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Package leaflet: Information for the user

B. Braun Medical Ltd. · Dublin 12, Ireland

Compound Sodium Lactate Intravenous Infusion BP

(Hartmann's Solution)

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

1. What Compound Sodium Lactate is and what it is used for
2. What you need to know before you use Compound Sodium Lactate
3. How to use Compound Sodium Lactate
4. Possible side effects
5. How to store Compound Sodium Lactate
6. Contents of the pack and other information

1. What Compound Sodium Lactate is and what it is used for

Compound Sodium Lactate is a solution for supply of fluid and salts to the body. It is supplied to you through a vein drip (an infusion). Its salt composition is similar to that of human blood.

You will receive this solution if
- you need to receive fluids and salts. This applies when your acid-base balance is normal or your blood is a little bit too acidic (mild acidosis)
- you have lost water
- you have lost water and salts
- you have lost blood and need this replaced for a short time
- your doctor wants to give you salts or some drugs that need to be dissolved or diluted.

2. What you need to know before you use Compound Sodium Lactate

Do not use Compound Sodium Lactate if you have
- an impairment to metabolise lactate connected with high levels of lactate in your blood (see also section "Take special care with...")
- too much water in your body (water intoxication)
- in premature neonates and neonates (≤ 28 days of age) which are receiving ceftriaxone.
- if you are allergic to Sodium chloride, Sodium lactate, Potassium chloride or Calcium chloride dihydrate, or any of the other ingredients of this medicine (listed in section 6).

Your doctor will not give you this medicine to correct abnormally high levels of acids in the blood caused by your metabolism (severe metabolic acidosis)

To avoid the risk of air embolism, pressure infusion must not be carried out with the polyethylene container Ecoflac plus because this container contains a significant volume of air.

Warnings and precautions
Your doctor will exercise particular caution if you have
- lost water while retaining the salts
- too high blood levels of potassium, sodium, calcium or chloride
- abnormally high levels of bases in the blood caused by your metabolism (severe metabolic alkalosis)
- failure of your heart, liver, kidneys or lungs
- excess water in your body (peripheral oedema, extracellular hyperhydration)
- a condition where you are retaining sodium, such as high blood pressure, toxaemia of pregnancy (see "Pregnancy and breast-feeding"), too high levels of aldosterone in your body, treatment with cortisone
- a condition where you are retaining potassium, e.g. acute deficiency of water in your body, extensive tissue destruction as occurs with severe burns
- a disease associated with high levels of vitamin D in your blood such as sarcoidosis
- kidney stones or a history of them

If you have constantly low blood sodium levels your doctor will take special care to give you this solution slowly. This will prevent possible brain damages (osmotic demyelinisation syndrome).

Children
Your doctor will take special care of your child aged less than 3 months if he/she receives this solution.
Your doctor will take special care if you are receiving an antibiotic (e.g.ceftriaxone) and he will not administrate you simultaneously calcium gluconate even via different infusion line or different infusion sites.

Use as vehicle solution
Please note: If this solution is used as vehicle solution the safety information of the additive provided by the respective manufacturer has to be taken into account.

While you receive this solution the following parameters will be checked to ensure that these are normal:
- your blood salt and lactate levels
- your acid-base balance
- your fluid balance

Other medicines and Compound Sodium Lactate
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Your doctor will administer this solution to you only with caution if you are taking
- cortisone or carbenoxolone
- medicines for the treatment of heart weakness (e.g. digitalis preparations, digoxin).
- medicines that cause an increase of your serum potassium level (see the list below).
  - medicines that increase your urine flow and retain potassium (e.g. triamterene, amiloride, spironolactone, alone or in association)
  - medicines that are used for the treatment of high blood pressure (ACE inhibitors, e.g. captopril, enalapril; Angiotensin II receptor antagonists, eg. valsartan, losartan)
  - some drugs that are used to suppress your immune system (e.g. tacrolimus, cyclosporine)
  - a special drug called suxamethonium used to relax your muscles
- simultaneously thiazide-diuretics and vitamin D
- concomitantly medicines for the treatment of brittle bone disease (e.g. bisphosphonates, fluorides) or specific antibiotics (e.g. fluoroquinolones, tetracyclines)
- stimulating medicinal products (e.g. ephedrine, pseudoephedrine, desamphetaminesulphate, fenfluramine hydrochloride).

Lactate leads to an alkalinisation of your urine. This may change the excretion of certain drug substances (e.g. salicylic acid).
Some drugs must not be mixed with Compound Sodium Lactate. These include drugs containing oxalate, phosphate or carbonate/bicarbonate. Doctors only add drugs to Compound Sodium Lactate if they are sure they are safe to mix.
Administration of calcium simultaneously with ceftriaxone will lead to precipitation.

Pregnancy and breast-feeding
Ask your doctor or pharmacist for advice before taking or using any medicine.

Pregnancy
If you are pregnant, please inform your doctor. Your doctor will administer this solution to you only if he thinks it is necessary.

Your doctor will exercise particular caution if you have pre-eclampsia (toxaemia of pregnancy). This is a condition of the third trimester when the patient has the following symptoms:
- high blood pressure
- swelling of body tissues
- protein in the urine.

Breast-feeding
Calcium is excreted in human milk, but at therapeutic doses of Compound Sodium Lactate no effects on the breastfed newborns/infants are anticipated. Therefore Compound Sodium Lactate can be used during breast-feeding.

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

3. How to use Compound Sodium Lactate

Dosage
This medicine will be administered to you by a doctor or health-care professional.
The doctor will decide the right dose of Compound Sodium Lactate depending on your fluid and electrolyte requirements. Thus your age, weight, clinical condition and physiological (acid-base) status will be taken into account.

The recommended dosages are:

Adults and adolescents
Maximum daily dose
Up to 40 ml per kg body weight per day.

Maximum infusion rate:
The infusion rate will be adjusted according to your clinical condition. The infusion rate should normally not exceed the following values:
5 ml per kg body weight per hour

Children
20 ml – 100 ml per kg body weight per day.

Maximum infusion rate
on average 5 ml per kg body weight per hour. Thus the amount to be given depends on the age of the patient:
6 – 8 ml per kg body weight per hour for infants[1]
4 – 6 ml per kg body weight per hour for toddlers[1]
2 - 4 ml per kg body weight per hour for schoolchildren[2]
[1] infants and toddlers: age range 28 days to 23 months
[2] schoolchildren: age range 2 years to 11 years

Elderly patients
Basically the same dosage as for adults applies, but caution will be exercised if you are suffering from further diseases like heart weakness or impaired kidney function that may frequently be associated with advanced age.

Patients with burns
Adults
During the first 24 hours you will receive 4 ml of solution per kg per percent burn.

Children
During the first 24 hours your child will receive 3 ml of solution per kg per percent burn. Thus the following volume is added as maintenance for children according to his/her weight
- for children weighing 0 – 10 kg the amount is 4 ml per kg body weight per hour;
- for children weighing 10 – 20 kg the amount is 40 ml per h + 2 ml per kg body weight per hour;
- for children weighing more than 20 kg, the amount is 60 ml per h + 1 ml per kg body weight per hour.

Use as vehicle solution
If Compound Sodium Lactate is used as vehicle solution for compatible electrolyte concentrates and medicinal products, the instructions for use relating to the medicinal product to be added will be observed.

If you use more Compound Sodium Lactate than you should
An overdose may lead to hyperhydration (excess fluid in the body), which will be followed by
- increased skin tension,
- congestion in your veins,
- swelling of body tissues
- water on the lungs or in your brain
- disorders of your fluid, salt and acid-base balance,
- high salt levels in your blood.

If an overdose occurs, 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, Compound Sodium Lactate can cause side effects, although not everybody gets them.
However, it is unlikely that any adverse effect occurs as long as this medicine is used as directed.Yet, if you notice any side effects, please tell your doctor or pharmacist.

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Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; e-mail: medsafety@hpra.ie.
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Compound Sodium Lactate

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 label. The expiry date refers to the last day of that month.
This medicinal product does not require any special storage conditions.
Containers are for single-use only. Once opened: Use immediately. Discard container and any unused content after use.
No special requirements for disposal. Only to be used if the solution is clear, colourless and the container and its closure do not show visible signs of damage.
Do not reconnect partially used containers.

6. Contents of the pack and other information

What Compound Sodium Lactate contains

- The active substances:

1000 ml of the solution contains

Sodium chloride	6.00 g
Sodium lactate solution (50% w/w) (equivalent to sodium lactate, 3.12 g)	6.24 g
Potassium chloride	0.40 g
Calcium chloride dihydrate	0.27 g

Electrolyte concentrations:

Sodium	131 mmol/l
Potassium	5 mmol/l
Calcium	2 mmol/l
Chloride	111 mmol/l
Lactate	29 mmol/l

- The other ingredient is

Water for injections

Theoretical osmolarity:	278 mOsm/l
Titration acidity:	< 1 mmol/l
pH:	5.0 – 7.0

What Compound Sodium Lactate looks like and contents of the pack

It is a solution for infusion, i.e. for administration by a vein drip.
It is a clear, colourless solution of salts in water.

It comes in

- polyethylene bottles containing 500 ml or 1000 ml,

available in packs of 10 × 500 ml and 10 × 1000 ml

Not all pack sizes may be marketed

Marketing authorisation holder and manufacturer

PA Holder:
B. Braun Medical Ltd.
3 Naas Road Industrial Park, Dublin 12, Ireland

PA Number:
PA 179/4/3

Manufacturer:
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34212 Melsungen
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or

B. Braun Medical S. A.
Carretera de Terrassa 121
08191 Rubí, Barcelona
Spain

Date of preparation

06.2015

The following information is only intended for health-care professionals:

Special warnings and precautions for use
In patients of any age ceftriaxone must not be mixed or administered simultaneously with any calcium-containing IV solutions even via different infusion lines or different infusion sites.
Cases of fatal reactions with calcium-ceftriaxone precipitates in lungs and kidneys in premature and full-term newborns aged less than 1 month have been described.
However, in patients older than 28 days of age ceftriaxone and calcium-containing solutions may be administered sequentially one after another if infusion lines at different sites are used or if the infusion lines are replaced or thoroughly flushed between infusions with physiological salt-solution to avoid precipitation. Sequential infusions of ceftriaxone and calcium-containing products must be avoided in case of hypovolaemia.
Lactate utilisation may be impaired in the presence of hypoxia or hepatic insufficiency.
Compound sodium lactate contains an amount of potassium that is similar to that of the physiological concentration of potassium in human blood. Nevertheless it is not suitable for the treatment of patients with severe potassium deficiency.
As the solution contains metabolisable ions (e.g. lactate) it may cause metabolic alkalosis.
Care should be taken to prevent extravasation during intravenous infusion.
In case of concomitant blood transfusion, the solution must not be administered via the same infusion set.
If lactate accumulates during infusion, the dosage and infusion rate should be reduced or administration of the solution should eventually be discontinued.

Important information about the container:
The plastic container contains a significant volume of air. To avoid risk of air embolism, pressure infusion must not be carried out with the polyethylene container.

Important information after admixture of additives
Chemical and physical in-use stability of any additive medication at the pH of "Compound Sodium Lactate Intravenous Infusion BP" in the container should be established prior to use. From a microbiological point of view, unless the method of opening precludes the risk of microbial contamination, the product should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user.

Treatment of overdose:
Cessation of infusion, administration of diuretics with continuous monitoring of serum electrolytes, correction of electrolyte and acid-base imbalances.
In severe cases of overdose dialysis may be necessary.

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