Summary of Product Characteristics

1. Name of the Medicinal Product

Bacteriostatic 0.9% Sodium Chloride Injection USP

2. Quality and Quantitative Composition

Each vial contains sodium chloride, 0.9% w/v.

Excipient(s) with known effect

Each vial contains benzyl alcohol, 0.9% w/v.

For the full list of excipients, see section 6.1.

3. Pharmaceutical Form

Solvent for parenteral use

4. Clinical Particulars

4.1 Therapeutic indication:

These parenteral preparations are indicated only for diluting or dissolving drugs for intravenous, intramuscular or subcutaneous injection, according to instructions of the manufacturer of the drug to be administered.

Reference 2: Package insert, Bacteriostatic Sodium Chloride Injection, USP, Fresenius Kabi, USA

4.2 Posology and method of administration:

NOT FOR INHALATION.

Before Bacteriostatic 0.9% Sodium Chloride Injection USP is used as a vehicle for the administration of a drug, specific references should be checked for any possible incompatibility with sodium chloride or benzyl alcohol.

The volume of the preparation to be used for diluting or dissolving any drug for injection is dependent on the vehicle concentration, dose and route of administration as recommended.

Isotonic solutions may be given subcutaneously, intravenously, and occasionally, intramuscularly.

Use Bacteriostatic 0.9% Sodium Chloride Injection USP with due regard for the compatibility of the benzyl alcohol it contains with the particular medicinal substance that is to be dissolved or diluted.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

Reference 2: Package insert, Bacteriostatic Sodium Chloride Injection, USP, Fresenius Kabi, USA

4.3 Contraindications

Due to potential toxicity of benzyl alcohol in newborns, Bacteriostatic 0.9% Sodium Chloride Injection USP containing benzyl alcohol must not be used in this patient population.

Bacteriostatic 0.9% Sodium Chloride Injection USP should not be for fluid or sodium chloride replacement.

Parenteral preparation containing 0.9% benzyl alcohol should not be used in patient more than 30 ml a day.

Reference 2: Package insert, Bacteriostatic Sodium Chloride Injection, USP, Fresenius Kabi, USA

4.4 Special warnings and precautions for use

Benzyl alcohol as a preservative in Bacteriostatic 0.9% Sodium Chloride Injection USP has been associated with toxicity in newborns. Data is unavailable on the toxicity of other preservatives in this age group. Preservative-free Sodium Chloride Injection, USP, 0.9% should be used for flushing intravascular catheters. Where a sodium chloride solution is required for preparing or diluting medications for use in newborns, only preservative-free Sodium Chloride Injection, USP, 0.9% should be used.

PRECAUTIONS

General

Bacteriostatic 0.9% Sodium Chloride Injection USP should not be used for those medicinals that specify the use of only Sodium Chloride Injection, USP, 0.9% as a sterile solvent.

Sodium chloride must be used with caution in the presence of congestive heart failure, circulatory insufficiency, kidney dysfunction or hypoproteinemia.

Excessive amounts of sodium chloride by any route may cause hypopotassemia and acidosis. Excessive amounts by the parenteral route may precipitate congestive heart failure and acute pulmonary edema, especially in patients with cardiovascular disease and in patients receiving corticosteroids or corticotropin or drugs that may give rise to sodium retention.

Warnings based on Thai Ministry of Public Health Announcement

Do not use in children under 2 year old.

Reference 2: Package insert, Bacteriostatic Sodium Chloride Injection, USP, Fresenius Kabi, USA

4.5 Interaction with other medicinal products and other forms of interaction

Not applicable.

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

4.6 Pregnancy and lactation

Animal reproduction studies have not been conducted with Bacteriostatic 0.9% Sodium Chloride Injection USP. It is also not known whether Bacteriostatic 0.9% Sodium Chloride Injection USP can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Bacteriostatic 0.9% Sodium Chloride Injection USP should be given to a pregnant woman only if clearly needed.

Reference 2: Package insert, Bacteriostatic Sodium Chloride Injection, USP, Fresenius Kabi, USA

4.7 Effects on ability to drive and use machines

Not applicable.

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

4.8 Undesirable effects

Benzyl alcohol is contained in the diluent and has been reported to be associated with a fatal "gasping syndrome" in premature infants.

Reaction which may occur because of Bacteriostatic 0.9% Sodium Chloride Injection USP, added drugs 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 is potentially capable of producing blood pressure changes.

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

Reference 2: Package insert, Bacteriostatic Sodium Chloride Injection, USP, Fresenius Kabi, USA

4.9 Overdose

Use only as a diluent or solvent. This parenteral preparation is unlikely to pose a threat of sodium chloride or fluid overload except possibly in very small infants. In the event these should occur, reevaluate the patient and institute appropriate corrective measures.

Reference 2: Package insert, Bacteriostatic Sodium Chloride Injection, USP, Fresenius Kabi, USA

5. Pharmacological properties

5.1 Pharmacodynamic properties

Sodium chloride in water dissociates to provide sodium (Na^+) and chloride (Cl^-) ions. These ions are normal constituents of the body fluids (principally extracellular) and are essential for maintaining electrolyte balance.

The distribution and excretion of sodium (Na^+) and chloride (Cl^-) are largely under the control of the kidney which maintains a balance between intake and output.

The small volume of fluid and amount of sodium chloride provided by Bacteriostatic 0.9% Sodium Chloride Injection USP, when used only as a vehicle for parenteral injection of drugs, is unlikely to exert a significant effect on fluid and electrolyte balance except possibly in very small infants.

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 to 1.5 liters each of 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.

Reference 2: Package insert, Bacteriostatic Sodium Chloride Injection, USP, Fresenius Kabi, USA

5.2 Pharmacokinetic properties

Not applicable.

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

6. Pharmaceutical Particulars

6.1 List of excipients

Benzyl alcohol

Water for injection

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years

6.4 Special precautions for storage

Store below 30°C. Discard any remaining solution after use.

6.5 Nature and contents of container

Clear glass vial (Type I) size 2, 3, 5, 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, 3, 6, 10, 12, 15, 20, 30, 50 and 100 vials.

6.6 Special precaution for storage

No special requirements.

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