PACKAGE LEAFLET: INFORMATION FOR THE USER

Hartmann's Solution

For Infusion

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 nurse.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

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In this leaflet:

1. WHAT HARTMANN'S SOLUTION IS AND WHAT IT IS USED FOR ?

HARTMANN'S SOLUTION is a sterile, colourless solution for infusion.
It is used for the treatment of extracellular dehydration (water loss), hypovolaemia (sudden drop in volume of circulating blood) and metabolic acidosis (increased acid in the body).

2. WHAT YOU NEED TO KNOW BEFORE YOU RECEIVE HARTMANN'S SOLUTION

You should not receive HARTMANN'S SOLUTION if you have:
- hyperhydration (too much fluid)
- decompensated congestive cardiac failure (your heart can't pump enough blood throughout the body)
- hyperkalemia (too much potassium in your blood),
- hypercalcemia (too much calcium in your blood),
- metabolic alkalosis (too much alkalis such as bicarbonate in the blood),
- in combination with digitalis (medicine used as cardiac stimulant) (see "Using other medicines" section).

Your doctor will check these.

Special care will be taken if you:
- suffer from swelling with sodium retention.
- suffer from acute illness, pain, post-operative stress, infections, burns, or diseases of the central nervous system
- have any type of heart, liver or kidney disease
- have been treated with a medicine increasing the effect of vasopressin (a hormone regulating the body's water retention) because this may increase the risk of hospital-acquired low sodium levels in the blood (hyponatraemia)

Especially in these situations, your doctor or nurse will take samples of blood and urine.

Your doctor or nurse will make sure that the solution is given to you properly.

Warnings and precautions
All patients should be closely monitored. In cases where normal regulation of the water content of the blood is disturbed due to increased secretion of vasopressin, also known as Antidiuretic Hormone (ADH), the infusion of fluids with a low concentration of sodium chloride (hypotonic fluids) may result in a low level of sodium in the blood (hyponatraemia). This can lead to headache, nausea, seizures, lethargy, coma, swelling of the brain (cerebral oedema) and death; therefore these symptoms (acute symptomatic hyponatraemic encephalopathy) are considered a medical emergency.

Children, women in the fertile age and patients with brain diseases such as meningitis, brain bleeding, brain contusion and brain oedema are at particular risk of the severe and life-threatening brain swelling caused by acute hyponatraemia.

Children and adolescents
Children are at particular risk of the severe and life-threatening brain swelling caused by acute hyponatraemia.

Other medicines and Hartmann's Solution
Tell your doctor or nurse if you are taking, have recently taken or might take any other medicines such as:
- digitalis (medicine used as cardiac stimulant)
- diuretics given alone or in combination (such as spironolactone, triamterene, amiloride) - medicines that increase water loss in the urine
- ACE inhibitors and angiotensin II receptor antagonists– medicines that are mainly used for controlling blood pressure, treating heart failure
- tacrolimus and cyclosporine- medicine used to prevent organ rejection
- Medicines leading to an increased vasopressin effect (see also section "Warnings and precautions" above), e.g.:
- Medicines potentiating vasopressin action (e.g. non-steroidal anti-inflammatory drugs)
- Medicines acting as vasopressin, so-called vasopressin analogues
- Other medicinal products increasing the risk of hyponatraemia including diuretics in general and antiepileptics.

Pregnancy and breast-feeding
HARTMANN'S SOLUTION can be used during pregnancy or breast-feeding. However, you should tell your doctor if you are pregnant, if you think you are pregnant or if you are breast-feeding.
This medicine should be given with special caution for pregnant women during labour particularly if combined with oxytocin (a hormone which may be given to induce labour and to control bleeding) due to the risk of hyponatraemia.

3. HOW YOU ARE GIVEN HARTMANN'S SOLUTION ?

You will receive your medicine by slow intravenous infusion ('IV drip'). The rate at which the infusion is given and the volume infused will depend on your own specific requirements. Your doctor will decide on the correct dose for you to receive.

If you are given more HARTMANN'S SOLUTION than you should:
It is very unlikely that you will receive more infusion than you should as your doctor or nurse will monitor you during the treatment. However, if you think that you have received too much solution, inform your doctor or nurse immediately.
Signs of overdose include: fluid overload with tightened skin, venous stasis and swelling. Extra renal dialysis may be necessary.
If overdose does occur, your infusion will be stopped and appropriate treatment will be given.

The following information is intended for medical or healthcare professionals only:

Posology
General advice
Fluid balance, serum electrolytes and acid-base balance may need to be monitored before and during administration, with particular attention to serum sodium in patients with increased non-osmotic vasopressin release (syndrome of inappropriate antidiuretic hormone secretion, SIADH) and in patients co-medicated with vasopressin agonist drugs, due to the risk of hospital acquired hyponatraemia. Monitoring of serum sodium is particularly important for physiologically hypotonic fluids.

For paediatric patients the dose and rate of administration should be determined by the consulting physician experienced in paediatric intravenous fluid therapy.

Warnings
This solution must not be given by intramuscular injection.
Keep to a slow infusion rate.
The infusion must be stopped if any abnormal sign develops.
Risk of complications related to volume and amount of electrolytes administered.
Risk of overload of cardiovascular system with pulmonary oedema, especially in predisposed individuals. Infusion of Hartmann's solution may cause metabolic alkalosis because of the presence of lactate ions. Hartmann's solution may not produce its alkalinizing action in patients with hepatocellular insufficiency since lactate metabolism may be impaired.
In case of concomitant blood transfusion and because of the presence of calcium, Hartmann's solution must not be administered via the same infusion system because of the risk of coagulation.

4. POSSIBLE SIDE EFFECTS

Like all medicines, HARTMANN'S SOLUTION can cause side effects, although not everybody gets them.

The following side effects have been reported if the solution is given too quickly:
- Swelling
- Water or sodium overload
- Headache, nausea, seizures, lethargy. This can be caused by a low level of sodium in the blood. When sodium levels in the blood become very low, water enters the brain cells and causes them to swell. This results in increased pressure in the skull and causes hyponatraemic encephalopathy

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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:
HPRA Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2, Tel@353 1 6764971; Fax +353 1 6762517; Website:www.hpra.ie; Email:medsafety@hpra.ie

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

5. HOW TO STORE HARTMANN'S SOLUTION ?

Keep out of sight and reach of children.
Do not use HARTMANN'S SOLUTION after the expiry date which is stated on the bottle.
Glass bottles and bags: Do not store above 25°C.
PE bottles: No special precautions for storage.
Your doctor or nurse will ensure the solution is clear and free from particles before use.
Any solution remaining after treatment should be discarded.
After opening or mixture with other drugs, the product should be used immediately.

6. FURTHER INFORMATION

What HARTMANN'S SOLUTION contains?
- The active substances are:

Bag or bottle:	50 ml	100 ml	250 ml	500 ml	1000 ml
Sodium chloride (g)	0.30	0.60	1.50	3.00	6.00
Potassium chloride (g)	0.02	0.04	0.10	0.20	0.40
Dihydrated calcium chloride (g)	0.01	0.03	0.07	0.14	0.27
50% sodium lactate solution (g)	0.32	0.63	1.59	3.17	6.34

Molar formula

Bag or bottle:	50 ml	100 ml	250 ml	500 ml	1000 ml
Sodium (mmol)	6.55	13.09	32.73	65.45	130.90
Potassium (mmol)	0.27	0.54	1.35	2.70	5.40
Calcium (mmol)	0.09	0.18	0.46	0.92	1.84
Chloride (mmol)	5.59	11.17	27.93	55.85	111.70
Lactate (mmol)	1.42	2.83	7.08	14.15	28.30

Osmolarity : 279 mOsm/l
Osmolality : 255 mOsm/kg
pH: 5.5 to 6.3

- The other ingredients are : hydrochloric acid, sodium hydroxide, water for injections.

What HARTMANN'S SOLUTION looks like and contents of the pack?

Hartmann's solution is a clear and colourless solution for infusion.

- 1 and 40 x 50 ml, 1 and 40 x 100 ml, 1 and 20 x 250 ml, 1 and 15 x 500 ml or 1, 8 and 10 x 1000 ml in polyester-polyethylene copolymer - polypropylene / styrene, ethylene, butadiene bag with overwrap.
- 1 and 40 x 250 ml, 1 and 20 x 500 ml or 1 and 10 x 1000 ml in polyester-polyethylene copolymer-polypropylene/styrene, ethylene, butadiene bag without overwrap.
- 1, 10, 20, 30 x 250 ml, 1, 10, 20 x 500 ml or 1, 10 x 1000 ml polyethylene bottles.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Fresenius Kabi Deutschland GmbH
Else-Kroener Strasse 1, Bad Homburg
v.d.H 61352, Germany

Manufacturer :
FRESENIUS KABI POLSKA Sp. z o.o.
25 ul. Sienkiewicza,
P-99-300 Kutno

This medicinal product is authorised in the Member States of the EEA under the following names:
Ireland: Hartmann's solution for infusion
Portugal: Lactato de Ringer Fresenius
Luxembourg: Ringer-lactat Lösung

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Precautions for use
The patients clinical status and laboratory parameters (blood and using electrolytes) must be monitored during use of this solution, especially in the following situations:
- congestive cardiac failure,
- severely impaired renal function,
- oedema with sodium retention.

Precautions for using bag:
- do not use an air entry;
- flush the infusion system in order to avoid any passage of air,
- do not connect in series since the residual of the first container might be carried on by the solution coming from the second container, with the risk of air embolism.
- for single use only; do not reconnect partially used container.

Physico-chemical incompatibilities:
It is up to the physician to determine the incompatibility of an added medicine regarding Hartmann's solution, by checking for any possible colour change and/or possible formation of precipitate, insoluble complex or crystals.
There is physical-chemical incompatibility with certain antibiotics when they are given intravenously : chlortetracycline, amphotericin B, oxytetracycline.
Before adding any medicine, check that the pH zone in which it is effective corresponds to that of Hartmann's solution.
Also check the package leaflet of the medicine to be added.
Check the colour and clarity of the solution, as well as that the container is not damaged before use. Discard any damaged or partially used container.
Once a medicine is added to Hartmann's solution, the mixture must be administered immediately.