Summary of Product Characteristics

1. Name of the Medicinal Product

Bacteriostatic Water for Injections USP

2. Quality and Quantitative Composition

Each vial contains water for injection and benzyl alcohol 0.9% w/v added as a bacteriostatic preservative.

3. Pharmaceutical Form

Solvent for parenteral use

4. Clinical Particulars

4.1 Therapeutic indication:

The product is intended as a diluent for Powder for Injection.

Reference 1: The electronic Medicines Compendium (eMC), Bacteriostatic Water for Injection.

4.2 Posology and method of administration:

This parenteral preparation is indicated only for diluting or dissolving drugs for intravenous, intramuscular or subcutaneous injection, according to instructions of the medicines to be administered.

Use aseptic technique for single or multiple entry and withdrawal from all containers.

When diluting or dissolving medicines mix thoroughly and use promptly.

Reference 2: Package insert, Bacteriostatic Water for Injection, Hospira Inc., USA

4.3 Contraindications

Hypersensitivity to benzyl alcohol.

Due to the potential toxicity of benzyl alcohol in neonates, solutions containing benzyl alcohol must not be used in this patient population.

Parenteral preparations with benzyl alcohol should not be used for fluid replacement.

Parenteral preparations containing benzyl alcohol should not be used in epidural or spinal anesthesia procedures.

Parenteral preparations containing 0.9% benzyl alcohol should not be used in patients more than 30 mL a day.

Bacteriostatic Water for Injection USP must be made approximately isotonic prior to use.

Reference 1: The electronic Medicines Compendium (eMC), Bacteriostatic Water for Injection.

Reference 2: Package insert, Bacteriostatic Water for Injection, Hospira Inc., USA

4.4 Special warnings and precautions for use

The solvent contains the preservative benzyl alcohol, which may cause anaphylactoid reactions.

Intravenous administration of the preservative benzyl alcohol has been associated with serious adverse events, and death in paediatric patients including neonates characterized by central nervous system depression, metabolic acidosis, gasping respirations, cardio-vascular failure and hematological anomalies (“gasping syndrome”). The minimum amount of benzyl alcohol at which toxicity may occur is not known. Use only if it is necessary and if there are no alternatives

possible. If given in high volumes, should be used with caution and preferably for short term treatment in subjects with liver or kidney impairment because of the risk of accumulation and toxicity (metabolic acidosis).

Premature and low-birth weight infants may be more likely to develop toxicity.

Benzyl alcohol containing products should not be used in pre-term or full-term neonates unless strictly necessary because of the risk of severe toxicity including abnormal respiration ("gasping syndrome").

Benzyl alcohol can cross the placenta and has the potential for toxicity in the newborn. Medicines containing benzyl alcohol should therefore be avoided in pregnant women at or near term (see section 4.6).

Warnings based on Thai Ministry of Public Health Announcement

Do not use in children under 2 year old.

Reference 1: The electronic Medicines Compendium (eMC), Bacteriostatic Water for Injection.

4.5 Interaction with other medicinal products and other forms of interactions

Some medicines for injection may be incompatible in a given vehicle, or when combined in the same vehicle or in a vehicle containing benzyl alcohol. Consult with pharmacist, if available.

Reference 2: Package insert, Bacteriostatic Water for Injection, Hospira Inc., USA

4.6 Pregnancy and lactation

Pregnancy: Animal reproduction studies have not been conducted with Bacteriostatic Water for Injection. It is also not known whether Bacteriostatic Water for Injection containing additives can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Bacteriostatic Water for Injection USP containing additives should be given to pregnant woman only if clearly needed.

Pediatric Use: The safety and effectiveness of Bacteriostatic Water for Injection USP have not been established in pediatric patients. Due to the potential for toxicity, solutions containing benzyl alcohol should not be used in neonates.

Reference 2: Package insert, Bacteriostatic Water for Injection, Hospira Inc., USA

4.7 Effects on ability to drive and use machines

None stated.

Reference 1: The electronic Medicines Compendium (eMC), Bacteriostatic Water for Injection.

4.8 Undesirable effects

Reactions which may occur because of this solution, added medicines or the technique of reconstitution or administration include febrile response, local tenderness, abscess, tissue necrosis or infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection and extravasation.

If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate countermeasures, and if possible, retrieve and save the remainder of the unused vehicle for examination.

Although adverse reactions to intravenous, intramuscular or subcutaneous injection of 0.9% benzyl alcohol are not known to occur in man, experimental studies of small volume parenteral preparations containing 0.9% benzyl alcohol

in several species of animals have indicated that an estimated intravenous dose up to 30 mL may be safely given to an adult without toxic effects. Administration of an estimated 9 mL to a 6 kg infant or neonate is potentially capable of producing blood pressure changes.

Reference 2: Package insert, Bacteriostatic Water for Injection, Hospira Inc., USA

4.9 Overdose

Use only as a diluent or solvent. This parenteral preparation is unlikely to pose a threat of fluid overload except possibly in very small infants. In the event these should occur, re-evaluate the patient and institute appropriate corrective measures. (see section 4.4 and 4.8)

Reference 2: Package insert, Bacteriostatic Water for Injection, Hospira Inc., USA

5. Pharmacological properties

5.1 Pharmacodynamic properties

Water is an essential constituent of all body tissues and accounts for approximately 70% of total body weight. Average normal adult daily requirement ranges from two to three liters (1.0 to 1.5 liters each for insensible water loss by perspiration and urine production).

Water balance is maintained by various regulatory mechanisms. Water distribution depends primarily on the concentration of electrolytes in the body compartments and sodium (Na^+) plays a major role in maintaining physiologic equilibrium.

The small volume of fluid provided by Bacteriostatic Water for Injection USP when used only as a pharmaceutic aid for diluting or dissolving medicines for parenteral injection, is unlikely to exert a significant effect on fluid balance except possibly in very small infants.

Reference 2: Package insert, Bacteriostatic Water for Injection, Hospira Inc., USA

5.2 Pharmacokinetic properties

None stated.

Reference 1: The electronic Medicines Compendium (eMC), Bacteriostatic Water for Injection.

5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of this Summary of Product Characteristics.

Reference 1: The electronic Medicines Compendium (eMC), Bacteriostatic Water for Injection.

6. Pharmaceutical Particulars

6.1 List of excipients

Benzyl alcohol

Water for injection

6.2 Incompatibilities: Some medicines for injection may be incompatible in a given vehicle. (see section 4.5)

6.3 Shelf life: 2 years

6.4 Special precautions for storage

Store below 30° C

6.5 Nature and contents of container

Clear glass vial (Type I) size 2, 3, 5, 7.8, 8, 10, 15, 15.6, 16, 20, 30, 31.2, 32, 40 mL with chlorobutyl rubber stopper, sealed with aluminium/polypropylene flip-off cap, packed or unpacked in a box of 1, 2, 5, 6, 10, 12, 15, 20, 30, 50 and 100 vials.

6.6 Special precaution for storage

Do not store reconstituted solutions of medicines for injection unless otherwise directed by the manufacturer of the solute.

Do not use unless the solution is clear and seal intact.

7. Marketing Authorization Holder

ABLE MEDICAL COMPANY LIMITED

111 Moo. 9 Nong Son, Chiang Yuen,

Mahasarakham 44160, Thailand

8. Marketing Authorization Numbers

xx xxx/xx

9. Date of authorization

DD/MM/YYYY

10. Date of revision of the text

DD/MM/YYYY