APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

PROPRIETARY NAME AND DOSAGE FORM

MODIFIED RINGER-LACTATE SOLUTION FRESENIUS infusion

Read the entire leaflet carefully before you are given Modified Ringer-Lactate Solution.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **Modified Ringer-Lactate Solution** has been prescribed for you personally and you should not share your medicine with other people. It may harm them even if their symptoms are the same as yours.

1. WHAT INTRAMED MODIFIED RINGER-LACTATE CONTAINS

Each 1 000 ml contains:

Active ingredients

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

Providing:

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

Excipients

Water for Injections

2. WHAT MODIFIED RINGER-LACTATE SOLUTION FRESENIUS IS USED FOR

Modified Ringer-Lactate Solution Fresenius is a solution that provides electrolytes and is a source of water in adults and children.

3. BEFORE YOU ARE GIVEN INTRAMED MODIFIED RINGER-LACTATE SOLUTION

You should not be given Modified Ringer-Lactate Solution Fresenius -

If you are hypersensitive (allergic) for sodium lactate in **Intramed Modified Ringer-Lactate Solution.**

This infusion will be given to you in a hospital or clinic. Your doctor will know if your clinical condition allows you (or your child) to receive the sodium, potassium or chloride ions.

Take special care with Intramed Modified Ringer-Lactate Solution

Tell your doctor if any of the below conditions apply to you (or where applicable, to your child) before **Modified Ringer-Lactate Solution Fresenius** is dripped into your vein:

- if you have congestive heart failure (inability of the heart to supply sufficient blood flow) or cardiac disease with kidney problems;
- if you have severely impaired kidney function or are unable to urinate due to blockage of your urinary tract;
- if you have lost a lot of fluid with, for example, vomiting or diarrhoea;
- if you have severe liver problems as this may lead to problems with lactate metabolism;
- if you are pregnant (see “Pregnancy and breastfeeding”);

- if your baby is a neonate or very small infant (less than 6 months). Lactate-containing solutions should be administered with particular caution to neonates and infants less than 6 months of age due to their immature metabolism.

Your doctor will take the necessary care if he/she determines that you have too much fluid in the body; a condition that causes water retention (swelling) or too much potassium in your body.

Pregnancy and breastfeeding

Safety during pregnancy and breastfeeding has not been established.

If you are pregnant or breastfeeding your baby please consult your doctor, pharmacist or other healthcare professional for advice before receiving **Intramed Modified Ringer-Lactate Solution.**

Driving and using machines

After receiving **Modified Ringer-Lactate Solution Fresenius** your ability to drive and use machines should not be compromised. However, do take care until you know how **Modified Ringer-Lactate Solution Fresenius** infusion affects you. Your doctor will decide when you can be discharged from the hospital or clinic.

Using other medicines with Intramed Modified Ringer-Lactate Solution

Always tell your doctor if you are taking any other medicine. (This includes complementary or traditional medicines).

Make sure that your doctor knows you are also receiving corticosteroids or corticotropin. Ask your doctor, pharmacist or professional health care provider if you are not sure about your medicine.

4 HOW MODIFIED RINGER-LACTATE SOLUTION FRESENIUS IS GIVEN

You will not be expected to give yourself **Intramed Modified Ringer-Lactate Solution**. It will be given to you by a person who is qualified to do so.

Dose

Modified Ringer-Lactate Solution Fresenius will be slowly infused (dripped) into a vein. Your medical doctor will determine your dose, the rate at which the medicine is dripped into your veins and for how long this should continue. The dose will depend on you or your child's age, weight, clinical condition and the laboratory results.

You will be carefully monitored and your dose adjusted according to the results of your blood tests.

Normally a dosage of up to 40 mmol of potassium per litre daily could be sufficient for 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. See also "WHAT MODIFIED RINGER-LACTATE SOLUTION FRESENIUS CONTAINS" above, for the number of mmol this infusion contains per litre.

Modified Ringer-Lactate Solution Fresenius should normally not be given to babies or very small infants (less than 6 months).

If you receive more Modified Ringer-Lactate Solution Fresenius than you should:

Modified Ringer-Lactate Solution Fresenius will be given to you in a hospital, under the supervision of a doctor. It is unlikely that you will be given too much or too little medicine; however, please tell your doctor or health care professional if you have any concerns. Your doctor will take appropriate supportive measures to treat the effects in the unlikely event of an overdosage.

If you have any further questions on the use of **Intramed Modified Ringer-Lactate Solution**, ask your doctor, health care professional or pharmacist for more information.

5. POSSIBLE SIDE EFFECTS

Modified Ringer-Lactate Solution Fresenius can cause side effects.

Not all side effects reported for **Modified Ringer-Lactate Solution Fresenius** are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while receiving **Intramed Modified Ringer-Lactate Solution**, please consult your doctor, pharmacist or other healthcare professional for advice.

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

- Fever, infection at site of injection, vein irritation, vein inflammation with clot formation, or swelling from too much fluid
- Too high salt concentration in the blood from unsuitable intravenous use of **Intramed Modified Ringer-Lactate Solution**. This may cause swelling and worsening of your heart condition if you have congestive heart failure
- Too much **Modified Ringer-Lactate Solution Fresenius** may cause your blood to become too acid, but your blood will be analysed by the laboratory and your doctor will correct the situation
- Digestive tract problems such as nausea, vomiting, stomach pain and diarrhoea (frequent or loose watery stools)
- Low blood pressure (you may feel lightheaded or dizzy)
- Heart problems such as rhythm disturbances, heart block, ECG-abnormalities and cardiac arrest (where the heart may stop working)

- Respiratory paralysis – inability to breathe
- Nervous system problems – mental confusion
- Muscle problems such as areflexia (muscle reflexes do not work), muscles paralysed (feeling lame), feeling weak
- Skin sensation problems – paraesthesia (numbness, tingling, pins and needles feeling)

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

6. STORING AND DISPOSING OF MODIFIED RINGER-LACTATE SOLUTION FRESENIUS

Store all medicines out of reach of children.

Store at or below 25 ºC.

Your professional health care provider will always inspect containers for intactness of seals and the solutions for injection for discolouration or presence of any visible particulate matter. The solution will not be used if it is not clear, if it has visible particles, or if the seals of the bag are not intact.

7. PRESENTATION OF INTRAMED MODIFIED RINGER-LACTATE SOLUTION

Modified Ringer-Lactate Solution Fresenius is packed in 200 ml PVC bag, or 250 ml Freeflex bag, or 1 000 ml PVC or Freeflex bags.

8. IDENTIFICATION OF INTRAMED MODIFIED RINGER-LACTATE SOLUTION

A sterile, clear, colourless solution.

9. REGISTRATION NUMBER OF MODIFIED RINGER-LACTATE SOLUTION FRESENIUS

L/24/340

10. NAME AND BUSINESS ADDRESS OF THE REGISTRATION HOLDER

Fresenius Kabi Manufacturing SA (Pty) Ltd
6 Gibaud Road
Korsten
Port Elizabeth 6001
South Africa

11. DATE OF PUBLICATION

Date of registration: 24 October 1979

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