Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Water for Injections

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml contains 1 ml of Water for Injections
For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solvent for parenteral use.
Clear, colourless solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Sterile 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

Posology
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. Following suitable admixture of prescribed additives, the dosage is usually dependent upon the age, weight and clinical condition of the patient as well as laboratory determinations.

Method of Administration
The solution is for dilution and delivery of the therapeutic additives. The directions for use related to the added medicinal product will dictate the appropriate volumes as well as the administration route.

4.3 Contraindications

Water for Injections should not be administered alone.
The contra-indications related to the added medicinal product should be considered.

4.4 Special warnings and precautions for use

Water for Injections is hypotonic and 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.
Hemolysis may occur following infusion of large volumes of hypotonic solutions using sterile Water for Injections as diluent.
When administering large volumes, the ionic balance should be regularly monitored.
The large volume presentations (500 and 1000ml) are for use as a bulk source of diluent in pharmacy compounding. They are not for direct intravenous administration.

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 Fertility, pregnancy and lactation

The risks during use in pregnancy and in lactation women are determined by the nature of the added medicinal products.

4.7 Effects on ability to drive and use machines

Not relevant.

4.8 Undesirable effects

Intravenous injections of water for injections may cause haemolysis if Water for Injections is administered alone. The nature of the additive will determine the likelihood of any other undesirable effects.

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2. Tel: +353 1 6764971. Fax: +353 1 6762517. Website: www.hpra.ie; e-mail: medsafety@hpra.ie.

4.9 Overdose

Haemolysis may occur following infusion of large volumes of hypotonic solutions using sterile 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: VO7AB

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

5.2 Pharmacokinetic properties

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

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

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

None.

6.2 Incompatibilities

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

6.3 Shelf life

Unopened: 3 years
Upon opening, use immediately and discard any used contents.

6.4 Special precautions for storage

Do not store above 25^{o}C.

6.5 Nature and contents of container

5 ml or 10 ml hermetically sealed translucent polypropylene Ph. Eur. plastic ampoules, packed in cardboard cartons to contain 10, 20, 50 and 100 ampoules.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

Any unused product or waste material should be disposed of in accordance with local requirements.
If only part of ampoule is used, discard the remaining solution.

7 MARKETING AUTHORISATION HOLDER

Mercury Pharmaceuticals (Ireland) Ltd
4045 Kingswood Road
Citywest Business Park
Co Dublin
Ireland

8 MARKETING AUTHORISATION NUMBER

PA0073/107/007

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 08 August 1991

Date of last renewal: 08 August 2006

10 DATE OF REVISION OF THE TEXT

January 2016