APPROVED PACKAGE INSERT

SCHEDULING STATUS

S3

PROPRIETARY NAME AND DOSAGE FORM

Modified Ringer-Lactate Solution Fresenius Infusion

COMPOSITION

Each 1 000 ml contains:

Active ingredients

Potassium chloride	0,4 g
Sodium chloride	6,0 g
Sodium lactate	3,25 g

Excipients

Water for injection

Osmolarity: 273 mOsml/L

pH: 6,0

Constituents:

Sodium ions:	131 mmol/L
Potassium ions:	5,4 mmol/L
Chloride ions:	108 mmol/L
Lactate:	29 mmol/L

PHARMACOLOGICAL CLASSIFICATION

A 24 Mineral substitutes, electrolytes

PHARMACOLOGICAL ACTION

Modified Ringer-Lactate Solution Fresenius provides electrolytes and is a source of water.

INDICATIONS

Modified Ringer-Lactate Solution Fresenius is indicated for use in adults and paediatric patients as a source of electrolytes and water.

CONTRA-INDICATIONS

Modified Ringer-Lactate Solution Fresenius is contra-indicated in clinical conditions where administration of sodium, potassium or chloride could be clinically detrimental.

WARNINGS AND SPECIAL PRECAUTIONS

The administration of **Modified Ringer-Lactate Solution Fresenius** can cause fluid/or solute overload resulting in dilution of serum electrolyte concentrations, overhydration, congested states or pulmonary oedema. The risk of dilutional states is inversely proportional to the electrolyte concentration. The risk of solute overload causing congested states with peripheral and pulmonary oedema is directly proportional to the electrolyte concentration.

Modified Ringer-Lactate Solution Fresenius should be used with great care in patients with congestive heart failure, severe renal insufficiency, and in clinical states in which there is sodium retention with oedema. Particular care is required if they are postoperative or elderly.

In patients with diminished renal function, administration of **Modified Ringer-Lactate Solution Fresenius** may result in sodium or potassium retention.

Modified Ringer-Lactate Solution Fresenius should be used with great care in patients with hyperkalaemia, severe renal failure, and in conditions in which potassium is raised.

In neonates or very small infants even small volumes of fluid may affect **Modified Ringer-Lactate Solution Fresenius** and electrolyte balance. Care must be exercised in treatment of neonates, especially pre-term neonates, whose renal function may be immature and whose ability to excrete fluid and solute loads may be limited. Fluid intake, urine output, and serum electrolytes should be monitored closely.

Modified Ringer-Lactate Solution Fresenius should be used with caution in the presence of cardiac disease, particularly when accompanied by renal disease.

Modified Ringer-Lactate Solution Fresenius should be used with care in patients with hypervolaemia, renal insufficiency, urinary tract obstruction, or impending or frank cardiac decompensation

The administration of **Modified Ringer-Lactate Solution Fresenius** should be done with great care in those conditions in which there is an increased level or an impaired utilisation of these ions, such as severe hepatic insufficiency.

Extraordinary electrolyte losses such as may occur during protracted nasogastric suction, vomiting, diarrhoea or gastrointestinal fistula drainage may necessitate additional electrolyte supplementation.

Additional essential electrolytes, minerals, and vitamins should be supplied as needed.

Potassium therapy should be guided primarily by serial electrocardiograms, especially in patients receiving digitalis. Serum potassium levels are not necessarily indicative of tissue potassium level.

To minimise the risk of possible incompatibilities arising from mixing **Modified Ringer-Lactate Solution Fresenius** with other additives that may be prescribed, the final infusate should be inspected for cloudiness or precipitation immediately after mixing, prior to administration, and periodically during administration.

If administration is controlled by a pumping device, care must be taken to discontinue pumping action before the container runs dry or air embolism may result.

Modified Ringer-Lactate Solution Fresenius is intended for intravenous administration using sterile equipment.

If an adverse reaction does occur, discontinue the infusion with **Intramed Modified Ringer-Lactate Solution**, evaluate the patient, institute appropriate therapeutic counter measures and save the reminder of the fluid for examination if deemed necessary.

INTERACTIONS

Modified Ringer-Lactate Solution Fresenius should be administered with caution to patients receiving corticosteroids or corticotropin, or to patients with salt retaining conditions.

PREGNANCY AND LACTATION

Safety during pregnancy and lactation has not been established.

DOSAGE AND DIRECTIONS FOR USE

Modified Ringer-Lactate Solution Fresenius is for intravenous use only.

A dosage is to be directed by a medical doctor and is depended upon age, weight, clinical condition of the patient and laboratory determination. Frequent laboratory determinations and clinical evaluation are essential to monitor changes in blood glucose and electrolyte concentrations, and fluid and electrolyte balance during prolonged parenteral therapy.

When a hypertonic solution is to be administered peripherally, it should be slowly infused through a small bore needle, placed well within the lumen of a large vein to minimise venous irritation. Carefully avoid infiltration.

Usually up to 40 mmol of potassium per litre daily is sufficient to replace normal losses in adults. Infusion rates should not exceed 10 mmol per hour or 120 mmol per day. A litre of fluid containing 40 mmol of potassium should be administered over an 8-hour period.

Fluid administration should be based on calculated maintenance or replacement fluid requirements for each patient.

Some additives may be incompatible. Consult with your pharmacist. When introducing additives, use aseptic techniques. Mix thoroughly. Do not store.

Modified Ringer-Lactate Solution Fresenius should be inspected visually for particulate matter and discolouration prior to administration, whenever solution and container permit.

SIDE EFFECTS

General disorders:

Adverse reactions which may occur because of **Modified Ringer-Lactate Solution Fresenius** or the technique of administration including a febrile response, infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection, extravasation, and hypervolaemia.

Too rapid infusion of **Modified Ringer-Lactate Solution Fresenius** may cause local pain and venous irritation. The rate of administration should be adjusted according to tolerance. Use of the largest peripheral vein and a small bore needle is recommended.

Symptoms may result from an excess or deficit of one or more of the ions present in the solution; therefore, frequent monitoring of electrolyte levels is essential.

Hypernatraemia may be associated with oedema and exacerbation of congestive heart failure due to the retention of water, resulting in an expanded extracellular fluid volume.

If **Modified Ringer-Lactate Solution Fresenius** is infused in large amounts, chloride ions may cause a loss of bicarbonate ions, resulting in an acidifying effect.

Gastrointestinal disorders:

The following side effects have been reported and the frequencies are unknown:

Nausea, vomiting, abdominal pain and diarrhoea

Cardiac disorders:

The following side effects have been reported and the frequencies are unknown:

Hypotension, cardiac dysrhythmias, heart block, electrocardiographic abnormalities and cardiac arrest.

Respiratory disorders:

The following side effects have been reported and the frequencies are unknown:

Respiratory paralysis.

Nervous system disorders:

The following side effects have been reported and the frequencies are unknown:

Mental confusion.

Muscular disorders:

The following side effects have been reported and the frequencies are unknown:

Areflexia, muscular paralysis, weakness and disruption of neuromuscular function.

Skin and subcutaneous tissue disorders:

The following side effects have been reported and the frequencies are unknown:

Paraesthesias of the extremities.

KNOWN SYMPTOMS AND OVERDOSAGE AND PARTICULARS OR ITS TREATMENT

In the event of a fluid or solute overload during parenteral therapy, re-evaluate the patient's condition and institute corrective treatment.

IDENTIFICATION

Clear, colourless solution.

PRESENTATIONS

200 ml PVC bag

250 ml freeflex bag

1 000 ml PVC/freeflex bags

STORAGE INSTRUCTIONS

Store at or below 25 ºC.

KEEP OUT OF REACH OF CHILDREN

REGISTRATION NUMBER

L/24/340

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

Fresenius Kabi Manufacturing SA (Pty) Ltd

6 Gibaud Road

Port Elizabeth

6001

DATE OF PUBLICATION OF THIS PACKAGE INSERT

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