

Compound Sodium Lactate (Hartmann's Solution) Intravenous Infusion BP

Compound Sodium Lactate (1% S. Hartmann's Solution) Intravenous Infusion BP
Anhydrous Dihydrate, Potassium Chloride, Sodium Chloride, Sodium Lactate



Read this leaflet carefully.
It tells you what to read it again.
For further questions, ask your doctor or pharmacist.
Side effects get serious, or if you notice any side effect in this leaflet, please tell your doctor or pharmacist.

This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

Compound Sodium Lactate (Hartmann's Solution) Intravenous Infusion BP is and what it is used for
Read to know before you are given Compound Sodium Lactate (Hartmann's Solution) Intravenous Infusion BP
This is given as Compound Sodium Lactate (Hartmann's Solution) Intravenous Infusion BP
Effects
Compound Sodium Lactate (Hartmann's Solution) Intravenous Infusion BP
The pack and other information
This medicine is called "Compound Sodium Lactate (Hartmann's Solution) Intravenous Infusion BP" but will be referred to as "Compound Sodium Lactate (Hartmann's Solution) Intravenous Infusion BP" throughout the leaflet.

Compound Sodium Lactate (Hartmann's Solution) Intravenous Infusion BP is and what it is used for
Compound Sodium Lactate (Hartmann's Solution) Intravenous Infusion BP is a solution of the following substances in water:
Sodium chloride
Sodium dihydrate
Sodium lactate
Sodium, calcium, chloride and lactate are chemical substances (electrolytes) found in the blood.
Compound Sodium Lactate (Hartmann's Solution) Intravenous Infusion BP
Loss of body water and chemicals (e.g. by heavy sweating, kidney disorders)
Low blood pressure (hypotension) if the volume of blood in your blood vessels is low (hypovolaemia) or if you have low blood pressure (hypotension)
Acidosis (when the blood becomes too acidic).
Read to know before you are given Compound Sodium Lactate (Hartmann's Solution) Intravenous

Compound Sodium Lactate (Hartmann's Solution) Intravenous Infusion BP if you are suffering from any of the following:
Newborn (less than 28 days old) receiving ceftriaxone (an antibiotic).
Allergic to sodium lactate or any of the other ingredients in Compound Sodium Lactate (Hartmann's Solution) Intravenous Infusion BP (listed in section 4).
Excess fluid in the spaces around the cells of the body (extracellular hyperhydration)
Excess fluid in the blood vessels (hypervolaemia)
Kidney failure (when your kidneys do not work well and you require dialysis)
Heart failure. This is heart failure that is not adequately treated and causes symptoms such as:
Shortness of breath
Swelling of the ankles
Excess potassium in the blood than normal (hyperkalaemia)
Excess calcium in the blood than normal (hypercalcaemia)
In which the blood becomes too alkaline (metabolic alkalosis)
Swelling that causes fluid to build up within the abdomen (ascitic cirrhosis)
Excess acidosis which is life-threatening (severe metabolic acidosis)
Excess lactic acidosis (lactic acidosis)
Liver failure (when the liver does not function properly and requires very intensive treatment)
Metabolic acidosis (this occurs in severe liver disease, as lactate is removed by the liver)
Taking cardiac glycosides (cardiotonics) used to treat heart failure, such as digitalis or digoxin. (see also "Taking other

Precautions
Read to know before you are given Compound Sodium Lactate (Hartmann's Solution) Intravenous Infusion BP if you have any of the following medical conditions:
Allergic to ceftriaxone (an antibiotic). (See also "Other medicines and Compound Sodium Lactate (Hartmann's Solution) Intravenous Infusion BP")
Kidney failure (lung disease) (special monitoring may be required in the above conditions)
Excess potassium in the blood than normal (hyperkalaemia)
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Warnings
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months of age.
Your doctor will take into account if you are receiving parenteral nutrition (nutrition given by infusion into a vein). If you are given Compound Sodium Lactate (Hartmann's Solution) Intravenous Infusion BP for a long time, you will be given an extra source of nutrients.
Other medicines and Compound Sodium Lactate (Hartmann's Solution) Intravenous Infusion BP
Tell your doctor or nurse if you are taking, have recently taken, or might take any other medicines.
It is particularly important that you inform your doctor if you are taking:
Ceftriaxone (an antibiotic), this should not be given through the same infusion line, unless thoroughly flushed.
Cardiac glycosides (cardiotonics) such as digitalis or digoxin used to treat heart failure, must not be used with Compound Sodium Lactate (Hartmann's Solution) Intravenous Infusion BP (see also section "You must NOT receive Compound Sodium Lactate (Hartmann's Solution) Intravenous Infusion BP if you are suffering from...").
The effects of these drugs can be increased by calcium.
This can lead to life-threatening changes to the heart rhythm
- corticosteroids (anti-inflammatory medicines) These medicines can cause the body to accumulate sodium and water, leading to:
- tissue swelling due to fluid collection under the skin (oedema)
- high blood pressure (hypertension)
- The following medicines can increase the concentration of potassium in the blood.
- This effect can be life-threatening. A rise in the blood potassium levels is more likely to occur if you have kidney disease.
- potassium-sparing diuretics (certain water tablets, e.g. amiloride, spironolactone, triamterene) (Note that these medicines may be included in combination medicinal products)
- angiotensin converting enzyme (ACE) inhibitors (used to treat high blood pressure)
- angiotensin II receptor antagonists (used to treat high blood pressure)
- tacrolimus (used to prevent rejection of a transplant and to treat some skin diseases)
- cyclosporin (used to prevent rejection of a transplant).

Other medicines that can affect or be affected by Compound Sodium Lactate (Hartmann's Solution) Intravenous Infusion BP include:
thiazide diuretics (such as hydrochlorothiazide or chlortalidone)
vitamin D
bisphosphonates (to treat bone diseases such as osteoporosis)
fluoride (for the teeth and bones)
fluoroquinolones (a type of antibiotic, including ciprofloxacin, norfloxacin, ofloxacin)* tetracyclines (a type of antibiotic, including tetracycline)
acidic medicines, including:
salicylates used to treat inflammation (aspirin)
barbiturates (sleeping tablets)
lithium (used to treat psychiatric illness)
alkaline (basic) medicines including:
sympathomimetics (stimulant medicines such as ephedrine and pseudoephedrine, used in cough and cold preparations)
other stimulants (e.g. dexamphetamine, phenfluramine).
Compound Sodium Lactate (Hartmann's Solution) Intravenous Infusion BP with food and drink
You should ask your doctor about what you can eat or drink.
Pregnancy, breast-feeding and fertility
If you are pregnant or breast feeding, think you may be pregnant or are planning to have a baby, ask your doctor or nurse for advice before taking this medicine.
Compound Sodium Lactate (Hartmann's Solution) Intravenous Infusion BP can be used safely during pregnancy or breast-feeding.
Your doctor will monitor the levels of chemicals in your blood and the amount of fluid in your body.
Calcium can reach your unborn baby through the placenta and, after birth, through the breast milk. However, if another medicine is to be added to your solution for infusion during pregnancy or breast-feeding you should:
consult your doctor
read the Patient Information Leaflet of the medicine that is to be added.
Driving and using machines
Ask your doctor or pharmacist for advice before driving or using machines.

3. How you will be given Compound Sodium Lactate (Hartmann's Solution) Intravenous Infusion BP
You will be given Compound Sodium Lactate (Hartmann's Solution) Intravenous Infusion BP by a doctor or nurse.
Your doctor will decide on how much you need and when it is to be given.
This will depend on your age, weight, condition and the reason for treatment.
The amount you are given may also be affected by other treatments you are receiving.
You should NOT be given Compound Sodium Lactate (Hartmann's Solution) Intravenous Infusion BP if there are particles floating in the solution or if the pack is damaged in any way.
Compound Sodium Lactate (Hartmann's Solution) Intravenous Infusion BP will usually be given to you through a plastic tube attached to a needle in a vein. Usually a vein in your arm is used to give you the infusion.
However, your doctor may use another method to give you the medicine.
Any unused solution should be thrown away.
You should NOT be given an infusion of Compound Sodium Lactate (Hartmann's Solution) Intravenous Infusion BP from a bag that has been partly used.

If you receive more Compound Sodium Lactate (Hartmann's Solution) Intravenous Infusion BP than you should
If you are given too much Compound Sodium Lactate (Hartmann's Solution) Intravenous Infusion BP (over-infusion) or it is given too fast, this may lead to the following symptoms:
- water and/or sodium (salt) overload with build up of liquid in the tissues (oedema) causing swelling
- hyperkalaemia (higher levels of potassium in the blood than normal) especially in patients with kidney failure, causing symptoms such as:
- pins and needles in the arms and legs (paraesthesia)
- muscle weakness
- an inability to move (paralysis)
- an irregular heartbeat (cardiac arrhythmias)
- heart block (a very slow heartbeat)
- cardiac arrest (the heart stops beating: a life-threatening situation)
- confusion
- hypercalcaemia (higher levels of calcium in the blood than normal) causing symptoms such as:
- a decreased appetite (anorexia)
- feeling sick (nausea)
- vomiting
- constipation
- abdominal pain
- mental disturbances such as irritability or depression
- drinking lots of water (polydipsia)
- producing more urine than normal (polyuria)
- kidney disease due to build up of calcium in the kidneys (nephrocalcinosis)
- kidney stones
- coma (unconsciousness)
- chalky taste
- redness (hot flushes)
- dilatation of the blood vessels in the skin (peripheral vasodilatation).

Hypokalaemia (lower levels of potassium in the blood than normal) and metabolic alkalosis (when the blood becomes too basic), especially in patients with kidney failure, causing symptoms such as:
- mood changes
- tiredness
- shortness of breath
- stiffness of the muscles
- twitching of the muscles
- contraction of muscles.
If you develop any of these symptoms you must inform your doctor immediately.

Your infusion will be stopped and you will be given treatment depending on the symptoms.
If a medicine has been added to your Compound Sodium Lactate (Hartmann's Solution) Intravenous Infusion BP before over-infusion occurs, that medicine may also cause symptoms.
You should read the Patient Information Leaflet of the added medicine for a list of possible symptoms.
Stopping your Compound Sodium Lactate (Hartmann's Solution) Intravenous Infusion BP
Your doctor will decide when to stop giving you this infusion.
If you have any further questions on the use of this product, ask your doctor or nurse.
4. Possible side effects
Like all medicines, this medicine can cause side effects, although not everybody gets them.
If you have any of the following symptoms you should tell your doctor or nurse immediately.
These may signify a very severe or even fatal hypersensitivity (allergic) reaction called anaphylactic shock:
- hives (urticaria) which may be localised to a part of the body or widespread
- skin rash
- redness of the skin (erythema)
- itching (pruritus)
- skin swelling (angioedema)
- coughing
- narrowing of the airways causing difficulty breathing (bronchospasm)
- a fast heartbeat (tachycardia)
- a slow heartbeat (bradycardia)
- decreased blood pressure
- chest discomfort or pain
- anxiety
- tightness of the chest (making it difficult to breathe)
- shortness of breath (dyspnea)
- flushing
- throat irritation
- pins and needles (paraesthesia)
- reduced sense in the mouth (hypoesthesia oral)
- altered taste (dysgeusia)
- fever (pyrexia)
- nausea
- headache
- Higher levels of potassium in the blood than normal (hyperkalaemia)
- Reactions due to the administration technique manifested by one or more of the following symptoms:
- local pain or reaction redness or swelling at the site of infusion
- irritation and inflammation of the vein into which the solution is infused (phlebitis).
- This can cause redness, pain or burning and swelling along the path of the vein into which the solution is infused.
- rash or itching (pruritus) of the infusion site.

Other side effects noted with similar products (other sodium-lactate containing solutions) include:
- Other manifestations of hypersensitivity/infusion reactions:
- a blocked nose (nasal congestion), sneezing, swelling in the throat making it difficult to breathe (laryngeal oedema also called Quincke's oedema), skin swelling (angioedema)
- Changes in the concentrations of the chemicals in the blood (electrolyte disturbances)
- A larger volume of blood in the blood vessels than there should be (hypervolaemia)
- panic attack
- Other reactions due to the administration technique:
infection at the site of infusion, escape of the infusion solution into the tissues around the vein (extravasation).
This can damage the tissues and cause scarring, numbness at the site of infusion.
If a medicine has been added to the solution for infusion, the added medicine may also cause side effects.
These side effects will depend on the medicine that has been added. You should read the Patient Information Leaflet of the added medicine for a list of possible symptoms.

Reporting of side effects
If you get any side effect, talk to your doctor or nurse.
This includes any possible side effect not listed in this leaflet.
5. How to Store Compound Sodium Lactate (Hartmann's Solution) Intravenous Infusion BP
Keep out of the reach and sight of children.
Do not store above 25°C. Do not freeze. Store in the original container.
Do not use after the expiry date.
The product should be used immediately after opening.
Any unused solution should be discarded. Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further Information
What Compound Sodium Lactate (Hartmann's Solution) Intravenous Infusion BP contains
The active substances are Sodium Chloride, Sodium Lactate, Potassium Chloride & Calcium Chloride Dihydrate. Compound Sodium Lactate BP
Each litre of solution contains 6 g of Sodium Chloride, 0.4 g of Potassium Chloride, 0.27 g of Calcium Chloride dihydrate and 3.2 g of Sodium Lactate.
Electrolyte content per liter: Sodium (Na⁺) 131 mmol; Chloride (Cl⁻) 111 mmol, Calcium (Ca²⁺) 2 mmol, Potassium (K⁺) 5 mmol & Lactate (C₃H₅O₂) 29 mmol.
½ S. Compound Sodium Lactate BP:
Each litre of solution contains 3 g of Sodium Chloride, 0.2 g of Potassium Chloride, 0.135 g of Calcium Chloride dihydrate and 1.6 g of Sodium Lactate.
Electrolyte content per liter:
Sodium (Na⁺) 65.5 mmol; Chloride (Cl⁻) 55.5 mmol, Calcium (Ca²⁺) 1 mmol, Potassium (K⁺) 2.5 mmol & Lactate (C₃H₅O₂) 14.5 mmol.
The other ingredient is water for injections.
What Compound Sodium Lactate (Hartmann's Solution) Intravenous Infusion BP or ½ S. Compound Sodium Lactate BP looks like and contents of the pack:
BP Compound Sodium Lactate (Hartmann's Solution) Intravenous Infusion BP or ½ S. Compound Sodium Lactate BP is a clear, colourless solution.
The solution is packed in P.E. Bottle sizes of 500 mL and P.P. (NON PVC) bag sizes of 50 mL, 100 mL, 250 mL, 500 mL, 1000 mL and 2000 mL.

THIS IS A MEDICATION
- Medication is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medication.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medications out of reach of children

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To report any side effects contact:
Ministry of public health Qatar
Other countries: Please contact the relevant competent authority
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