**PATIENT INFORMATION LEAFLET**

**POLİFLEKS 5% DEXTROSE LACTATED RINGER SOLUTION FOR I.V. INFUSION**
Used intravenously

***Active ingredients:*** Each liter of solution contains 50 grams of glucose (dextrose monohydrate), 3 g sodium lactate, 6 g sodium chloride, 0.3 g potassium chloride, 0.2 g calcium chloride dehydrate

***Excipients:*** Sterile water for injection, hydrochloric acid

**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 topics are included in this PATIENT INFORMATION LEAFLET:**

**1. What is POLİFLEKS 5% DEXTROSE LACTATED RINGER SOLUTION FOR I.V. INFUSION and what is it used for?**

POLİFLEKS 5% DEXTROSE LACTATED RINGER SOLUTION FOR I.V. INFUSION is a solution that contains electrolytes that are building blocks of the body and it is administered intravenously.

POLİFLEKS 5% DEXTROSE LACTATED RINGER SOLUTION FOR I.V. INFUSION is available in PVC and PP bags with volumes 100, 150, 250, 500 and 1000 ml PVC and PP bags with or without sets.

POLİFLEKS 5% DEXTROSE LACTATED RINGER SOLUTION FOR I.V. INFUSION is used in the treatment of deficiency of water and salt in the body (dehydration) and to prevent the appearance of these conditions. It is beneficial in the replacement of the fluid and salt lost from the body. Furthermore, it meets a portion of the energy requirement of the body. Also, it is used in the regulation and maintenance of the acid-base balance of the body that had been impaired during some anabolic or katabolic processes.

POLİFLEKS 5% DEXTROSE LACTATED RINGER SOLUTION FOR I.V. INFUSION is also used to dilute before intravenous administration some concentrated drugs suitable for intravenous administration.

**2. *Before you are given* POLİFLEKS 5% DEXTROSE LACTATED RINGER SOLUTION FOR I.V. INFUSION?**

POLİFLEKS 5% DEXTROSE LACTATED RINGER SOLUTION FOR I.V. INFUSION 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 5% DEXTROSE LACTATED RINGER SOLUTION FOR I.V. INFUSION under following conditions:**

In case you have had allergic reaction when you took drugs containing the same active substances or inactive ingredients with POLİFLEKS 5% DEXTROSE LACTATED RINGER SOLUTION FOR I.V. INFUSION, 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 that you are allergic, please consult your doctor.

If:
-you are hypersensitive against sodium lactate,

Do not use POLİFLEKS 5% DEXTROSE LACTATED RINGER SOLUTION FOR I.V. INFUSION**.**

Furthermore, your doctor can decide not to use this drug under the following conditions:

- Presence of signs of excessive fluid accumulation in the body
- Severe liver insufficiency
- Cirrhosis with a course of widespread swelling (edema) and intra-abdominal fluid accumulation
- Impairment of the processes related to the destruction of lactate in the body (lactate metabolism)
- Severe renal insufficiency (too little urinary output or no urine at all)
- Untreated cardiac insufficiency
- Conditions that the substances contained in the drug are found already in excessive amounts (excessive potassium, excessive sodium, excessive calcium, excessive chloride, or excessive lactate)
- Shift of the acid-base balance in the body to the basic side (metabolic alkalosis)
- Serious shift of the acid-base balance in the body to the acidic side (severe metabolic acidosis)
- Shift of the acid-base balance in the body to the acidic side in relation with lactic acid (lactic acidosis)
- If you are under digitalis therapy

If you are using an antibiotic called ceftriaxone that is used intravenously, your doctor will not administer this solution through set used for ceftraiaxone administration.

**Use POLİFLEKS 5% DEXTROSE LACTATED RINGER SOLUTION FOR I.V. INFUSION CAREFULLY under following conditions:**

If you have any of the following diseases:

- Cardiac diseases, cardiac insufficiency, hypertension;
- Respiratory diseases, respiratory insufficiency;
- Accumulation of fluid in your body, extremities or lungs (edema);
- Impairment of kidney functions, renal insufficiency;
- Higher-than-normal vitamin D levels (with reasons including sarcoidosis, etc.);
- Renal stones;
- Pregnancy hypertension;
- Conditions called aldosteronism causing excessive sodium accumulation in the body or other conditions with courses of sodium accumulation;
- Acute dehydration with sudden onset, some renal diseases and serious burns that create tendency for increases in potassium levels in the body; in such cases, your doctor will pay extra attention when administering POLİFLEKS 5% DEXTROSE LACTATED RINGER SOLUTION FOR I.V. INFUSION to you.

Your doctor will use POLİFLEKS 5% DEXTROSE LACTATED RINGER SOLUTION FOR I.V. INFUSION with special care in infants younger than 6 months of age.

Furthermore, your doctor will follow your clinical status and laboratory values (electrolyte levels in blood and urine and acid-base balance) with regular intervals during the use of this solution.

The healthcare personnel who will administer the drug,

- Will take care that the operation of the pump stops before complete emptying of the bag, if this drug will be administered to you through an electronic pump.
- Will take care to replace the pipes (sets) used to administer this drug to you every 24 hours;
- Will use the solution only is the bag and covers are intact and the solution is clear;
- Will take care to prevent the leakage of the solution outside the vein.

**Use of POLİFLEKS 5% DEXTROSE LACTATED RINGER SOLUTION FOR I.V. INFUSION with foods or drinks**

POLİFLEKS 5% DEXTROSE LACTATED RINGER SOLUTION FOR I.V. INFUSION 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.*

Do not use POLİFLEKS 5% DEXTROSE LACTATED RINGER SOLUTION FOR I.V. INFUSION during pregnancy unless specifically recommended by your doctor.

*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 infant, inform your doctor about this. Do not use POLİFLEKS 5% DEXTROSE LACTATED RINGER SOLUTION FOR I.V. INFUSION during lactation if not specifically approved by your doctor.

**Driving and use of machines**
POLİFLEKS 5% DEXTROSE LACTATED RINGER SOLUTION FOR I.V. INFUSION has no effects on driving or using machines.

**Important information about some ingredients of POLİFLEKS 5% DEXTROSE LACTATED RINGER SOLUTION FOR I.V. INFUSION**

No adverse effects are expected related to the inactive ingredients included in the contents of POLİFLEKS 5% DEXTROSE LACTATED RINGER SOLUTION FOR I.V. INFUSION unless you are hypersensitive against such substances.

**Taking other medicines**

If you plan to take, currently taking or have taken recently any other drugs also including OTCs, vaccines or herbal drugs please inform your doctor.

POLİFLEKS 5% DEXTROSE LACTATED RINGER SOLUTION FOR I.V. INFUSION is incompatible with some drugs. This information can be obtained from the product information of the drugs to be added.

Drugs known to be incompatible with the solution must not be added; other solutions must be preferred to dilute such drugs. With the purpose of minimizing ant incompatibility risk with any other drug to be added to the solution, the healthcare personnel will check if there is any turbidity or precipitation in the final solution after the mixing procedure, immediately after mixing, before the administration and with certain intervals during the administration.

Some drugs incompatible with POLİFLEKS 5% DEXTROSE LACTATED RINGER SOLUTION FOR I.V. INFUSION:

- Amino caproic acid
- Amphotericin B
- Cortisone acetate
- Diethylstilbestrol
- Ethamivane
- Ethyl alcohol
- Phosphate and carbonate solutions
- Oxytetracycline
- Thiopental sodium
- Versenate disodium
- Ceftriaxone

Some of the drugs that are partially incompatible with the POLİFLEKS 5% DEXTROSE LACTATED RINGER SOLUTION FOR I.V. INFUSION:

- Tetracycline
- Ampicillin sodium
- Minocycline
- Doxycycline

Furthermore, effects of the following drugs must be taken into consideration when using together with POLİFLEKS 5% DEXTROSE LACTATED RINGER SOLUTION FOR I.V. INFUSION.

- Corticoids/steroid and carbenoxolone (related to the risk of retention of sodium and water).
- Diuretics including amiloride, spironolactone or triamterene singly or in combination (because of the risk of sodium accumulation in the body).
- Angiotensin converting enzyme inhibitors and possible angiotensin II receptor antagonists (because of the risk of sodium accumulation in the body).
- Tacrolimus and cyclosporine (because of the risk of sodium accumulation in the body).
- Digitalis group glycosides (effects of these drugs increase in the presence of calcium and can cause serious or fatal cardiac arrhythmias).
- Tiazide group diuretics or vitamin D (because of the risk of calcium in the body).
- Biphosphonates, fluoride, some fluorokinones and tetracyclines (their absorptions are reduced when administered together with calcium)
- Acidic drugs including salicylates, barbiturates and lithium (renal excretion of these drugs and increase and they can fail in making the expected effect).
- Alkaline drugs including sympathomymetic drugs (e.g. ephedrine, pseudoephedrine) and stimulant drugs (dexamphetamine sulfate, fenfluramine hydrochloride) (renal excretion of such drugs will be decreased and their effects can exceed the expected level).

POLİFLEKS 5% DEXTROSE LACTATED RINGER SOLUTION FOR I.V. INFUSION must not be administered through the same set with blood.

*If you are currently using any prescribed drug or OTC, or if you have used them recently, please inform your doctor or pharmacist about these.*

## 3. How POLİFLEKS 5% DEXTROSE LACTATED RINGER SOLUTION FOR I.V. INFUSION 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.

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

Your doctor will inform you about the period of your treatment with POLİFLEKS 5% DEXTROSE LACTATED RINGER SOLUTION FOR I.V. INFUSION. 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 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 5% DEXTROSE LACTATED RINGER SOLUTION FOR I.V. INFUSION are too powerful or too weak, consult your doctor or pharmacist.*

**In case you have used greater amount of POLİFLEKS 5% DEXTROSE LACTATED RINGER SOLUTION FOR I.V. INFUSION then you should:**

*Consult a doctor or a pharmacist if you had used POLİFLEKS 5% DEXTROSE LACTATED RINGER SOLUTION FOR I.V. INFUSION in an amount more than you should.*

If you have used POLİFLEKS 5% DEXTROSE LACTATED RINGER SOLUTION FOR I.V. INFUSION 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 5% DEXTROSE LACTATED RINGER SOLUTION FOR I.V. INFUSION:**
*Do not take double dosage to balance the skipped dosage.*

**Possible effects related to the termination of the treatment with POLİFLEKS 5% DEXTROSE LACTATED RINGER SOLUTION FOR I.V. INFUSION:**
None

**4. Possible side effects**

Like all drugs, POLİFLEKS 5% DEXTROSE LACTATED RINGER SOLUTION FOR I.V. INFUSION can cause adverse effects in individuals who are sensitive to the contents.

Inform your doctor immediately in case you encounter any of the following:

Inform your doctor or nurse immediately in case you encounter any of the following. These can be the signs of very serious or fatal hypersensitivity (allergic) reactions called anaphylactic shock:

- Local or widespread ( urticarial)
- Skin rashes
- Redness in the skin (erythema)
- Itching (pruritus)
- Swelling of the skin
- Swelling around the eyes or in the whole face (periorbital or facial edema)

You will be treated based on your signs.

Other adverse effects have been listed according to their frequency.

Very common adverse effects (those seen in more than 1 of each 10 patient)

- Nasal obstruction
- Cough
- Sneezing
- Narrowing of airways to a level that will make breathing difficult (bronchospasm)
- Changes in the concentrations of chemicals in blood (electrolyte imbalances)

If you are suffering cardiac disease or fluid accumulation in your lungs (pulmonary edema):

- Fluid in excessive amount in the body (hyperhydration)
- Cardiac arrest

Common adverse effects (seen in less than 1 patient out of each 10; however, more than 1 patient out of each 100)

- Compression of chest (making breathing more difficult)
- Chest pain
- Heartbeats being faster (tachycardia)
- Heartbeats being slower (bradycardia)
- Anxiety

Uncommon adverse effects (seen in less than 1 in each 100 patient; however, in less than 1 of each 1000 patients)

- Contractions

Other

- Panic attack

Reactions related to the application technique:

- Fever
- Infection in the infusion site
- Local pain or reaction (redness or swelling in the infusion site)
- Irritation (phlebitis) in the vein that the solution is administered though. This can cause redness and pain or burning sensation or swelling in the venous access that the solution is administered through.
- Formation of a clot (venous thrombosis) in the administration site of the solution causing pain, swelling and redness.
- Leakage of the infusion solution into the tissues surrounding the vein (extravasation). This can damage the tissues and leave sequel.
- Excess fluid in the blood vessels (Over-increase in the blood amount)

If any drug has been added to the infusion solution, the added drug can also cause adverse effects. Such adverse effects will be related to the added drug. You must read the PATIENT INFORMATION LEAFLET of the added drug for the list of potential side effects.

If you become aware of any listed or unlisted adverse effect, please inform your doctor and nurse. Infusion must be stopped in case of any adverse effect.
*If you encounter any side effects not mentioned in this leaflet, inform your doctor or pharmacist.*

## 5. How to store POLİFLEKS 5% DEXTROSE LACTATED RINGER SOLUTION FOR I.V. INFUSION

*Store POLİFLEKS 5% DEXTROSE LACTATED RINGER SOLUTION FOR I.V. INFUSION in places out of sight and reach 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 5% DEXTROSE LACTATED RINGER SOLUTION FOR I.V. INFUSION after the expiry date indicated on the packaging.*

***Marketing Authorisation Holder & Manufacturer:***
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*These PATIENT INFORMATION LEAFLET have been approved on 29/12/2016.*

**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 apyrogen sets.

**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 by squeezing the bag.

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.