Summary of Product characteristic

TOP BALANCE SALT SOLUTION (Multiple Electrolytes Injection Type 1)

1. Name of the Medicinal Product

TOP Balance salt solution (Multiple electrolyte injection Type 1)

2. Quality and Quantitative Composition

Each 100 ml contains

Sodium chloride	0.526 g.
Sodium gluconate	0.502 g.
Sodium acetate trihydrate	0.368 g.
Potassium chloride	0.037 g.
Magnesium chloride hexahydrate	0.030 g.

Packaging size / **Electrolyte**	**1000 ml**
Na+	140 mEq
K+	5 mEq
Mg2+	3 mEq
Cl-	98 mEq
Acetate-	27 mEq
Gluconate	23 mEq

For the full list of excipients, see section 6.1

3. Pharmaceutical Form

Sterile solution for parenteral use

4. Clinical Particulars

4.1 Therapeutic indication

TOP Balance salt solution is indicated as a source of water and electrolytes or as an alkalinizing agent.

4.2 Posology and method of administration

The choice of product, dosage, volume, rate, and duration of administration is dependent upon the age, weight and clinical condition of the patient and concomitant therapy, and administration should be determined by a physician experienced in intravenous fluid therapy.

TOP Balance salt solution is administer by intravenous infusion.

4.3 Contraindication

TOP Balance salt solution is contraindicated in patients with a known hypersensitivity to the product.

4.4 Special warning and precautions for use

TOP Balance salt solution must be use with special warning in following conditions

1. Acidosis : TOP Balance salt solution is not for use for the treatment of lactic acidosis or severe metabolic acidosis in patients with severe liver and/or renal impairment.

2. TOP Balance salt solution can cause electrolyte disturbances such as overhydration, and congested states, including pulmonary congestion and edema.

3. Carefully use in patients with alkalosis or at risk for alkalosis

4. Carefully use in patients whom at risk in electrolyte imbalance

4.1 Patients with or predisposed to hypermagnesemia, including patients with severe renal impairment and those patients receiving magnesium therapy (e.g., treatment of eclampsia and myasthenia gravis).

4.2 With conditions predisposing to hyperkalemia and/or associated with increased sensitivity to potassium, such as patients with severe renal impairment, acute dehydration, extensive tissue injury or burns, certain cardiac disorders such as congestive heart failure.

4.3 Hypernatremia may occur with TOP Balance salt solution. Conditions that may increase the risk of hypernatremia, fluid overload and edema (central and peripheral), include patients with: primary hyperaldosteronism, secondary hyperaldosteronism and pre-eclampsia.

5. Hypersensitivity and infusion reactions when administration with any intravenous infusion.

6. Patients with renal impairment (administration of TOP Balance salt solution may result in sodium and/or potassium or magnesium retention.)

4.5 Interaction with other medicinal products and other forms of interaction

1. Avoid use of TOP Balance salt solution in patients receiving such products, such as corticosteroids or corticotropin.

2. Drugs with pH Dependent Renal Elimination. Due to its alkalinizing effect, renal clearance of acidic drugs may be increased while renal clearance of alkaline drugs may be decreased.

3. Renal clearance of lithium may be increased.

4. Patients receiving products that can cause hyperkalemia or increase the risk of hyperkalemia, such as potassium sparing diuretics, ACE inhibitors, angiotensin II receptor antagonists, or the immunosuppressants tacrolimus and cyclosporine.

4.6 Pregnancy and lactation

It is not known whether this drug can cause fatal harm to a pregnant woman or excreted in human milk.

4.7 Effects on ability to drive and use machines

Not applicable

4.8 Undesirable effects

- Hypersensitivity and Infusion Reactions: tachycardia, chest pain, chest discomfort, dyspnea, flushing, hyperemia, asthenia, pyrexia, hypotension, wheezing, urticaria, cold, sweat, chills.

- General Disorders and Administration Site Conditions: infusion site pain, burning sensation.

- Metabolism and nutrition disorders: hyperkalemia, hyponatremia.

- Nervous System Disorders: hyponatremic encephalopathy.

4.9 Overdose

- May cause fluid overload with a risk of edema (peripheral and/or pulmonary), particularly when renal sodium excretion is impaired.

- Hypernatremia and hyperkalemia, especially in patients with severe renal impairment.

- Hypermagnesemia.

- Metabolic alkalosis with or without hypokalemia and decreased ionized serum calcium and magnesium concentrations.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Acetate and gluconate are using Hydrogen ion for bicarbonate-producing to eliminate Carbon dioxide and water as alkalinizing agents.

5.2 Pharmacokinetic properties

Not applicable

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.

6. Pharmaceutical Particulars

6.1 List of excipients

- Hydrochloric acid
- Sodium hydroxide
- Water

6.2 Incompatibilities

Not applicable

6.3 Shelf life

24 months

6.4 Special precautions for storage

This medicinal product does not required any special condition for storage. Generally, this product have to store below 30°C

6.5 Nature and contents of container

The bags are composed with polypropylene plastic soft bag and the bag size is 1000 ml.

7. Marketing authorisation holder

Thai Otsuka Pharmaceutical Co.,Ltd.

50-50/1 Moo 8, Sethakij 1 Road, Khlong Madua, Kra Tum Ban, Samutsakorn, 74110, Thailand.

8. Marketing authorisation number(s)

xx xxx/xx

9. Date of first authorisation/renewal of the authorization

DD MM YYYY

10. Date of revision of the text

DD MM YYYY