Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Water for Injections Ph. Eur., viaflo container.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each bag contains 100 % w/v Water for Injections.

3 PHARMACEUTICAL FORM

Solvent for parenteral use.

Clear and Colourless solution.

pH between 4.5 and 7.0.

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 contraindications 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.

Haemolysis may occur following infusion of Sterile Water for Injections. Haemoglobin induced renal failure has been reported following haemolysis.

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

No interaction studies have been performed.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 lactating 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

The following adverse reactions have been reported in post-marketing experience. The frequency of the adverse drug reactions listed in this section cannot be estimated from the available data.

ADVERSE REACTIONS		
System Organ Class (SOC)	MedDRA Preferred Term	*Frequency*
Blood and lymphatic system disorders	- haemolysis	Not known

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 over-infusion of hypotonic solutions using sterile water for injections as diluent (see 4.4 Warnings and Precautions).

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 medicinal product, 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 administration 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

Additives may be incompatible. Those additives known to be incompatible should not be used.

Before adding drugs, verify:

- They are soluble and stable in water at the pH of Water for Injections.
- They are compatible with each other.

6.3 Shelf life

Shelf life as packaged:
50 ml bag: 18 months.
100 ml bag: 2 years.
250, 500 and 1000 ml bags: 3 years.

In-use shelf life: Additives

Chemical and physical stability of any additive at the pH of Water for Injections in the Viaflo container should be established prior to use.

From a microbiological point of view, the diluted product must be used immediately unless dilution has taken place in controlled and validated aseptic conditions. If not used immediately, in-use storage times and conditions are the responsibility of the user.

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

Bag sizes: 50, 100, 250, 500 and 1000mL. (Not all pack sizes may be marketed).

The bags known as Viaflo are composed of polyolefin/polyamide co-extruded plastic (PL-2442).

The bags are overwrapped with a protective plastic pouch composed of polyamide/polypropylene.

Outer carton contents:

50 bags of 50 ml
50 bags of 100 ml
30 bags of 250 ml
20 bags of 500 ml
10 bags of 1000 ml

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

Discard after single use.

Discard any unused portion.

Do not reconnect partially used bags.

Do not remove unit from overwrap until ready for use. The inner bag maintains the sterility of the product.

Use only if the solution is clear without visible particles and container undamaged. In case an infusion set has been inserted, administer immediately.

Thorough and careful aseptic mixing of any additive is mandatory.

Make the infusion isotonic prior to parenteral administration.

The following (technical caused) filling volumes should be considered during preparation of the final solution:

59 ml	for the 50ml container
111ml	for the 100ml container
271ml	for the 250ml container
530 ml	for the 500ml container
1040ml	for the 1000ml container

Additives may be introduced before administration or during administration through the resealable medication port.

Solutions containing additives should be used immediately after preparation unless preparation has taken place in controlled and validated aseptic conditions.

Do not use plastic containers in series connections. Such use could result in air embolism due to residual air being drawn from the primary container before the administration of the fluid from the secondary container is completed.

To open

Check for minute leaks by squeezing inner bag firmly. If leaks are found, discard solution, as sterility may be impaired.

Preparation for administration after rendering isotonic

1. Suspend container from eyelet support.
2. Remove plastic protector from outlet port at bottom of container.
3. Use an aseptic method to set up the infusion.
4. Attach administration set. Refer to complete directions accompanying set.

Warning: Additives may be incompatible.

To add medicinal products before administration

1. Disinfect medication site.
2. Using syringe with 19 gauge (1.10 mm) to 22 gauge (0.70 mm) needle, puncture resealable medication port and

inject.
3. Mix solution and medication thoroughly. For high-density medication such as potassium chloride, tap the ports gently while ports are upright and mix.

To add medicinal products during administration

1. Close clamp on the set.
2. Disinfect medication site.
3. Using syringe with 19 gauge (1.10 mm) to 22 gauge (0.70 mm) needle, puncture resealable medication port and inject.
4. Remove container from IV pole and/or turn to an upright position.
5. Evacuate both ports by tapping gently while the container is in an upright position.
6. Mix solution and medication thoroughly.
7. Return container to in use position, re-open the clamp and continue administration.

7 MARKETING AUTHORISATION HOLDER

Baxter Healthcare Ltd.
Caxton Way, Thetford
Norfolk IP24 3SE
United Kingdom

8 MARKETING AUTHORISATION NUMBER

PA 0167/065/004

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 3rd May 2002

Date of last renewal: 9th January 2006

10 DATE OF REVISION OF THE TEXT

October 2015