

**WATER FOR INJECTIONS
PL 14894/0344**

UKPAR

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**WATER FOR INJECTIONS
PL 14894/0344**

LAY SUMMARY

The MHRA granted Ranbaxy (UK) Ltd a Marketing Authorisation (licence) for the medicinal product Water for Injections (PL 14894/0344). This is a prescription only medicine to be used to prepare and dilute suitable medicines that require mixing with water before they are injected.

Water for Injections is a specially prepared form of distilled water. It is a clear, colourless sterile liquid and it does not contain any other ingredients.

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

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SCIENTIFIC DISCUSSION

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INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the UK granted a Marketing Authorisation for the medicinal product Water for Injections to Ranbaxy (UK) Ltd on 03 March 2008. The product is a prescription only medicine.

The product contains no active ingredient and is indicated to serve as a vehicle for dilution and reconstitution of suitable medicinal products for parenteral administration.

Water for Injections is a solvent and diluting agent.

PHARMACEUTICAL ASSESSMENT

COMPOSITION

The product is formulated as a solvent for parenteral use with no active pharmaceutical ingredient. There are no excipients present.

Water for Injections is presented in flat bottomed, transparent, Type I glass 2ml, 4ml, 5ml, 6ml, or 10ml ampoules in packs of 1, 5, and 10 ampoules.

DRUG SUBSTANCE

Not applicable.

DRUG PRODUCT

Manufacture

A full description and a detailed flow-chart of the manufacturing method including in-process control steps has been provided.

In-process controls are appropriate considering the nature of the product and the method of manufacture. Process validation has been carried out on batches of all ampoule sizes. The results are satisfactory.

Finished product specification

The proposed finished product specification is acceptable and the analytical methods used have been suitably validated. Batch analysis data have demonstrated compliance with the proposed release specification.

Container closure system

Satisfactory specifications and certificates of analysis have been provided for the packaging components.

Stability

Finished product stability data support the proposed shelf-life of 5 years with storage conditions "Do not store above 25°C."

Bioequivalence/bioavailability

Not required due to the nature of the product.

SPC, PIL and Labels

The SPC, PIL and labels are pharmaceutically acceptable.

The marketing authorisation holder has provided a commitment to update the Marketing Authorisation with a patient information leaflet (PIL) in compliance with Article 59 of Council Directive 2001/83/EC and that the leaflet shall reflect the results of consultation with target patient groups, no later than 01 July 2008.

CONCLUSION

The data provided in support of the product demonstrate compliance with regulatory and, where applicable, official standards. These demonstrate that the product can be consistently manufactured to a satisfactory standard and comply with that standard over the declared shelf-life, when stored as directed.

It is recommended that a Marketing Authorisation should be granted for this application.

PRECLINICAL ASSESSMENT

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

CLINICAL ASSESSMENT

No clinical data have been supplied with this application and none are required for a formulation of this type.

OVERALL CONCLUSION AND RISK BENEFIT ASSESSMENT

QUALITY

The important quality characteristics of Water for Injections are well defined and controlled. The specifications and batch analytical results indicate consistency from batch to batch. There are no outstanding quality issues that would have a negative impact on the benefit/risk balance.

PRECLINICAL

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

EFFICACY

Not required. The product contains no active ingredient and is intended for preparation and administration of medicines for parenteral administration.

No new or unexpected safety concerns arose from this application.

RISK BENEFIT ASSESSMENT

The quality of the product is acceptable and no new preclinical or clinical safety concerns have been identified. The risk benefit is, therefore, considered to be positive.

**WATER FOR INJECTIONS
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STEPS TAKEN FOR ASSESSMENT

- 1 The MHRA received the Marketing Authorisation application on 23 December 2004.
- 2 Following standard checks and communication with the applicant, the MHRA considered the application valid on 04 February 2005.
- 3 Following assessment of the application, the MHRA requested further information relating to the quality dossier on 19 May 2005, 13 July 2006 and 04 October 2007.
- 4 The applicant responded to the MHRA's requests, providing further information on 07 December 2005, 13 June 2007, 30 October 2007 and 08 January 2008 for the quality section.
- 5 The application was determined on 03 March 2008.

**WATER FOR INJECTIONS
PL 14894/0344**

STEPS TAKEN AFTER AUTHORISATION – SUMMARY

Date submitted	Application type	Scope	Outcome
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SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Water for Injections

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Water for Injections, each ampoule contains either 2ml, 4ml, 5ml, 6ml or 10ml.

For excipients, see 6.1

3 PHARMACEUTICAL FORM

Solvent for Parenteral use. Clear, colourless liquid.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Water for injection is indicated to serve as a vehicle for dilution and reconstitution of suitable medicinal products for parenteral administration.

4.2 Posology and method of administration

Dosage:

The dosage administered will be dictated by the nature of the additive used. The administration rate will be dependent upon the dose regimen of the prescribed drug.

Administration:

For parenteral use. The directions for use related to the added medicinal product will dictate the appropriate volumes as well as the administration route.

4.3 Contraindications

None known.

The contraindications related to the added medicinal product should be considered.

4.4 Special warnings and precautions for use

Water for injections is hypotonic and it should not be administered alone.

Do not use for intravenous injection unless adjusted to approximate isotonicity with a suitable solute.

When Water for Injections is used as diluent of hypertonic solutions, appropriate dilution should be applied to bring the solution close to isotonicity.

Haemolysis may occur following infusion of large volumes of hypotonic solutions using Water for Injections as diluent.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

The possible clinical interactions between the different medicinal products to be dissolved should be considered.

4.6 Pregnancy and lactation

May be used during pregnancy and lactation.

The risk during use in pregnancy and in lactating women are determined by the nature of the added medicinal product.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

None known. Intravenous injections of Water for Injection may cause haemolysis if Water for Injections is administered alone.

The nature of the additive will determine the likelihood of any undesirable effects.

4.9 Overdose

No effects anticipated with the proposed use.

Haemolysis may occur following infusion of large volumes of hypotonic solutions using Water for Injections as diluent.

The signs and symptoms of overdose will also be related to the nature of the medicinal product being added. In the event of accidental overdose, the treatment should be discontinued and the patient should be observed for the appropriate signs and symptoms related to the medicinal product administered.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Solvents and diluting Agents

ATC Code: V07AB

Water for Injections being only the vehicle for the administration of the added medicinal product, the pharmacodynamics will depend on the nature of the drug added.

5.2 Pharmacokinetic properties

Not applicable.

Water for Injections being only the vehicle for the administration of the added medicinal product, the pharmacokinetics will depend on the nature of the drug added.

5.3 Preclinical safety data

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

Water for Injections being only the vehicle for the administration of the added medicinal product, the preclinical safety data will depend on the nature of the drug added.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

None.

6.2 Incompatibilities

Water for injection should not be mixed with any other agents unless their compatibility has been established.

6.3 Shelf life

5 years

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Type I glass ampoule, transparent, flat bottomed. Ampoules containing 2ml, 4ml, 5ml, 6ml or 10ml ampoules in packs of 1, 5 or 10 ampoules.

Not all pack sizes may be marketed

6.6 Special precautions for disposal

No special requirements.

Discard any contents remaining in the ampoule immediately after use

7 MARKETING AUTHORISATION HOLDER

Ranbaxy (UK) Limited

20 Balderton Street,

London, W1K 6TL

United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 14894 / 0344

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

03/03/2008

10 DATE OF REVISION OF THE TEXT

03/03/2008

PATIENT INFORMATION LEAFLET



PATIENT INFORMATION LEAFLET

Water for Injections.

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 is Water for Injections and what is it used for?**
- 2. Before you use Water for Injections**
- 3. How to use Water for Injections**
- 4. Possible side effects**
- 5. Storing Water for Injections**

1. What is Water for Injections and what is it used for?

Water for Injections is a specially prepared form of distilled water. It is a clear, colourless sterile liquid and it does not contain any other ingredients.

Water for injections is available in 2ml, 4ml, 5ml, 6ml and 10ml ampoules, in packs of 1, 5 or 10. Not all pack sizes are marketed.

Marketing authorisation holder:

Ranbaxy (UK) Limited,
20 Balderton Street London
W1K 6TL,
United Kingdom

Manufacturer: **Laboratory Reig Jofre,**
Gran Capita, 10-08970 Sant Joan Despi,
Barcelona,
Spain

Water for Injections is called a diluent because its main use is for diluting and preparing medicines before use.

Water for Injections is used to prepare and dilute suitable medicines that require mixing with water before they are injected.

2. Before you use Water for Injections

The contents of the ampoules should be examined before use to ensure that the liquid is clear and is not discoloured in any way.

Do not use Water for injections

- The contraindications related to the added medicinal product should be considered.
- Do not use for intravenous injection unless adjusted to approximate isotonicity with a suitable solute.

Take special care with Water for Injections:

- Water for injections should not be administered alone.
- When large volumes are given, the ionic balance should be monitored
- Water for Injections may cause degradation of red blood cells (haemolysis) if given alone or as a hypotonic solution

Taking other medicines

Water for Injections is not known to interact with other medicinal products.

Pregnancy and breast-feeding

Water for Injections may be used during pregnancy and breast-feeding. The risk during use in pregnancy and breast-feeding are determined by the nature of the added medicinal product.

3. How to use Water for Injections

In the preparation of the medicine for use, the required volume of Water for Injections will vary, depending on the medicine to which it is added. The method of administration is intravenous or intramuscular, depending on the medication to which it is added.

If you take more medicine than you should:

It is most unlikely that you will be given too much medicine by the nurse or doctor. Your doctor and nurse will be monitoring your progress, and checking the medicine that you are given. The signs and symptoms of overdose will be related to the nature of the medicinal product being added. Always ask if you are not sure why you are getting a dose of medicine.

If you forget to take your medicine:

Your doctor or nurse have instructions when to give you your medicine. It is most unlikely that you will not be given the medicine as it has been prescribed. If you think that you may have missed a dose then talk to your nurse or doctor. It is important that the course of treatment your doctor has prescribed is taken. You may start to feel better but it is important not to

stop taking this medicine, until the doctor advises, otherwise your condition may get worse again.

4. Possible side effects

Water for Injections has no known side effects. Intravenous injections of Water for Injection may cause harm if administered alone.

The nature of the additive will determine the likelihood of any undesirable effects. To understand the possible side effects of the medicine you are taking with Water for Injections consult the Patient Information Leaflet of the medicine or ask your doctor or nurse.

5. Storing Water for Injections

The ampoules should not be used after the expiry date printed on the labelling.

Do not store above 25°C.

Do not use if the ampoule is damaged or if the contents are discoloured.

Keep any medicine out of the reach and sight of children.

If only part used, discard the remaining solution.

REMEMBER this medicine is for you. Only a doctor can prescribe it for you. Never give it to others. It may harm them even if their symptoms are the same as yours.

Further information:

You can get more information on Water for Injections from your doctor or pharmacist.

Date of revision January 2008

LABELLING







Water for Injections.

Each ampoule contains 2 ml

Water for Injections.

For Intramuscular or
Intravenous injection only. **POM**

BN:

Exp:

Water for Injections.

Each ampoule contains 5 ml

Water for Injections.

For Intramuscular or
Intravenous injection only. **POM**

BN:

Exp:

Water for Injections. **POM**

Each ampoule contains 10 ml

Water for Injections.

For Intramuscular or
Intravenous injection only. BN:

Exp: