Ringer's Solution for Infusion
Sodium chloride, potassium chloride, calcium chloride

In this leaflet:
1. What Ringer's Solution for Infusion is and what it is used for
2. What you need to know before you use Ringer's Solution for Infusion
3. How to use Ringer's Solution for Infusion
4. Possible side effects
5. How to store Ringer's Solution for Infusion
6. Contents of the pack and other information

1. What Ringer's Solution for Infusion is and what it is used for

Ringer's Solution for Infusion is a solution for supply of fluid and salts to the body.
In terms of sodium potassium and calcium its composition is similar to that of human blood.
It is used to provide fluid and salts to you if:
- your fluid and salt balance must be maintained by administering the right amount of fluid and salts directly into your circulation, and especially if you have a low blood chloride level
- you are dehydrated
- you have lost chloride (which may occur e.g. by severe vomiting)
- you have lost blood and need this replaced for a short time

2. What you need to know before you use Ringer's Solution for Infusion

Do not use Ringer’s Solution for Infusion
- if you have too much water in your body (hyperhydration)
- if you have too less water in your body (dehydration) due to abnormally high levels of electrolyte (salts) in your body fluids and tissues
- if you have abnormally high levels of chloride in your blood (hyperchloraemia)
- if you are receiving medication with digitalis preparations

Warnings and precautions
Your doctor will exercise particular caution if you have
- too high blood levels of potassium and sodium
- impaired kidney function, in particular if this could lead to an increase of your blood potassium level,
- any other condition where your sodium intake must be low, like heart failure, swelling, water on your lungs, high blood pressure, toxaemia of pregnancy (see section "Pregnancy and breast-feeding").
Because of the presence of calcium in this solution:
- care will be taken to prevent the fluid from spilling into tissue around the vein
- special caution will be observed if you have kidney disease or diseases with high vitamin D blood levels such as sarcoidosis
- blood transfusions will be administered through a separate line to prevent clotting.
While you receive this solution your blood levels of salts and your fluid balance will be monitored.

Special warning on air content of the bottle
The polyethylene bottle contains a significant volume of air. To avoid risk of air embolism, all air must be expelled before starting a pressure infusion.

Other medicines and Ringer's Solution for Infusion
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.
Your doctor will take special care about you if you receive/take
- medicines that increase the level of sodium or water in your body (corticosteroids)
- medicines that increase the amount of potassium in your blood (e.g. potassium saving diuretics like amilorid, triamteren, spironolacton; ACE inhibitors like enalapril; cyclosporin or tacrolimus)
- medicines that increase the level of calcium in your blood (thiazide diuretics or vitamin D)
- medicines for the treatment of heart weakness (e.g. digitalis preparations, digoxin). Ringer's Solution for Infusion may increase the effect of these medicines.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding or think you may be pregnant, ask your doctor or pharmacist for advice before taking any medicine.

Pregnancy
If you are pregnant please inform your doctor. It is safe for him to give Ringer's Solution for Infusion to you except if you have complications in a late state of pregnancy (conditions in the third trimester when you have high blood pressure, swelling and protein in the urine).

Breast-feeding
If you are breast-feeding, please inform your doctor. It is safe for him to give you Ringer's Solution for Infusion.

Driving and using machines
This medicine has no influence on the ability to drive and use machines.

3. How to use Ringer’s Solution for Infusion

Administration
This medicine will be given to you as a drip directly into a vein (intravenous infusion). It will be administered to you by a doctor or a nurse.

Dosage
Adults
The doctor will decide the right dose of Ringer's Solution for Infusion depending on your age, weight and your condition.
Normally the dose for adults is up to 40 ml per kg body weight per day, given into a vein. Normally your doctor will give you up to 5 ml per kg body weight per hour.

Children, adolescents and elderly patients
For children, adolescents and elderly people the dose will be determined individually according to the patient’s requirements.
If you receive more Ringer’s Solution for Infusion than you should

An overdose may lead to hyperhydration (excess fluid in the body), which will be followed by increased skin tension, congestion of your veins, swelling, including swelling of the brain, water on the lungs, disorders of your fluid, salt and acid-base balance. It may also lead to high salt levels in your blood.

If you have received too much of Ringer’s Solution, you might get symptoms of a potassium overdose. This may include: numbness of limbs, muscle weakness, lameness, heart disorders, and mental confusion.

If you have received too much of Ringer’s Solution, you might get symptoms of a calcium overdose. This may include: loss of appetite, sickness, vomiting, constipation, gut pain, muscle weakness, mental disturbance, massive thirst, passing large amounts of urine, calcification of kidneys, and, in severe cases, irregular heart beat and loss of consciousness. Too rapid injection of calcium salts may also lead to chalky taste, hot flushes, and vein dilatation.

If an overdose occurs the infusion will be stopped and your doctor will give you any necessary treatment.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Side effects are mainly caused by inappropriate dosing or infusion rates. Their frequency is dose-dependent. In those cases especially your blood chloride level may rise while you receive this medicine.

Not known: frequency cannot be estimated from available data: Too much water (hyperhydration) and heart failure in patients with heart or lung oedema

Electrolytes disturbances, which can cause:
- difficulty in breathing, sudden severe chest pain
- slowing or quickening of your heart beat
- too high or low blood pressure
- bad fainting attacks, convulsions (fit) or collapse
- weakness, lameness, motor disturbances (of muscular movements)
- numbless, swelling or heaivness of your limbs
- cold skin or paleness
- difficulty in swallowing
- confusion
- feeling sick, vomiting
- diarrhoea or pain in your abdomen
- dry mouth or feeling thirsty
- sweating or feeling feverish
- headaches or dizziness
- restlessness

At the injection site you may feel pain or tenderness. It is possible that you may get an infection, vein irritation, venous thrombosis or phlebitis extending from the site of injection and extravasation.

Adverse reactions may be associated with the medications added to the solution, the nature of the additive will determine the likelihood of any other undesirable effect.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects noted in this leaflet. You can also report side effects directly via:

United Kingdom
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Ringer’s Solution for Infusion

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the bottle and the outer carton. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Only use Ringer’s Solution for Infusion if the solution is clear and the container is undamaged.

Containers are for single use only. After use discard container and any unused contents. Do not reconnect partially used containers.

6. Contents of the pack and other information

What Ringer’s Solution for Infusion contains

The active substances:
Each litre of the solution contains
Sodium Chloride 8.60 g
Potassium Chloride 0.30 g
Calcium Chloride Dihydrate 0.33 g

Electrolyte concentrations:
Sodium 147 mmol/l
Potassium 4.0 mmol/l
Calcium 2.2 mmol/l
Chloride 156 mmol/l

Theoretical osmolarity: 309 mOsm/l
Acidity (titration to pH 7.4): < 0.3 mmol/l
pH: 5.0 – 7.0

The other ingredient is
Water for injections

What Ringer’s Solution for Infusion looks like and contents of the pack

It is a solution for infusion, i.e. it is a solution that is administered by a vein drip.

It is a clear colourless solution of salts in water.

It comes in:
- Polyethylene bottles, contents: 500 ml, 1000 ml available in packs of
  10 x 500 ml
  10 x 1000 ml

Not all pack sizes may be marketed.

Marketing Authorisation Holder
B. Braun Melsungen AG
 Carl-Braun-Strasse 1
34212 Melsungen, Germany
Phone: +49-5661-71-0
Fax: +49-5661-71-4567

Manufacturer
B. Braun Melsungen AG
Carl-Braun-StraBe 1
34212 Melsungen, Germany
or
B. Braun Medical S.A.
Carretera de Terrassa 121
08191 Rubi, Barcelona, Spain

This leaflet was last revised in 08/2013

B. Braun Melsungen AG
34209 Melsungen
Germany