PATIENT INFORMATION LEAFLET

POLİFLEKS LACTATED RINGER SOLUTION FOR IV INFUSION
Used intravenously
Sterile

Active ingredients: Each liter of solution included 3 grams of sodium lactate, 6 gram sodium chloride, 0,4 gram potassium chloride and 0,3 gram calcium chloride dihydrate.
Excipients: Sterile water for injection

Please read this PATIENT INFORMATION LEAFLET carefully before starting to use the drug; because important information is included here.

- *Keep these PATIENT INFORMATION LEAFLET. You may need to re-read it later.*
- *In case you have additional questions, please consult your doctor or pharmacist.*
- *This drug is prescribed personally for you, do not give to others.*
- *During the use of this drug, please tell your doctor that you are using this drug when you visit your doctor or a hospital.*
- *Please follow these instructions strictly. Do not use dosages* ***higher or lower*** *than the dosage recommended to you.*

The following headlines are included in this *PATIENT INFORMATION LEAFLET*:

1. What is POLİFLEKS LACTATED RINGER and what is it used for?

POLİFLEKS LACTATED RINGER is a solution administered intravenously and that contains the electrolytes, which are the building blocks of the body.

POLİFLEKS LACTATED RINGER is available in PVC and PP bags with volumes 100, 150, 250, 500, 1000 and 2000 ml with or without sets.

POLİFLEKS LACTATED RINGER is used in the treatment of water and chemical loss in the body (for example, excessive sweating, kidney disorders), low blood volume in the blood vessels (hypovolemia) or low blood pressure (hypotension) and metabolic acidosis (very acidic blood).

2. *Before you are given* POLİFLEKS LACTATED RINGER

POLİFLEKS LACTATED RINGER is a safe drug in many patients. However, if you have problems in your heart, kidneys, liver or lungs, if you are diabetic or if you have swelling (edema) in your body related to excessive salt accumulation in your body, your doctor can decide not to administer this drug to you.

DO NOT USE POLİFLEKS LACTATED RINGER under following conditions:
In case you have had allergic reaction when you took drugs containing the same active substances or excipients with POLİFLEKS LACTATED RINGER, that is, if you have experienced sudden stopping of breath, wheezing, skin rashes, itching or swelling in your body, DO NOT USE this drug.

If you are not sure if you are allergic, consult your doctor.

If,
-you are a newborn (less than 28 days old) using ceftriaxone (an antibiotic),
-you are allergic to sodium lactate or any other substance in the POLİFLEKS LACTATED RINGER,
-there is too much fluid in the spaces around the body cells (extracellular hyperhydration),
-the blood volume in the blood vessels is higher than it should be (hypervolemia),
-severe kidney failure (when your kidneys are not working well and dialysis is needed),
-uncompensated heart failure. This heart failure has not been adequately treated and causes the following symptoms:
    -Shortness of breath
    -Swelling in the ankles
-potassium levels in the blood are higher than normal (hyperkalaemia),
-calcium levels in the blood are higher than normal (hypercalcemia),
-very basic blood disturbance (metabolic alkalosis),
-liver discomfort (acidic cirrhosis) that causes increased fluid in the abdomen,
-your blood is as acidic as life threatening (severe metabolic acidosis),

-a type of metabolic acidosis (lactic acidosis),
-severe liver disease (when the liver is not working properly and requires intensive treatment),
-insufficient lactate metabolism (occurs when the liver is destroyed by severe liver conditions)
-you are using cardiac glycosides (heart enhancers) such as digitalis or digoxin for the treatment of heart failure (see also the section "Use with other medicines").

Use POLİFLEKS LACTATED RINGER CAREFULLY under following conditions:
If you have one of the following diseases:
- If you are using ceftriaxone (an antibiotic) (see also the section "Using with other medicines").
- Heart failure
- Respiratory failure (lung discomfort) (special imaging may be required under the above conditions)
- Insufficient kidney function
- The level of chlorine in the blood is higher than normal (hyperchloremia)
- High blood pressure (hypertension)
- Fluid accumulation affecting the whole body under the skin (general edema)
- Fluid accumulation under the skin, especially around the ankle (environmental edema)
- Fluid accumulation in the lungs (pulmonary edema)
- High blood pressure during pregnancy (prsypsy)
- Hormone levels called aldosterone (aldosteronism)
- Other conditions related to higher levels of sodium in the blood (hypernatremia) or sodium retention (when the body holds too much sodium), such as treatment with steroids (see also "Using with Other Drugs" section).
- Any form of heart disease
- High potassium levels in the blood (hyperkalaemia):
    - Kidney failure
    - Adrenocortical insufficiency (discomfort of the adrenal gland affecting hormones that control chemical concentrations in the body)
    - Acute dehydration (water loss in the body due to vomiting or diarrhea)
    - Widespread tissue damage (such as severe burns)

    Potassium levels in the blood should be closely monitored.
- Diseases associated with high vitamin D levels (eg sarcoidosis, which affects the skin and internal organs)
- Kidney stones
- Insufficient liver function
- Diabetes

When an infusion is applied to you, your doctor will analyze your blood and urine samples:
- The amount of chemicals in your blood, such as sodium and potassium
- Acidity of your blood and urine (your acid-base balance).

Although POLİFLEKS LACTATED RINGER contains potassium, it is not enough to raise and treat the level of potassium in the blood.

Calcium chloride can be harmful if injected into body tissues. Therefore, POLİFLEKS LACTATED RINGER should not be injected into the muscles (intramuscular injection). Your doctor will also make an effort to avoid leaking the solution into the tissues around the vein.
POLİFLEKS LACTATED RINGER should not be given through the same needle used in blood transfusion. This can damage red blood cells or cause them to clump.
POLİFLEKS LACTATED RINGER contains lactate, making your blood very alkaline (metabolic alkalosis).
POLİFLEKS LACTATED RINGER should be given to babies younger than 6 months carefully. Your doctor will take this into account if you are receiving parenteral nutrition (infusion administered by intravenous infusion). If the POLİFLEKS LACTATED RINGER has been applied to you for a long time, you should be given an extra food source.

Please consult your doctor if these warnings are valid for you, even at any time in the past.

Use of POLİFLEKS LACTATED RINGER with foods or drinks

POLİFLEKS LACTATED RINGER does not interact with foods and drinks in relation with the route of its administration.

Pregnancy
Consult your doctor or pharmacist before using this drug.

Your doctor will monitor the levels of chemicals in your blood and the amount of fluid in your body. Do not use the POLİFLEKS LACTATED RINGER during pregnancy, unless it is deemed particularly appropriate by your doctor.
Calcium can pass to your unborn baby through the placenta and through breast milk after birth. In addition, if any other device will be added to your infusion solution during your pregnancy or lactation period, you must:
- Consult your doctor
- Read the Instructions for Use of the device to be added.

In case you become aware that you are pregnant during treatment, immediately consult your doctor or pharmacist.

Lactation
Consult your doctor or pharmacist before using this drug.

If you are breastfeeding your baby, please declare it to your doctor. Unless otherwise considered appropriate by your doctor, do not use POLİFLEKS LACTATED RINGER during lactation period.

Driving vehicle and using machine
POLİFLEKS LACTATED RINGER does not have any effect on driving or using machines.

Some important information about some ingredients of POLİFLEKS LACTATED RINGER

No adverse effects are expected related to the excipients included in the contents of POLİFLEKS LACTATED RINGER unless you are hypersensitive against such substances.

Taking other medicines
Please inform your doctor if you plan, are taking, or have recently taken any other medicines, including over-the-counter medicines, vaccines, and herbal medicines.

It is important to inform your doctor if you use the following:
- Ceftriaxone (an antibiotic) should not be given through the same infusion unless it is thoroughly washed.
- Cardiac glycosides (heart enhancers) such as digitalis or digoxin should not be used in conjunction with the POLİFLEKS LACTATED RINGER (see also "DO NOT USE POLİFLEKS LACTATED RINGER"). The effects of these drugs may increase with calcium. This can be life-threatening by changing the heart rhythm.
- Corticosteroids (anti-inflammatory drugs).
- These drugs can cause sodium and water to accumulate in the body. This situation;
    -Tissue swelling due to water accumulation under the skin (edema)
    -High blood pressure (hypertension)

The following medicines can increase potassium concentrations in the blood. This effect can be life threatening. Increased potassium levels in the blood may occur if you have kidney problems.
- Potassium-sparing diuretics (certain water tablets, such as amiloride, spironolactone, triamterene) (it should be noted that these drugs may be combined with medicinal products)
- Angiotensin converting enzyme (ACE) inhibitors (used to treat high blood pressure)
- Angiotensin II receptors antagonists (used to treat high blood pressure)
- Tachromilus (used to prevent the body from rejecting organ transplants and in the treatment of skin conditions)
- Cyclosporine (used to prevent the body from rejecting organ transplants)

Other drugs affected or likely to be affected by POLİFLEKS LACTATED RINGER
- Thiazide productions such as hydrochlorothiazide or chlortalidone
- Vitamin D
- Bisphosphonates (used to treat bone disorders such as osteoporosis)
- Fluoride (for teeth and bones)
- Fluoroquinolones (a type of antibiotic such as ciprofloxacin, norfloxacin, ofloxacin)
- Tetracyclines (a type of antibiotic containing tetracycline)
- Acidic drugs,
    -Salicylates (aspirin) used to treat inflammations
    -Barbiturates (sleeping pills)
    -Lithium (used to treat psychiatric diseases),
- Alkali drugs,
    -Sympathomimetics (stimulant drugs such as ephedrine and pseudoephedrine are used in cough and cold)
    -Other stimulant drugs (eg dexamphetamine, fenfluramine)

If you are currently using any prescription or non-prescription medication, or if you have used it recently, please inform your doctor or pharmacist about them.

3. How POLİFLEKS LACTATED RINGER will be given?
Instructions for proper use and dosage/application intervals:
Your doctor will decide the amount of this drug that you need and the time of application. S/he will consider your age, body weight and the reason for the administration of this drug will also be considered. Follow these instructions unless otherwise is recommended by your doctor.

If there are floating particles in the solution or if the packaging is damaged in any way, do not use the POLİFLEKS LACTATED RINGER.

Do not forget to take your drug in a timely manner.

Your doctor will inform you about the period of your treatment with POLİFLEKS LACTATED RINGER. Do not stop the treatment earlier, because if you do, you will not obtain the expected results.

• Route and method of administration:
This drug is administered to your vein through a proper plastic pipe (set).

Different age groups
Pediatric use:
The dosage and the size of the administration set for children will be decided by the doctor that recommends the administration..

Use in the elderly:
The dosage to be administered and rate of administration must be decided based on the weight, clinical and biological status and the drugs used concomitantly will be decided by the doctor, like in adults.

Conditions of special use:
Renal/ hepatic impairment
Sodium salts must be used carefully in renal insufficiency.

Since the lactate metabolism can be impaired in patients with liver insufficiency, the alkalizing effect of the drug may fail.

If you have the impression that the effects of POLİFLEKS LACTATED RINGER are too powerful or too weak, *consult your doctor or pharmacist.*

In case you have used greater amount of POLİFLEKS LACTATED RINGER than you should:

Consult a doctor or a pharmacist if you had used POLİFLEKS LACTATED RINGER in an amount more than you should.

If you have used POLİFLEKS LACTATED RINGER in an amount more than you should, or if the solution has been administered to you very rapidly, the following signs can be seen:

- Water and/or sodium (salt) that can cause fluid accumulation (edema) and swelling in your tissues
- Hyperkalemia (higher-than-normal potassium levels in your blood) that can cause pins and needles or numbness in limbs that is more frequent particularly in those with renal failure
- Muscular weakness
- Inability to move/ paralysis
- Irregular heartbeats (cardiac arrhythmia)
- Cardiac blockade (very slow heartbeats)
- Cardiac arrest (a life-threatening condition that heart had stopped)
- Confusion
- Hypercalcemia (blood calcium level being higher than normal) that will result in the following:
    - Anorexia
    - nausea
    - vomiting
    - constipation
    - abdominal pain
    - mental status disorders including easy excitability or depression
    - drinking excessive amounts of water (polydipsia)
    - urination in amounts higher than normal (polyuria)
    - renal disease related to calcium accumulation in kidneys (nephrocalcinosis)
    - renal stones
    - coma (loss of conscious)
    - chalk-like taste in mouth
    - flushing in face and neck
    - dilation of the blood vessels in the skin.

- Hypokalemia (lowering of the potassium level in your blood to levels below normal) and metabolic alkalosis (your blood being more alkaline than normal) so as to cause the following signs, which are more frequent particularly in those with renal insufficiency:
    - Mood changes
    - Fatigue
    - Stopping of breathing
    - Muscular hardening
    - Muscular fasciculation
    - Muscular contractions.

Urgently notify your doctor if any of these signs are seen in you. The drug being administered to you will be stopped and treatment will be started based on your signs.

In case you forget to take POLİFLEKS LACTATED RINGER:
Do not take double dosage to balance the skipped dosage.

Possible effects related to the termination of the treatment with POLİFLEKS LACTATED RINGER:
None

4. Possible side effects
Like all drugs, POLİFLEKS LACTATED RINGER can cause adverse effects in individuals who are sensitive to the contents.

Side effects are listed as shown in the following categories:
Very common: It can be seen in at least one of 10 patients.
Common: Less than one in 10 patients, but more than one in 100 patients.
Uncommon: Less than one in 100 patients, but more than one in 1,000 patients.
Rare: Less than one in 1,000 patients, but more than one in 10,000 patients.
Very rare: Less than one in 10,000 patients can be seen.
Unknown: It cannot be estimated from the available data.

If you notice any of the following, stop the POLİFLEKS LACTATED RINGER and report it to your doctor IMMEDIATELY or contact the emergency department of the nearest hospital:
- Common hives (urticaria)
- Rash on the skin
- Skin flushing (erythema)
- Itching (pruritus)
- Skin swelling (angioedema)
- Cough
- Difficulty breathing as a result of narrowing of the airways (bronchospasm)
- Rapid heartbeat (tachycardia)
- Slow heart rate (bradycardia)
- Decreased blood pressure
- Discomfort or pain in the chest
- Anxiety state (anxiety)
- Chest tightness (making breathing difficult)
- Shortness of breath (dyspnea)
- Al flushes
- Irritation in the throat
- Tingling (paresthesia)
- Reduced sensation in the mouth (decreased mouth sensation)

- Change in the sense of taste
- Fever (pyrexia)
- Nausea
- Headache

- Potassium levels in the blood higher than normal (hyperkalaemia)
These are all very serious side effects.

If you have one of these, you have a serious allergy to POLYFLEX LACTORY RINGER. You may need an emergency medical intervention or hospitalization.

Unknown:
Depending on the route of administration, one or more of the following reactions may be seen.
- Local pain or reaction, redness or swelling in the infusion site
- Irritation or inflammation in the vein where the solution is infused (phlebitis). This may cause redness, pain or burning and swelling along the vascular access where the solution is infused)
- Rash or itching in the infusion site (pruritus)

Other side effects noted with similar products (other sodium lactate-containing solutions) are as follows:
- Other symptoms of hypersensitivity / infusion reactions: nasal congestion (nasal congestion), sneezing, swelling in the throat, making it difficult to breathe (throateal edema, also called Quincke's edema), swelling of the skin (angioedema)
- Change in chemical concentrations in the blood (electrolyte distribution)
- The blood volume in the blood vessels is more than it should be (hypervolemia)
- Panic attack,
- Other reactions depending on the application technique: infection in the infusion site, infusion of infusion solution into the tissues around the vein (extravasation). This can damage tissues and cause scarring and numbness in the infusion site.

In case you encounter any adverse effects not mentioned in this patient information leaflet, please inform your doctor or pharmacists.

5. How to store POLİFLEKS LACTATED RINGER
Store POLİFLEKS LACTATED RINGER in places out of sight and reaches of children and within the original packaging.

Keep at temperatures under 25°C.

This drug is for single use. Partially used bags must not be kept and must be discarded according to the medical waste procedures of the healthcare organization.

The expiry date is indicated on the label of each bag. This drug will not be administered to you if this date has expired.

Use this drug according to the expiry date.
Do not use POLİFLEKS LACTATED RINGER after the expiry date indicated on the packaging.

Do not dispose of expired or unused drugs! Give to the collection system determined by the Ministry of Environment and Urbanization.

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THE FOLLOWING INFORMATION IS FOR THE HEALTHCARE PERSONNEL WHO WILL ADMINISTER THIS DRUG

It is for single use. **Partially used solution must not be kept.**
Partially used drugs must not be connected to systems applied to patients again.

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The solution must be checked before administration.
Administration must be made intravenously using sterile/non-pyrogen sets (if the solution will be used as an irrigation solution, through the intra-articular route or by pouring directly).

Use only clear products not containing particles within intact packaging.

Administration must be started within the shortest time possible after the application set is attached to the product.

To prevent any air embolism related to the residual air in the bag, no serial connection must be established with other infusion fluids.

The solution must be administered through a sterile application set using the aseptic technique.

Fluid must be passed through the application set before administration to prevent entry of air into the system.

Additional drugs can be mixed from the injection end with the help of a needle under aseptic conditions before or during the infusion.

Isotonicity of the end product must be determined before the parenteral administration.

The added drug must be completely mixed before being administered to the patient. Solutions containing additional drugs must be used immediately after mixing, and must not be maintained to be used later.

Adding drugs to the solution or wrong application technique can cause fever reaction related to contamination of the drug with pyrogens. Infusion must be stopped immediately in case of any adverse effects.

How to open:

1. Check the intactness of the outer packaging and if there is any leakage; do not use the packaging if the packaging is damaged.
2. Tear off the protective outer packaging.
3. Check if the bag within the protective packaging is intact.
4. Check the clarity of the solution within the bag and there is no foreign material within.

Preparations for the administration:

1. Hang the bag.
2. Remove the protective cap at the application tip.

3. Stab the spike of the application set to the application tip tightly. The PATIENT INFORMATION LEAFLET of the set must be followed when administrating solution to the patients.

Mixing additional drugs:

Caution: Like all the parenteral solutions, all the substances to be added to the product must be compatible with the product. If any drug will be added to the solution, compatibility in the final mixture must be checked before administration to the final mixture.

Addition of drugs before administration

1. The administration end will be disinfected.
2. The drug to be added will be added into the bag using and injector with a 19-22 gauge tip.
3. The solution with the added drug will be mixed thoroughly. (For drugs with high density like potassium chloride, mixing will be ensured by tapping the application outlet of the bag gently when it is in the upside position.)

Caution: Bags with added drugs must not be stored.

Mixing drugs during administration

1. The clamp of the set will be closed.
2. The administration end will be disinfected.
3. The drug to be added will be added into the bag using and injector with a 19-22 gauge tip.
4. Solution is removed from the hanger and turned upside down. In this position, mixing of the added drug and the solution will be ensured by tapping the administration end and the injection input gently of the bag.
5. The bag will be brought to the previous position and administration will be continued.