

# SUMMARY OF PRODUCT CHARACTERISTICS

## 1 NAME OF THE MEDICINAL PRODUCT

Ringer's Solution for Infusion

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Name	% (w/v)
Sodium Chloride	0.86
Potassium Chloride	0.03
Calcium Chloride Dihydrate	0.033

For the full list of excipients, see section 6.1

## 3 PHARMACEUTICAL FORM

Solution for infusion.

Clear solution.

pH range: 4.5 – 7.0

Theoretical osmolarity: 308 mosm/l

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic indications

Ringer's Solution is used as an intravenous infusion where an isotonic solution is needed for the treatment of dehydration with salt depletion and where there has been some loss of intracellular potassium.

### 4.2 Posology and method of administration

#### Adults and Children

The volume and rate will depend upon the condition of the individual patient and the judgement of the physician.

#### Elderly

Care should be taken in the elderly to avoid circulatory overload, particularly in patients with cardiac and renal insufficiency.

#### **4.3 Contraindications**

- Hypersensitivity to the active substances or to any of the excipients listed in section 6.1.
- Patients with sodium or potassium overload. This may occur with myocardial and renal damage, but also in the first five or six days after surgery or severe trauma when there may be an inability to excrete unwanted sodium
- Fluid overload (hyperhydration)
- Decompensated congestive cardiac failure.

#### **4.4 Special warnings and precautions for use**

Although this solution contains potassium, the quantity may be inadequate in the presence of intracellular potassium loss. The solution should not be administered rapidly or for prolonged periods.

The label states: Do not use unless the solution is clear and free from particles.

#### **4.5 Interaction with other medicinal products and other forms of interaction**

No clinically significant interactions known.

#### **4.6 Fertility, pregnancy, and lactation**

The use of potassium-containing solutions during pregnancy and lactation has not been assessed, but their use during these periods is not considered to constitute a hazard.

#### **4.7 Effects on ability to drive and use machines**

Ringer's Solution has no influence on the ability to drive and use machines.

#### **4.8 Undesirable effects**

Thrombosis of the chosen vein is always possible with intravenous infusion. Rapid Infusion may cause sudden cardiac arrest or circulatory overloading.

#### **Reporting 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 the Yellow Card Scheme Website:

[www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store.

## 4.9 Overdose

Overdose may lead to hypervolaemia with tightened skin, venous stasis, pulmonary or cerebral oedema as well as disturbed acid-base and electrolyte balance.

In these cases, the infusion should be stopped immediately and measures must be taken to increase renal elimination by application of fast acting diuretics (e.g. furosemide) and to achieve a corresponding negative balance.

In cases of oliguria or anuria, fluid withdrawal by hypertonic haemofiltration may be necessary to remove excessive fluid.

# 5 PHARMACOLOGICAL PROPERTIES

## 5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Plasma substitutes and solutions for infusion/electrolytes  
ATC-Code: B05BB01

Ringer's Solution is an isotonic solution of electrolytes. The constituents of Ringer's Solution for Infusion and their concentrations are designed to match those of plasma. The product is used for correction of disturbances in the fluid and electrolyte balance. Electrolytes are given to achieve or to maintain normal osmotic conditions in the extracellular as well as the intracellular compartment. Due to the high chloride content Ringer's Solution has a slight acidotic effect.

The kidneys are the main regulator of the sodium and water balance. In interaction with hormonal regulation mechanisms (renin-angiotensin-aldosterone-system, antidiuretic hormone) and the atrial natriuretic peptide, the kidneys are mainly responsible for the volume stability and composition of the extracellular fluid.

Ions, such as sodium, circulate through the cell membrane using various mechanisms of transport among which is the sodium pump ( $\text{Na}^+/\text{K}^+$ -ATPase). Sodium plays an important role in neurotransmission and cardiac electrophysiology.

Potassium is essential for numerous metabolic and physiological processes including nerve conduction, muscle contraction, and acid-base regulation. A normal concentration of potassium in plasma is about 3.5 – 5.0 mmol/l. Potassium is predominantly an intracellular cation, primarily found in muscle; only about 2% are present in the extracellular fluid. The passage of potassium into the cells and retention against the concentration gradient requires active transport via the  $\text{Na}^+/\text{K}^+$ -ATPase.

Chloride is mainly an extracellular anion found in low concentration in bone and in high concentration in some components of connective tissue such as collagen. Intracellular chloride concentration is high in red blood cells and gastric mucosa. The balance of anions and cations are regulated by the kidneys. Reabsorption of chloride generally follows reabsorption of sodium.

Calcium is an important electrolyte in metabolic processes. The normal concentration of serum calcium ranges from 2.15 – 2.58 mmol/l. Calcium is essential for blood

coagulation, cardiac function, muscle excitability, bone mineralization, capillary and membrane permeability, acid-base balance, nerve transmission, and a variety of rather basic enzymatic reactions. In cells it serves as a second messenger transmitting extracellular signals of hormones and neurotransmitters to intracellular effectors.

## 5.2 Pharmacokinetic properties

The cation  $\text{Na}^+$  and the anion  $\text{Cl}^-$  are the predominant electrolytes in extracellular fluid. Maintenance of normal sodium balance is essential for proper blood volume and water distribution in the body. Fluid homeostasis is regulated by various related systems. The healthy body can compensate for widely divergent water and sodium chloride intakes by adaptation of the elimination. The kidneys, adrenals, pituitary gland, lungs and the sympathetic nervous system are mainly involved. Regulatory mechanisms for the body's water balance are associated with the cation  $\text{Na}^+$ . Consequently, disturbances of water homeostasis cause sodium changes and vice versa. Furthermore, sodium is involved in all bio-electrical processes and in the function of numerous enzyme systems.

Chloride is essential for the maintenance of appropriate acid-base balance and plays an important role in the control of fluid homeostasis. High chloride concentrations exist in gastric fluids. Loss through diarrhoea, vomiting or other disturbances may result in hypochloraemia and metabolic alkalosis. The reduced chloride content of Ringer's Solution compared to sodium chloride 0.9% solution helps to prevent the development of hyperchloraemic metabolic acidosis.

Factors influencing potassium transfer between intracellular and extracellular fluid such as acid-base disturbances can distort the relationship between plasma concentrations and total body stores. Potassium is excreted mainly by the kidneys; it is secreted in the distal tubules in exchange of sodium or hydrogen ions. The capacity of the kidneys to conserve potassium is poor and some urinary excretion of potassium continues even when there is severe depletion. Some potassium is excreted in the faeces and small amounts may also be excreted in sweat.

Calcium is excreted in the urine (up to 400 mg per day), in the sweat, the bile, the pancreatic juice, saliva, faeces, and milk. Normally, approximately 99% of the calcium filtered by the glomerulus is reabsorbed from the kidney, while less than 1% is excreted. A variety of substances and metabolic processes enhance or decrease calcium excretion. All mechanisms determining the homeostasis of calcium, including elimination and reabsorption, are influenced by parathormone, calcitonin, and vitamin D.

Ringer's Solution distributes to both the interstitial and the intravascular space. Approximately 2/3 of the infused solution extravasates, and only 1/3 of the fluid administered remains transiently in the intravascular space. Therefore, the solution has a short lasting haemodynamic effect.

## 5.3 Preclinical safety data

Preclinical safety data of Ringer's Solution in animals are not relevant, since the constituents are physiological components in animal and human plasma.

No toxic effects are expected under the conditions of clinical application when used according to the treatment recommendations.

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Water for injections  
Hydrochloric acid  
Sodium hydroxide

### **6.2 Incompatibilities**

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products/additives.

Those medicinal products/additives known to be incompatible must not be used. As guidance, medicinal products which are incompatible with Ringer's Solution include: carbonate, oxalate- or phosphate-containing solutions, amphotericin B, cortisone, erythromycin-lactobionate, etamivan, ethyl alcohol, sodium thiopental, disodium edetate (non-exhaustive listing).

Because of the nature of the plastic material of the Steriflex bag (PVC) this solution must not be used as a vehicle for the administration of drugs which, may be sorbed to the surface of the bag to varying and significant degrees.

### **6.3 Shelf life**

500 & 1000ml PVC Bags – 2 years.  
500 & 1000ml Polyolefin Bags – 3 years.

### **6.4 Special precautions for storage**

Store below 25°C.

### **6.5 Nature and contents of container**

- a) A hermetically sealed polythene bag.
- b) A rectangular pouch consisting of polyamide/polythene composite
- c) Polyamide/Polyethylene-Propylene composite laminate welded to polypropylene ethylene propylene composite, plugged with a polycarbonate plug with either a bromobutyl (West 448 1/45) or gum (West 7006/45) stopper.

Or

A flexible 500 or 1000ml polyolefine bag sealed in a polyolefine overwrap.

### **6.6 Special precautions for disposal and other handling**

Use only if the solution is clear, without visible particles and if the container is undamaged.

Ringer's solution should be administered with sterile equipment using an aseptic technique.

Compatibility of the medicinal product to be added to Ringer's solution must be assessed before addition. If medications are added, care should be taken to maintain aseptic conditions and ensure complete mixing. Once a medicine is added to Ringer's Solution, the mixture must be administered immediately.

Opening the overwrap:

Locate the corner tabs at the end of the bag. Grip the two tabs and pull the two halves of the overwrap apart, releasing the bag onto a clean surface.

Setting up the solution:

Position the roller clamp of the giving-set to just below the drip chamber and close.

Hold the base of the giving set port firmly and grip the wings of the twist off tab.

Twist to remove the protective cover.

Still holding the base of the giving-set port push the set spike fully into the port to ensure a leak proof connection.

Prime the set in accordance with the manufacturer's instructions.

Any solution remaining after single administration must be discarded.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements

## **7      MARKETING AUTHORISATION HOLDER**

Fresenius Kabi Limited  
Cestrian Court  
Eastgate Way  
Manor Park  
Runcorn  
Cheshire  
WA7 1NT

## **8      MARKETING AUTHORISATION NUMBER(S)**

PL 08828/0063

## **9      DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

16/05/1989 / 26/02/2009

## **10     DATE OF REVISION OF THE TEXT**

25/07/2025