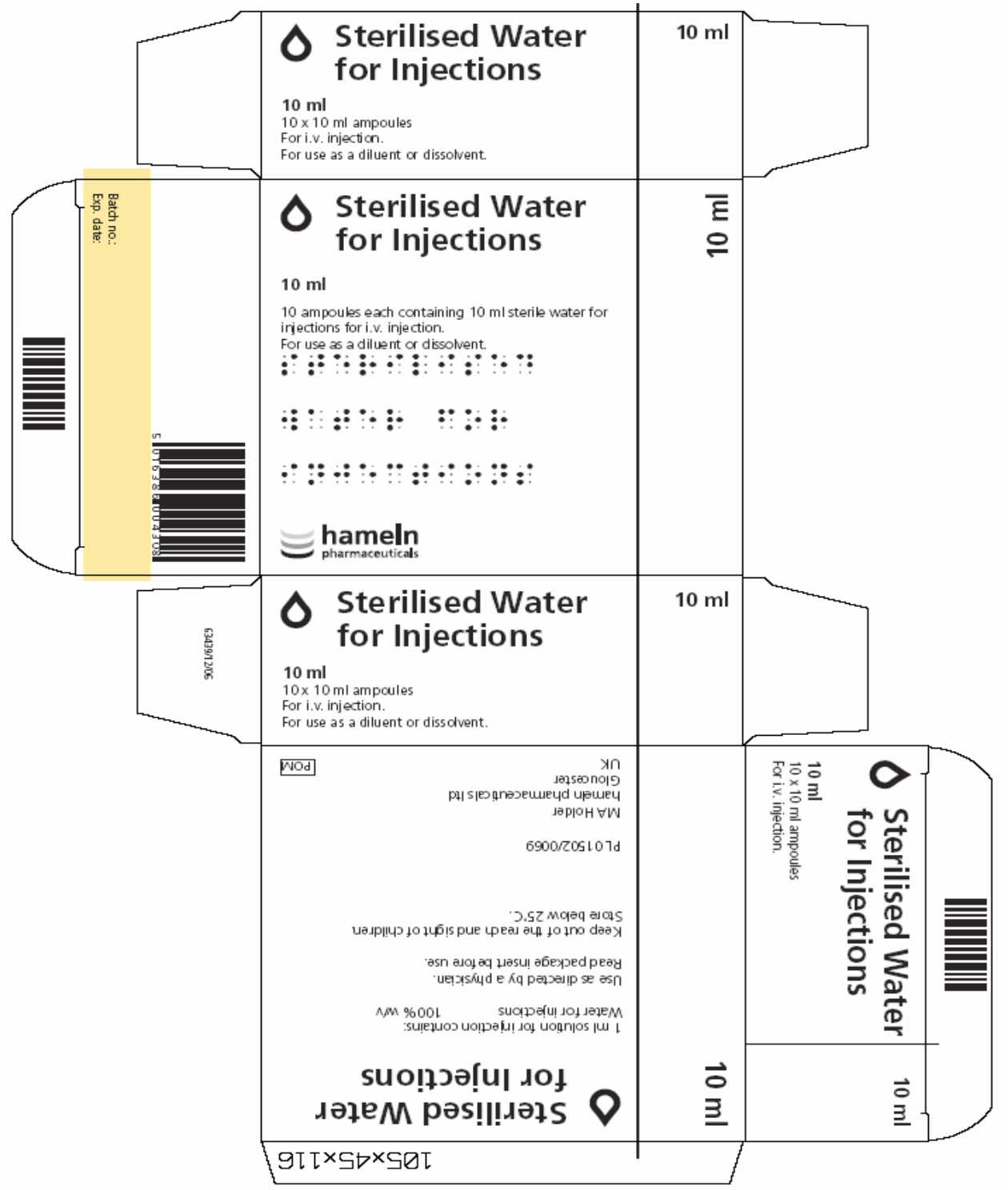
5 ml carton:


Sterilised Water for Injections
5 ml
5 ml
10 x 5 ml ampoules
For i.v. injection.
For use as a diluent or dissolvent
Batch no.:
Exp. date:
5 010386 033339
10 ampoules each containing 5 ml sterile water for injections for i.v. injection.
For use as a diluent or dissolvent.
hameln pharmaceuticals
63438/12/06
POM
UK
Gloucester
hameln pharmaceuticals ltd
MA Holder
PL 01502/0069
Keep out of the reach and sight of children.
Store below 25°C.
Use as directed by a physician.
Read package insert before use.
1 ml solution for injection contains:
Water for injections 100% w/v

10 ml label:


10 ml
Sterilised Water for Injections
For i.v. injection.
For use as a diluent or dissolvent.
PL 01502/0069
POM
hameln pharmaceuticals ltd
44187/12/06
Batch no.:
Exp. date:

10 ml carton:


Sterilised Water for Injections
10 ml
10 x 10 ml ampoules
For i.v. injection.
For use as a diluent or dissolvent.
10 ml
Batch no.:
Exp. date:
Sterilised Water for Injections
10 ml
10 ampoules each containing 10 ml sterile water for injections for i.v. injection.
For use as a diluent or dissolvent.
10 ml
hameln pharmaceuticals
Sterilised Water for Injections
10 ml
10 x 10 ml ampoules
For i.v. injection.
10 ml
POM
UK
Gloucester
hameln pharmaceuticals ltd
MA Holder
PL 01502/0069
Keep out of the reach and sight of children.
Store below 25°C.
Read package insert before use.
Use as directed by a physician.
Water for injections 100% w/v
1 ml solution for injection contains:
Sterilised Water for Injections
10 ml
10 x 10 ml ampoules
For i.v. injection.
10 ml
105x45x116