COMPOUND SODIUM LACTATE (HARTMANN'S)

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I being given COMPOUND SODIUM LACTATE (HARTMANN'S)?

COMPOUND SODIUM LACTATE (HARTMANN'S) contains the active ingredient sodium lactate, sodium chloride, potassium chloride and calcium chloride dihydrate. COMPOUND SODIUM LACTATE (HARTMANN'S) is used to replace body fluid and mineral salts that may be lost for a variety of medical reasons. It is especially suitable when the losses result in too much acid being present in the blood.

For more information, see Section 1. Why am I being given COMPOUND SODIUM LACTATE (HARTMANN'S)? in the full CMI.

2. What should I know before I am given COMPOUND SODIUM LACTATE (HARTMANN'S)?

Do not use if you have ever had an allergic reaction to COMPOUND SODIUM LACTATE (HARTMANN'S) or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I am given COMPOUND SODIUM LACTATE (HARTMANN'S)? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with COMPOUND SODIUM LACTATE (HARTMANN'S) and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How is COMPOUND SODIUM LACTATE (HARTMANN'S) given?

Your doctor will have had a lot of experience in injecting COMPOUND SODIUM LACTATE (HARTMANN'S) and will choose the best dose for you.

Your doctor or specially trained nurse will give the medicine by infusion or drip into the vein.

More instructions can be found in Section 4. How is COMPOUND SODIUM LACTATE (HARTMANN'S) given? in the full CMI.

What should I know after being given COMPOUND SODIUM LACTATE (HARTMANN'S)?

Things	you
should	do

 Remind any doctor, dentist or pharmacist you visit that you are using COMPOUND SODIUM LACTATE (HARTMANN'S).

For more information, see Section <u>5. What should I know after being given COMPOUND SODIUM LACTATE (HARTMANN'S)?</u> in the full CMI.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary.

The most common side effects are some swelling of the hands, ankles and feet may be experienced due to retention of fluid in your body, difficulty breathing, chest tightness, chest pain, fast or slow heart beat and other heart issues, coughing, sneezing, abdominal cramps, paralysis, weakness, tingling or numbness of hands and feet, nausea (feeling sick), vomiting and diarrhoea, headache, dizziness, drowsiness, confusion, inflammation at the site of injection, swelling of your veins or infection near the site of injection.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

COMPOUND SODIUM LACTATE (HARTMANN'S)

Active ingredient(s): sodium lactate, sodium chloride, potassium chloride and calcium chloride dihydrate

Consumer Medicine Information (CMI)

This leaflet provides important information about using COMPOUND SODIUM LACTATE (HARTMANN'S). You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using COMPOUND SODIUM LACTATE (HARTMANN'S).

Where to find information in this leaflet:

- 1. Why am I being given COMPOUND SODIUM LACTATE (HARTMANN'S)?
- 2. What should I know before I am given COMPOUND SODIUM LACTATE (HARTMANN'S)?
- 3. What if I am taking other medicines?
- 4. How is COMPOUND SODIUM LACTATE (HARTMANN'S) given?
- 5. What should I know after being given COMPOUND SODIUM LACTATE (HARTMANN'S)?
- 6. Are there any side effects?
- 7. Product details

Why am I being given COMPOUND SODIUM LACTATE (HARTMANN'S)?

COMPOUND SODIUM LACTATE (HARTMANN'S) contains the active ingredient sodium lactate, sodium chloride, potassium chloride and calcium chloride dihydrate.

COMPOUND SODIUM LACTATE (HARTMANN'S) is used to replace body fluid and mineral salts that may be lost for a variety of medical reasons. It is especially suitable when the losses result in too much acid being present in the blood.

Your doctor may have prescribed it for another reason. Ask your doctor if you have any questions about why this medicine has been prescribed for you.

2. What should I know before I am given COMPOUND SODIUM LACTATE (HARTMANN'S)?

Warnings

Do not use COMPOUND SODIUM LACTATE (HARTMANN'S) if:

- you are allergic to
 - sodium lactate, sodium chloride, potassium chloride and calcium chloride dihydrate, or any of the ingredients listed at the end of this leaflet

 Any similar medicines to Compound Sodium Lactate (Hartmann's)

Some symptoms of an allergic reaction may include:

- · Shortness of breath
- Wheezing or difficulty breathing
- Swelling of the face, lips, tongue or other parts of the body
- Skin rash, itching or hives

Always check the ingredients to make sure you can use this medicine.

Compound Sodium Lactate (Hartmann's) should not be given;

- You have congestive heart failure (constant wheezing, shortness of breath);
- you have severely reduced kidney function;
- you have too much sodium and chloride in your blood that is not being corrected with medication;
- it is intended to be administered at the same time and through the same injection equipment as blood preparations (citrate anticoagulated/preserved blood) or ceftriaxone, an antibiotic (if a baby < 1 month of age is to be treated, administration at the same time as ceftriaxone must never occur)
- the expiry date printed on the pack on the bottom of the bag has passed, or if the packaging is torn or shows any signs of tampering.

Check with your doctor if you:

- have allergies to any other medicines, foods, preservatives or dyes.
- have any other medical conditions especially the following:
 - Heart problems
 - Kidney problems including kidney stones
 - You have too much potassium or calcium in your blood that is not being corrected with medication
 - Diabetes
 - are taking any other medicines including those you can buy without a prescription, in particular digoxin (a medicine for heart problems), medicines for high blood pressure (diuretics, ACE inhibitors or ARAs), immunosuppressant medicines (tacrolimus or cyclosporine), potassium supplements, corticosteroids, lithium or vitamin D;
 - Any other illness

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with COMPOUND SODIUM LACTATE (HARTMANN'S) and affect how it works.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect COMPOUND SODIUM LACTATE (HARTMANN'S).

4. How is COMPOUND SODIUM LACTATE (HARTMANN'S) given?

How much is given

The dosage you will be given will depend on your age, weight, medical condition and response. Your doctor will have had a lot of experience in injecting COMPOUND SODIUM LACTATE (HARTMANN'S) and will choose the best dose for you.

How it will be given

COMPOUND SODIUM LACTATE (HARTMANN'S) will be given to you by your doctor or specially trained nurse by infusion or drip into the vein.

If you are given too much

If you think that you have used too much COMPOUND SODIUM LACTATE (HARTMANN'S), you may need urgent medical attention.

This rarely happens as it is usually administered under the care of a trained professional in a hospital or clinic setting. However, if you are particularly sensitive to COMPOUND SODIUM LACTATE (HARTMANN'S) you may become confused or dehydrated.

You should immediately:

phone the Poisons Information Centre (by calling 13 11 26), or

contact your doctor, or

go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know after being given COMPOUND SODIUM LACTATE (HARTMANN'S)?

Things you should do

Tell any other doctors, dentists, and pharmacists who treat you that you have been given this medicine.

Frequent clinical evaluation and laboratory tests may be required as COMPOUND SODIUM LACTATE (HARTMANN'S) is normally given in a hospital. Your doctor or nurse will make appropriate records during your treatment and will note any unexpected effects you may experience.

Looking after your medicine

Store below 25°C for the Freeflex bags.

Getting rid of any unwanted medicine

Any COMPOUND SODIUM LACTATE (HARTMANN'S) which is not used and which is left in the container, will be disposed of in a safe manner by your doctor or pharmacist.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

- Some swelling of the hands, ankles and feet may be experienced due to retention of fluid in your body
- Difficulty breathing
- Chest tightness
- Chest pain
- Fast or slow heart beat and other heart issues
- Coughing
- Sneezing
- Abdominal cramps
- Paralysis
- Weakness
- Tingling or numbness of hands and feet
- Nausea (feeling sick)
- Vomiting and diarrhoea
- Headache
- Dizziness
- Drowsiness
- Confusion
- Inflammation at the site of injection
- Swelling of your veins or infection near the site of injection

Do not be alarmed by this list. You may not experience any of them.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

What COMPOUND SODIUM LACTATE (HARTMANN'S) contains

Active ingredient (main ingredient)	sodium lactate, sodium chloride, potassium chloride and calcium chloride dihydrate
Other ingredients	water for injections
(inactive ingredients)	sodium Hydroxide
	Hydrochloric acid

Do not take this medicine if you are allergic to any of these ingredients.

What COMPOUND SODIUM LACTATE (HARTMANN'S) looks like

COMPOUND SODIUM LACTATE (HARTMANN'S) is a clear and colourless solution.

COMPOUND SODIUM LACTATE (HARTMANN'S) is available as

250mL freeflex® Bags: AUST R 148935
500mL freeflex® Bags: AUST R 29771
1000mL freeflex® Bags: AUST R 47410

Who distributes COMPOUND SODIUM LACTATE (HARTMANN'S)

Fresenius Kabi Australia Pty Limited Level 2, 2 Woodland Way Mount Kuring-gai NSW 2080

Australia

Telephone: (02) 9391 5555

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