MODULE-1
ADMINISTRATIVE INFORMATION FOR RL

PATIENT INFORMATION LEAFLET (PIL)

Read all of this leaflet carefully before you are given 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

What is in this leaflet:

1. What RL is and what it is used for

RL contains Compound Sodium Lactate Intravenous Infusion which belongs to a group of medicines called Electrolytes.

Sodium Chloride, Potassium Chloride & Calcium Chloride Dihydrate ions are important for maintaining the correct balance of fluid in and around the body's cells and tissues, and are involved in nerve signals and muscle contractions. Compound Sodium Lactate Intravenous Infusion may be given for a variety of reasons:

-to help restore fluid levels and the normal salt balance

-to correct for low blood pressure or decreased blood volume

-to treat metabolic acidosis, a condition where there is increased acid in the body.

- Short term volume replacement (alone or in association with colloid) in case of hypovolaemia or hypotension

The solution may be given alone but may be given with other medicines added.

You will be given Compound Sodium Lactate Intravenous Infusion in hospital by a doctor or nurse.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE RL

You MUST NOT be given Compound Sodium Lactate Intravenous Infusion if you have:

• increased levels of **sodium, potassium, calcium or chloride** in the blood.

These conditions can be detected in blood tests

• severe kidney disease and you are passing little or no urine

• suffered heart failure

• increased blood volume or fluid retention (water intoxication, or excess water content in the body)

• severe metabolic acidosis or lactic acidosis, when you have increased acid in the body

• metabolic alkalosis, when you have less acid in the body than normal

• severe liver disease or cannot breakdown lactate

• swelling caused by fluid retention

• heart disease which is being treated with the medicine digitalis

• a requirement to take additional medicines which may lead to increased potassium levels in the body, such as diuretics (water pills)

Warnings and precautions

Talk to your doctor or nurse before being given Compound Sodium Lactate Intravenous Infusion if you:

• have heart, kidney or liver disease, or swelling caused by fluid retention

• have high blood pressure

• have any condition which causes increased levels of Vitamin D

• have or have had kidney stones

• have any condition which may lead to increased potassium levels in the blood, such as extensive tissue destruction as occurs with severe burns, or acute dehydration

• have pre-eclampsia of pregnancy

• are very young or elderly.

Other medicines and Compound Sodium Lactate Intravenous Infusion

Tell your doctor or nurse if you are taking, have recently taken or might take any other medicines.

In particular, please tell your doctor if you are taking any of the following:

• digitalis (for heart disease). You must not be given Compound Sodium Lactate Intravenous Infusion if you are taking digitalis

• the water tablets spironolactone, triamterene, amiloride, potassium canrenoate (diuretics used in congestive heart failure)

• thiazide diuretics

• medicines for treatment of high blood pressure (ACE inhibitors and angiotensine II inhibitor)

• corticosteroids, used to treat inflammation

• tacrolimus and ciclosporin (medicines used to prevent tissue rejection after transplantation)

• Vitamin D

• salicylates, barbiturates and lithium

• adrenaline and the stimulants dexamphetamine sulphate, phenfluramine hydrochloride

• biphosphonates (for the treatment of bone disorders, and menopausal symptoms)

• the antibiotic tetracycline and some fluoroquinolones

• carbenoxolone used to treat ulcers

• pseudoephedrine used to treat sinus or nasal congestion from colds, hayfever, allergies

• fluoride (used to prevent dental caries).

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 for advice before being given this medicine.

The solution should be used with care during pregnancy and breast-feeding.

Breastfeeding mothers should be aware that calcium will pass into breast-milk.

Driving and using machines

The solution has no effect on your ability to drive or use machines.

3. HOW RL IS GIVEN

The solution will be given to you in hospital.

You will receive the solution by infusion into a vein probably in your arm, administered by a doctor or nurse. The amount and rate at which the infusion is given depends on your requirements, such as your age, weight and clinical condition. Your doctor will decide on the correct volume for you to receive.

Your doctor will check your response to the treatment by the relief of your symptoms, and will probably take samples of blood and urine for laboratory testing.

If your levels of potassium could be raised, the level of this salt in your blood will be carefully checked.

Your doctor will monitor you carefully if you have heart or lung disease and you need to be given high volumes of the solution.

Levels of potassium in Compound Sodium Lactate Intravenous Infusion are not high enough to treat severely low blood potassium.

If you are given solutions by infusion for a long period of time, your doctor will also provide you with suitable intravenous feeding.

If you are given more solution than you should

It is unlikely you will be given too much solution as your doctor or nurse will be checking your response to the treatment. If too much solution is given or if it is infused too quickly, the levels of potassium, sodium, calcium and lactate in the body may become too high. If you are concerned about the volume of solution given, or are worried about any effects. you notice, talk to your doctor or nurse.

If you have any further questions on the use of this medicine, ask your doctor or nurse.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop using this medicine if you experience an adverse reaction.

If you are given the solution for a long time, you may notice the following:

- irritation, swelling, redness and tenderness at the site of injection. You may get inflammation of the vein and blood clots in the vein.

Very common side effects are:

• symptoms of an allergic reaction such as urticaria (hives), skin redness, rash, itching, swelling of the face, lips, throat or tongue, respiratory symptoms such as nasal congestion, difficulty in breathing, wheezing, coughing, sneezing

• upset levels of electrolytes (salts) in your body giving symptoms such as muscle weakness, swelling, prickling sensation in hands and feet, low or high blood pressure, shortness of breath, confusion, nausea

• if you have heart disease or fluid accumulation in your lungs you may experience water intoxication, or excess water content in the body and heart failure

Common side effects are:

• chest tightness

• chest pain with a decrease or increase in heart rate

• feelings of anxiety

Uncommon side effects are:

• panic attacks and seizure, caused by increases of lactate levels in the blood.

Reporting of side effects

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

5. How to store RL

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 after EXP.

The expiry date refers to the last day of that month.

Store below 30ºC. Protect from light. Do not refrigerate or freeze.

The solution should only be used if it is clear and the container is not damaged. It should be used immediately on removal from the overwrap. For single use only. Any unused solution in the bag must be discarded.

Do not throw away any medicines via wastewater or household waste. The doctor or nurse will dispose of this medicine. These measures will help to protect the environment.

6. CONTENT OF THE PACK AND OTHER INFORMATION

What **RL** contains

- The active substance is Sodium Chloride BP, Potassium chloride BP, Calcium chloride Dihydrate BP & Sodium Lactate BP.
- The other ingredients are Sodium Hydroxide BP, Hydrochloric Acid BP & Water for Injections BP.

What RL looks like and contents of the pack

A Colorless solution

Pack: 1 x 500 mL LDPE Bottle with helmet cap/eurohead cap, with pre-printed label, wrapped in a transparent BOPP film.