SUMMARY OF PRODUCT CHARACTERISTICS
LACTATED RINGER'S INJECTION
Solution for Intravenous Infusion

1. TRADE NAME

LACTATED RINGER'S INJECTION/DEMO

2. QUANTITATIVE AND QUALITATIVE COMPOSITION

100ml of solution contain: 600mg of Sodium chloride, 320mg of Sodium lactate, 40mg of Potassium chloride and 27mg of Calcium chloride dehydrate.

3. PHARMACOTECHNICAL FORM: Solution for infusion

4. CLINICAL PROPERTIES

4.1 Indications: Electrolyte replacement, maintenance and/or restitution of the extracellular volume, reduction of blood volume (hypovolaemia), adjustment of acid-base equilibrium.

4.2 Dosage and way of administration

Adults: intravenous infusion, according to clinical condition and balance of electrolyte intake-disposition (500 to 3000ml/24 hours).

4.3 Contraindications: Increase of blood volume, hyperkalemia, hypercalcinemia, cardiac and renal impairment, oedemas and cirrhotic ascites, lactic acidosis, alkalosis.

4.4 Special precautions and warnings for use: Aseptic conditions should be applied during preparation of the infusion. The clarity and the absence of visible particles should be checked before use. The solution should be used immediately after opening of the container. The infusion rate should be checked.

In cases of hypertension, peripheral and pulmonary oedema and pregnancy toxemia the administered dose should be reduced.
Great caution is required when administered to patients suffering from renal dysfunctions or failure.

4.5 Interactions with other medicines or other forms of interaction

The pH should be checked during mixing with other medicines.
Before any mixing takes place, the compatibility should be checked.

4.6 Pregnancy and lactation

There are no special precautions for administration during pregnancy and lactation.

4.7 Effects on the ability to drive and use machines

Not applicable

4.8 Adverse reactions

Administration of high doses could cause sodium and water retention, pulmonary oedema and hyperkalaemia.

Reporting of suspected adverse reactions:
Reporting suspected adverse reactions is an important way to gather more information to continuously monitor the benefit/risk balance of the medicinal product. Any suspected adverse reactions should be reported to
For Greece: National Organization for Medicines, 284 Mesogeion Av.,15562 Xolargos, Athens, Greece, Tel.: +30 213 2040 200, Fax: +30 210 65 45 535, http://www.eof.gr
For Cyprus: Pharmaceutical Services, Ministry of Health, CY-1475, www.moh.gov.cy/phs Fax: + 357 22608649

4.9 Overdosage

In case of overdose systematic treatment should be performed

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

LACTATED RINGER'S solution contains Sodium lactate, Sodium chloride, Potassium chloride and Calcium chloride dihydrate. Calcium has a vital part as electrolyte of the body. It is involved in the preservation of the muscle and nerve normal function, it has an important role in cardiac function and blood thrombosis. The potassium cation is also important. It is the principal cation of intracellular fluid and it is closely related to the function and the metabolism of the cell. Sodium in the main cation of the extracellular space and it is met mainly with the chlorine anion. The sodium ion is the main osmotic factor of the extracellular space. Sodium lactate after 1 to 2 hours in the organism is metabolized in sodium bicarbonate, which neutralizes the acid excretion in stomach with release of carbon dioxide.

5.2 Pharmacokinetic properties

Calcium concentrations in plasma are approximately 2.5mmol/lt. It is absorbed by the intestine. Calcium absorption increases with 1,25-dihydroxycholecalciferol, the active metabolite of vitamin D. Potassium concentration in intracellular fluid and in plasma is 160 and 3.5 to 5 mmol/lt respectively. The total amount of potassium in the body is approximately 3500mmol and it depends on the size of the non-fatty body flesh. The amount of Sodium chloride that is normally excreted with sweat is low and the osmotic balance is maintained with the redundancy excretion in urine. The maintenance of normal osmomolarity of the extracellular fluid (280-300mOsm/L) is primarily a sodium, chlorine and bicarbonate function.

6. PHARMACEUTICAL PROPERTIES

6.1 List of excipients

Water for injections

6.2 Incompatibilities:

With hydrocortisone, tetracyclines, cephalotine, amphotericine, erythromycin, ampicillin, sodium bicarbonate, ascorbic acid, oestrogens, histamine, silver and lead salts.

6.3 Shelf life

36 months

6.4 Special precautions during storage:

It should be stored at a temperature below 25°C.

6.5 Nature and component of the container

The product is packed in polyethylene (PE) or polyprolpylene (PP) bottles of 500 and 1000ml.

6.6 Instructions for use:

The solution should mot be used if the container is destroyed.
It should be discarded after the first use.
It should be used only if the solution is totally clear.
In case that even the smallest precipitation is observed, the solution should not be used.

7. MARKETING AUTHORIZATION HOLDER IN GREECE AND CYPRUS

DEMO S.A. Pharmaceutical Industry,

21st km National Road Athens-Lamia,

145 68 Kryoneri, Attiki, Greece,

Tel.: +30 210 8161802, Fax: +30 210 8161587

8. MARKETING AUTHORIZATION NUMBER IN CYPRUS

20399

9. DATE OF FIRST AUTHORIZATION

08/10/08

10. DATE OF REVISION OF THE TEXT

June 2024

LACTATED RINGER'S INJECTION

Solution for infusion

Composition: Active ingredients: Sodium lactate, Sodium chloride, Potassium chloride, Calcium chloride dihydrate

Excipients: Water for injections

Pharmacotechnical form: Solution for infusion

Content in active ingredients: 100ml of the solution contain: 600mg of Sodium Chloride, 320mg of Sodium lactate, 40mg of Potassium chloride and 27mg of Calcium chloride dihydrate

Description – packaging: Clear, colorless aqueous solution contained in plastic polyethylene bottles of 500 and 1000ml.

Pharmacotherapeutic category: Large volume parenteral solution

Marketing Authorization Holder – Manufacturer:

DEMO SA, 21st km National Road Athens - Lamia, 145 68 Kryoneri, Athens, Greece, Tel. +30 210 8161802, Fax: +30 210 8161587

WHAT YOU SHOULD KNOW ABOUT THE MEDICINE YOUR DOCTOR PRESCRIBED TO YOU

General: LACTATED RINGER'S solution contains Sodium lactate, Sodium chloride, Potassium chloride and Calcium chloride dihydrate. Calcium has a vital part as electrolyte of the body. It is involved in the preservation of the muscle and nerve normal function, it has an important role in cardiac function and blood thrombosis. The potassium cation is also important. It is the principal cation of intracellular fluid and it is closely related to the function and the metabolism of the cell. Sodium in the main cation of the extracellular space and it is met mainly with the chlorine anion. The sodium ion is the main osmotic factor of the extracellular space. Sodium lactate after 1 to 2 hours in the organism is metabolized in sodium bicarbonate, which neutralize the acid excretion in stomach with release of carbon dioxide.

Indications: Electrolyte replacement, maintenance and/or restitution of the extracellular volume, reduction of blood volume (hypovolaemia), adjustment of acid-base equilibrium.

Contraindications: Increase of blood volume, hyperkalemia, hypercalcinemia, cardiac and renal failure, oedemas and cirrhotic ascites, lactic acidosis, alkalosis.

Special precautions and warnings during usage: Aseptic conditions should be applied during preparation of the infusion. The clarity and the absence of visible particles should be checked before use. The solution should be used immediately after opening of the container.

The infusion rate should be checked.

In cases of hypertension, peripheral and pulmonary oedema and pregnancy toxemia the administered dose should be reduced.

Great caution is required when administered to patients suffering from renal disorder or failure.
There are no special precautions for administration during pregnancy and lactation.

Interactions with other medicines or substances: The pH should be checked during mixing with other medicines.
Before any mixing takes place, the compatibility should be checked.
Incompatibilities: With hydrocortisone, tetracyclines, cephalotine, amphotericine, erythromycin, ampicillin, sodium bicarbonate, ascorbic acid, oestrogens, histamine, silver and lead salts.

Dosage: Adults: intravenous infusion, according to clinical condition and balance of electrolyte intake-disposition (500 to 3000ml/24 hours)

Overdose: Not applicable

Adverse effects: Administration of high doses could cause sodium and water retention, pulmonary oedema and hyperkalaemia.

What you should know in case you missed a dose: Not applicable

Expiry date of the product: Do not use this product if it has expired.

Storage precautions: Store below 25°C.

INFORMATION ON THE RATIONAL USE OF MEDICINES

- This medicine was prescribed to you by your doctor for your particular medical condition. You should not give it to other people or use it for any other condition without first consulting your doctor.
- If any problem occurs during treatment with this medicine, please consult your doctor or pharmacist immediately.
- If you have any questions about information concerning this medicine or your medical condition, do not hesitate to ask your doctor or your pharmacist.
- In order for this medicine to be safe and effective, it should be taken according to the instructions given to you.
- To protect your health and ensure your safety, you should read carefully all the instructions provided to you.
- Do not store this medicine in bathroom closets, because heat and humidity may affect the medicine and render it harmful to your health.
- Do not keep medicines that you no longer need or that have already expired.
- Store all medicines in a safe place away from the reach of children.

This product is administered by medical prescription only.

DEMO S.A.
Pharmaceutical Industry
21st km National Road Athens-Lamia,
145 68 Kryoneri, ATHENS, GREECE
Tel. +30 210 8161802, Fax: +30 2108161587