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Prescriber Information Leaflet

B. Braun Pharmaceuticals EPZ Ltd.

Compound Sodium Lactate Intravenous Infusion BP Ringer-Lactate

Please read this leaflet carefully before you start to administer Compound Sodium Lactate Intravenous Infusion BP

What is in the bottle?

Compound Sodium Lactate Intravenous Infusion BP is a solution of Sodium Lactate, Calcium Chloride Dihydrate, Potassium Chloride and Sodium Chloride in Water for Injection.

What Compound Sodium Lactate Intravenous Infusion BP looks like and contents of the pack

Compound Sodium Lactate Intravenous Infusion BP is a clear solution, free from visible particles. It is supplied in plastic containers of 500ml.

What is Compound Sodium Lactate Intravenous Infusion BP Used for?

It is intended for restoring the electrolyte balance and water for hydration. A combination of multiple electrolytes and sodium lactate, alkalinising agent, will provide electrolyte balance and normalise the pH of the acid-base balance of the physiological system.

Before You Administer Compound Sodium Lactate Intravenous Infusion BP

DO NOT administer Compound Sodium Lactate Intravenous Infusion BP if the patient is suffering from any of the following conditions:

- Known hypersensitivity to sodium lactate
- Congestive heart failure or severe impairment of renal function
- Clinical states in which the administration of sodium and chloride is detrimental
- In patients older than 28 days (including adults), ceftriaxone must not be administered simultaneously with intravenous calcium-containing solutions, through the same infusion line. If the same infusion line is used for sequential administration, the line must be thoroughly flushed between infusions with a compatible fluid.

If another medicine is to be added to the solution for infusion always read the patient information leaflet of that medicine. This way you can check to see if that medicine is safe to be administered with the infusion to the patient.

Warnings and Precautions

Do not use if the container is found leaking upon squeezing, if the solution is not clear or if the solution contains particulate matter.

Please verify if the patient has had any of the following medical conditions:

- Heart failure
- Respiratory failure (lung disease)
- Poor kidney function
- Reduced production of urine (oliguria or anuria)
- Excess water in the body (water intoxication)
- Head injury within 24 hours
- A high pressure within the skull (intracranial hypertension)
- A stroke due to a clot in a blood vessel in the brain (ischaemic stroke)

When this infusion is administered, the patient's blood and urine samples must be taken to monitor:

- The amount of chemicals such as potassium in their blood (plasma electrolytes)
- The amount of Compound Sodium Lactate

Compound Sodium Lactate Intravenous Infusion BP must not be given through the same needle as a blood transfusion. This can damage the red blood cells or cause them to clump together.

Use in Pregnancy and Breast-feeding

Verify if the patient is pregnant or breast feeding.
Compound Sodium Lactate Intravenous Infusion BP can be used safely during pregnancy, giving birth (labour) or breast-feeding.
However, if another medicine is to be added to the solution for infusion during pregnancy or breast-feeding:

- Read the patient information leaflet of the medicine that is to be added.

Use in Children

The potential risks and benefits for each specific patient should be carefully considered before using for paediatric use. Safety and effectiveness in paediatric patients have not been established by adequate and well controlled trials, however, the use of electrolyte solutions in the paediatric population is referenced in the medical literature. Do Not administer Compound Sodium Lactate Intravenous Infusion BP to babies less than 28 days, with concomitant administration of Ceftriaxone (even in separate infusion lines), due to fatal Ceftriaxone-Calcium salt precipitation.

Other Medicines and Compound Sodium Lactate Intravenous Infusion BP

Compound Sodium Lactate Intravenous Infusion BP and other medicines taken at the same time can affect each other.

How to Administer Compound Sodium Lactate Intravenous Infusion BP

Compound Sodium Lactate Intravenous Infusion BP is administered by a doctor or a nurse. The doctor will decide on how much to administer and when it is to be given. This will depend on the patient's age, weight, condition, the reason for treatment and whether or not the infusion is being used to deliver or dilute another medicine.

Compound Sodium Lactate Intravenous Infusion BP will usually be administered through a plastic tube attached to a needle in a vein.

The amount administered may also be affected by other treatments the patient is receiving.

Compound Sodium Lactate Intravenous Infusion BP should NOT be administered after the expiry date, which is stated on

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the container label. The expiry date refers to the last day of the month.

Compound Sodium Lactate Intravenous Infusion BP must not be administered if there are particles floating in the solution or if the pack is damaged in any way.

Any unused solution should be thrown away. Compound Sodium Lactate Intravenous Infusion BP must NOT be administered from a bottle that has been partly used.

What to do if more Compound Sodium Lactate Intravenous Infusion BP is administered than should be

Overdose may lead to oedema or loss of balance of ions in the body.

Excess administration of sodium lactate may lead to metabolic alkalosis accompanied by hypokalaemia.

When assessing overdose, any additive in this product must also be considered.

The effects of overdose may require immediate medical attention and treatment.

When to stop Administering Compound Sodium Lactate Intravenous Infusion BP

The doctor will decide when to stop administering this infusion.

Possible side effects

Infusion of excess volume may overload the circulation and precipitate heart failure (increased breathlessness, wheezing and distended neck veins). Volume overload is unlikely if the patient is correctly assessed initially and it is unlikely indeed if the patient response is assessed after initial 250ml of infusion. If there is evidence of this complication, the patient should be transported immediately to the nearest suitable referral hospital while receiving high flow Oxygen. Do not give further fluid.

Some swelling of hands, ankles and feet may be experienced due to fluid retention in the body. In rare circumstances this may involve the lungs which may cause some breathing difficulties.

How to store Compound Sodium Lactate Intravenous Infusion BP

Keep this medicine out of sight and reach of children.
Store below 30°C.

CRITICAL POINTS OF CARE FOR SAFE ADMINISTRATION AND USE OF INTRAVENOUS SOLUTIONS WHICH FORM AN INTEGRAL PART OF THE DRUG DELIVERY SYSTEM

What material is the container of the fluid made of?

The container is made from pharmaceutical grade Low Density PolyEthylene complying with Pharmacopoeial requirements of plastics for packaging of preparations for parenteral use. The inert material offers drug compatibility. As the container material does not contain any additives there is no leaching of any substance into the drug solution.

Is the fluid container collapsible?

Yes, the fluid container is self collapsible. A closed drug delivery system is achieved as the container design allows for easy fluid flow dynamics thus avoiding the risky unconventional local /regional practice of providing a flow vent in a non-collapsible container with a needle pierced through the container wall in a risky hospital environment prone to infectious disease carriers.

What container closure system is provided?

The bottle is closed system container. This system provides two injection ports and resealing ports for the infusion giving set thus giving a high level of drug delivery and administration practice.

Who makes Compound Sodium Lactate Intravenous Infusion?

Compound Sodium Lactate Intravenous Infusion BP is manufactured by

B. BRAUN PHARMACEUTICALS EPZ LTD.
L.R. No. 18474/84 Athi River
P.O. Box 51200-00100
Nairobi, Kenya

Product registration No. in Kenya: H2014/CTD1375/014

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Useful Handling Tips for Closed System Container

Infusion Administration

Opening

Peel off the covering foil of port.

Injection Port

Swab injection port.

Handling during spiking

When inserting an infusion set or a needle into the port, grip the neck of the Closed System Container to stabilize the container or leave it free standing.

Using infusion sets

When the set is removed, the port on Closed System Container reseals automatically.
Avoid rotating the spike when piercing the port.

No venting required

During infusion, Closed System Container collapses completely without any need for ventilation.

Collapsed Closed System Container

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Kenya

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