

## PATIENT INFORMATION LEAFLET

### **POLIFLEKS 5% DEXTROSE, 0.45% SODIUM CHLORIDE, 0.3% POTASSIUM CHLORIDE SOLUTION FOR I.V. INFUSION**

**Active ingredients:** Each one liter solution contains 4.5 grams of sodium chloride ,50 grams of dextrose (glucose) and 3 gram potassium chloride.

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

- 1. What is POLIFLEKS 5% DEXTROSE, 0.45% SODIUM CHLORIDE, 0.3% POTASSIUM CHLORIDE SOLUTION FOR I.V. INFUSION and what is it used for?***
- 2. Before you are given POLIFLEKS 5% DEXTROSE, 0.45% SODIUM CHLORIDE, 0.3% POTASSIUM CHLORIDE SOLUTION FOR I.V. INFUSION***
- 3. How you will be given POLIFLEKS 5% DEXTROSE, 0.45% SODIUM CHLORIDE, 0.3% POTASSIUM CHLORIDE SOLUTION FOR I.V INFUSION?***
- 4. Possible side effects***
- 5. How to store POLIFLEKS 5% DEXTROSE, 0.45% SODIUM CHLORIDE, 0.3% POTASSIUM CHLORIDE SOLUTION FOR I.V INFUSION***

**1. What is POLIFLEKS 5% DEXTROSE, 0.45% SODIUM CHLORIDE, 0.3% POTASSIUM CHLORIDE SOLUTION FOR I.V INFUSION and what is it used for?**

POLIFLEKS 5% DEXTROSE, 0.45% SODIUM CHLORIDE, 0.3% POTASSIUM CHLORIDE SOLUTION FOR I.V INFUSION is a sterile solution used intravenously, which used in some situations where body is dehydrated and unsalted.

POLIFLEKS 5% DEXTROSE, 0.45% SODIUM CHLORIDE, 0.3% POTASSIUM CHLORIDE SOLUTION FOR I.V INFUSION is presented in PVC and PP bags, with a volume of 250. 500 milliliters and 1000 milliliters. It has two forms with and without set.

It is used for replacing the fluid and salt lost from the body. Furthermore it meets some part of the energy need of the body. POLIFLEKS 5% DEXTROSE, 0.45% SODIUM CHLORIDE, 0.3% POTASSIUM CHLORIDE SOLUTION FOR I.V INFUSION is also used for diluting the some medicine suitable for intravenous application, which are in concentrated form, before applying intravenously.

**2. Before you are given POLIFLEKS 5% DEXTROSE, 0.45% SODIUM CHLORIDE, 0.3% POTASSIUM CHLORIDE SOLUTION FOR I.V INFUSION**

POLIFLEKS 5% DEXTROSE, 0.45% SODIUM CHLORIDE, 0.3% POTASSIUM CHLORIDE SOLUTION FOR I.V INFUSION is a safe medicine for a lot of patients. However if you have problems with your heart, kidneys, liver, or lungs, if you are diabetic or there are swells (edema) depending on excessive salt accumulation in your body, your physician may decide to apply this medicine to you.

**Don't use POLIFLEKS 5% DEXTROSE, 0.45% SODIUM CHLORIDE, 0.3% POTASSIUM CHLORIDE SOLUTION FOR I.V INFUSION in cases below.**

If you had allergic reaction when you took the medicine containing the active ingredient or containing excipients of POLIFLEKS 5% DEXTROSE, 0.45% SODIUM CHLORIDE, 0.3% POTASSIUM CHLORIDE SOLUTION FOR I.V INFUSION in the past, that is, if you had symptoms such as sudden gasp for breathing, wheezing, skin rashes, itching, or swelling in the body formed, DO NOT use this medicine.

If you are not sure whether you are allergic or not, apply to your physician.

DO NOT use this medicine also in the situations below, where application of any one of the ingredients inside the solution is harmful:

- In cases where blood volume increases (hypervolemia),
- In cases where blood sodium increases (hypernatremia),
- In cases where blood potassium increases (hyperkalemia),

- If you have severe kidney failure (too little or no urine). If you have a disease (Addison's disease) due to the poor functioning of the adrenal gland. If you have untreated heart failure.
- If you have had a head injury (hit your head) in the past 24 hours.
- If you have diabetes and are not under control.
- If you have intolerance to sugar (glucose intolerance).
- If your blood sugar is high (hyperglycemia).
- If you are in a coma due to excessive blood sugar (hyperosmolar coma).
- If you have high lactate levels in the blood (hyperlactaemia)
- If you have hypersensitivity (allergy) to corn products.

**Use POLIFLEKS 5% DEXTROSE, 0.45% SODIUM CHLORIDE, 0.3% POTASSIUM CHLORIDE SOLUTION FOR I.V. INFUSION with care in the situations below:**

If you have one of the following diseases, your doctor will pay special attention to you while using POLIFLEKS 5% DEXTROSE, 0.45% SODIUM CHLORIDE, 0.3% POTASSIUM CHLORIDE SOLUTION FOR I.V. INFUSION:

- If you have a heart failure or respiratory failure that progresses with symptoms such as water retention (edema), breathing, or difficult breathing in your body, arms and legs or lungs.
- If you have heart disease, especially if you are using a heart medicine for this disease called digitalis.

If you have high blood pressure or pregnancy blood pressure.

If you have conditions called aldostrenosim that cause excessive accumulation of sodium in the body or other diseases that progress with sodium accumulation.

If you are being treated with medicines called corticosteroids or corticotropin.

If you have a condition that increases your susceptibility to elevated potassium levels in your body, such as sudden developing dehydration (acute dehydration), certain kidney diseases, and severe burns.

If you have impaired kidney function or adrenal gland, or if you have kidney failure.

If you have diabetes.

- You are experiencing a sudden stroke (paralysis).

**Use of POLIFLEKS 5% DEXTROSE, 0.45% SODIUM CHLORIDE, 0.3% POTASSIUM CHLORIDE SOLUTION FOR I.V. INFUSION with foods or drinks**

POLIFLEKS 5% DEXTROSE, 0.45% SODIUM CHLORIDE, 0.3% POTASSIUM CHLORIDE SOLUTION FOR I.V. INFUSION is a medicine applied through veins; it doesn't have any interaction with the foods and beverages with regards to the application method.

## **Pregnancy**

*Before using the medicine consult your physician or pharmacist.*

Unless it is especially approved by your physician, do not use POLIFLEKS 5% DEXTROSE, 0.45% SODIUM CHLORIDE, 0.3% POTASSIUM CHLORIDE SOLUTION FOR I.V. INFUSION during pregnancy.

*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, notify this situation to your physician. Unless it is especially approved by your physician, do not use POLIFLEKS 5% DEXTROSE, 0.45% SODIUM CHLORIDE, 0.3% POTASSIUM CHLORIDE SOLUTION FOR I.V. INFUSION during breastfeeding period.

## **Driving and use of machines**

POLIFLEKS 5% DEXTROSE, 0.45% SODIUM CHLORIDE, 0.3% POTASSIUM CHLORIDE SOLUTION FOR I.V. INFUSION has no effect on the vehicle or machine usage.

## **Important information about some ingredients of POLIFLEKS 5% DEXTROSE, 0.45% SODIUM CHLORIDE, 0.3% POTASSIUM CHLORIDE SOLUTION FOR I.V. INFUSION**

If you are not sensitive against excipients contained in the contents of POLIFLEKS 5% DEXTROSE, 0.45% SODIUM CHLORIDE, 0.3% POTASSIUM CHLORIDE SOLUTION FOR I.V. INFUSION, a negative effect depending on these materials isn't expected.

## **Taking other medicines**

If you are planning to take, take or took recently nonprescription medicine, any other medicine including vaccines and herbal medicine, please notify your physician.

POLIFLEKS 5% DEXTROSE, 0.45% SODIUM CHLORIDE, 0.3% POTASSIUM CHLORIDE SOLUTION FOR I.V. INFUSION should not be given from the same set as blood. The solution is incompatible with some drugs. This situation can be learned from the product information of the drugs to be added.

These drugs known to be incompatible should not be added to the solution; other solutions should be preferred to dilute these drugs. In order to minimize the risk of incompatibility with any other Drug to be added to the solution, it will be checked by the healthcare provider whether there is any turbidity or precipitation in the final mixture to be applied at regular intervals immediately after mixing, before and during application.

In addition, the effects of these drugs should be taken into account during the combination of POLIFLEKS 5% DEXTROSE, 0.45% SODIUM CHLORIDE, 0.3% POTASSIUM CHLORIDE SOLUTION FOR I.V. INFUSION and the following drugs:

- In the treatment of some diseases that cause the deficiency of the hormone called steroids in the body, in the treatment of some diseases that are caused by inflammation, in the treatment of some autoimmune diseases (the attack system of the defense system also tries to destroy their own body cells) and asthma, eczema, Corticoids / steroids used to prevent organ rejection after transplant surgery with allergic rhinitis treatment (due to the risk of sodium and water accumulation in the body).
- Carbenoxolone used in stomach ulcers (due to the risk of sodium accumulation in the body)
- Diuretic drugs such as amiloride, spironolactone, triamterene alone or in combination (due to the risk of potassium accumulation in the body).
- Blood pressure medications from the group of angiotensin converting enzyme inhibitors and angiotensin II receptor antagonists (due to the risk of potassium buildup in the body).
- Tacrolimus, cyclosporine, used to prevent organ rejection after transplant (organ transplant) surgery (due to the risk of potassium build-up in the body).
- Heart medications from the digitalis group.

*If you are currently using any medicine with your prescription or without prescription, or if you have used it recently, please inform your doctor or pharmacist about them.*

### **3. How POLIFLEKS 5% DEXTROSE, 0.45% SODIUM CHLORIDE, 0.3% POTASSIUM CHLORIDE SOLUTION FOR I.V. INFUSION will be given?**

#### **Instructions for proper use and dosage/application intervals:**

Your doctor shall decide you need this medicine at which amount and when it will be applied to you. He/she shall decide depending on your age, body weight and the reason why this medicine is applied to you. Follow these directives unless the physician gives you another recommendation.

Recommended dose for the treatment of carbohydrates, sodium, and fluid loss is generally a 24-hour of 500 ml and 3 liters in adults.

Treatment to mild potassium lack and prevent of potassium deficiency, 1 to 1.25 liters of POLIFLEKS 5% DEXTROSE, 0.45% SODIUM CHLORIDE, 0.3% POTASSIUM CHLORIDE SOLUTION FOR I.V. INFUSION per day is usually sufficient.

Don't forget to take your medicine in due time.

Your physician will notify you how much it will your treatment with POLIFLEKS 5% DEXTROSE, 0.45% SODIUM CHLORIDE, 0.3% POTASSIUM CHLORIDE SOLUTION FOR I.V. INFUSION take. Don't quit treatment early because you can't get the required result.

**Route and method of administration:**

It is used through a plastic pile (set) suitable for your vein.

**Different age groups****Pediatric use:**

The dose and the size of the application set for children are decided by the doctor who recommends the treatment.

Babies and children in general, the amount of solution in 24 hours for body weight babies up to 10 kg to 100 ml / kg, 1-1.5 liters for children over 10 kg, for children over 20 kg is between 1.5-2,5 liters.

**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:**

There is no special use case.

*If you are under impression that the effect of the POLIFLEKS 5% DEXTROSE, 0.45% SODIUM CHLORIDE, 0.3% POTASSIUM CHLORIDE SOLUTION FOR I.V. INFUSION is too weak or strong, consult your doctor or pharmacist.*

**If you use POLIFLEKS 5% DEXTROSE, 0.45% SODIUM CHLORIDE, 0.3% POTASSIUM CHLORIDE SOLUTION FOR I.V. INFUSION more than you are required to:**

If you use more POLIFLEKS 5% DEXTROSE, 0.45% SODIUM CHLORIDE, 0.3% POTASSIUM CHLORIDE SOLUTION FOR I.V. INFUSION than you should use, especially in cases where there is a malfunction in the excretion of sodium from your kidneys, you may develop water in your body or arms or legs (edema), difficulty in breathing, difficulty in breathing while lying or climbing stairs (for congestive heart failure symptoms). dialysis treatment may be needed.

If you have kidney failure and you have used more than the recommended POLIFLEKS 5% DEXTROSE, 0.45% SODIUM CHLORIDE, 0.3% POTASSIUM CHLORIDE SOLUTION FOR I.V. INFUSION, your blood potassium levels increase (hyperkalaemia). When potassium levels in your blood increase, symptoms of potassium poisoning may appear. Symptoms due to potassium poisoning include numbness, , laxity in your arms or legs; weakness in your muscles,

feeling of heaviness, paralysis, loss of reflexes or slowing of your breathing movements; blurred in your consciousness and unconscious; there are symptoms related to a drop in your blood pressure, fast, slow or irregular operation of your heart, cardiac arrest and nausea, vomiting, diarrhea, abdominal pain, etc.). Hyperkalaemia can be treated with calcium, insulin (with glucose), sodium bicarbonate, ion exchange resins or dialysis.

Excessive application of chloride salts in the composition of POLIFLEKS 5% DEXTROSE, 0.45% SODIUM CHLORIDE, 0.3% POTASSIUM CHLORIDE SOLUTION FOR I.V. INFUSION can acidify your blood.

If you have used more POLIFLEKS 5% DEXTROSE, 0.45% SODIUM CHLORIDE, 0.3% POTASSIUM CHLORIDE SOLUTION FOR I.V. INFUSION than you should, dextrose in the composition of the solution may increase your blood sugar. When your blood sugar gets too high, your blood density may increase, sugar in your urine may appear, and you will start to make plenty of watery urine.

*If you use POLIFLEKS 5% DEXTROSE, 0.45% SODIUM CHLORIDE, 0.3% POTASSIUM CHLORIDE SOLUTION FOR I.V. INFUSION more than you are required to, consult your doctor or pharmacist.*

**In case you forget to take POLIFLEKS 5% DEXTROSE, 0.45% SODIUM CHLORIDE, 0.3% POTASSIUM CHLORIDE SOLUTION FOR I.V. INFUSION:**

*Do not take double doses to balance the doses forgotten.*

**Possible effects related to the termination of the treatment with POLIFLEKS 5% DEXTROSE, 0.45% SODIUM CHLORIDE, 0.3% POTASSIUM CHLORIDE SOLUTION FOR I.V. INFUSION:**

None

#### **4. Possible side effects**

Like all drugs, POLIFLEKS 5% DEXTROSE, 0.45% SODIUM CHLORIDE, 0.3% POTASSIUM CHLORIDE SOLUTION FOR I.V. INFUSION can cause adverse effects in individuals who are sensitive to the contents. The side effects reported during the application of POLIFLEKS 5% DEXTROSE, 0.45% SODIUM CHLORIDE, 0.3% POTASSIUM CHLORIDE SOLUTION FOR I.V. INFUSION are listed below.

Side effects are listed as shown in the below mentioned categories:

- Very common: It may be seen at least 1 of 10 patients
- Common: It may be seen less than 1 of 10 patients, but more than 1 of 100 patients.
- Uncommon: It may be seen less than 1 of 100 patients, but more than 1 of 1000 patients
- Rarely seen: It may be seen less than 1 of 1000 patients, but more than 1 of 10.000 patients
- Unknown: Cannot be estimated by available data

**If you notice any one of the things below, stop using POLIFLEKS 5% DEXTROSE, 0.45% SODIUM CHLORIDE, 0.3% POTASSIUM CHLORIDE SOLUTION FOR I.V. INFUSION and IMMEDIATELY notify your physician or apply to the emergency department of the hospital closest to you;**

- Itchy rash / swelling, burning sensation in the area where the drug is applied;
- Respiratory distress, wheezing, pain in the chest;
- Feeling of excessive heat or cold in the body;
- Swelling in the hands, feet, lips, face, or whole body;
- Dizziness, feeling faint;
- Heart palpitations.

These are all very critical side effects.

If you have any one them, this means that you have serious allergy against POLIFLEKS 5% DEXTROSE, 0.45% SODIUM CHLORIDE, 0.3% POTASSIUM CHLORIDE SOLUTION FOR I.V. INFUSION. Emergent medical intervention or hospitalization may be required.

In addition, if symptoms such as fever and chills occur in your body (febrile reaction), inform your doctor IMMEDIATELY; In this case, the doctor may interrupt the application and take urgent medical intervention.

All of these very critical side effects are seen very rarely.

**If you notice any one of the things below, immediately notify your doctor or apply to the emergency department of the hospital closest to you:**

**Unknown:**

- Elevated electrolyte levels in the blood (hyperpotasemia, hypernatremia, hyperchloremia) and related symptoms:
  - Fever
  - Weakness
  - Head ache.
  - Dizziness,
  - Restlessness
  - Irritation
  - Convulsion
  - Numbness, laxity in the arms or legs
  - Weakness in the muscles
  - Twitching and stiffness in the muscles



- Feeling of heaviness in the muscles
  - The disappearance of reflexes
  - Muscle stroke
  - Slow breathing movements
  - Respiratory arrest
  - Blurring in consciousness
  - Loss of consciousness
  - Loss of reflexes
  - Coma
  - Blood pressure drop (hypotension) or rise (hypertension)
  - Your heart is working faster, slower or irregularly than usual.
  - Cardiac arrest
  - Nausea
  - Vomiting
  - Diarrhea
  - Cramps in the abdomen
  - Feeling thirsty
  - Decrease in saliva
  - Decreased sweating
  - Kidney failure
  - Collection of water in the body and / or arms or legs (edema)
  - Water collection in the lungs (pulmonary edema)
  - Difficulty in breathing
  - Difficulty breathing while lying down or climbing stairs
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- Increased degree of acidity in the blood
  - Increased blood density (hyperosmolarity)
  - High blood sugar (hyperglycemia)
  - Urinary sugar in the urine (glucosuria)
  - Osmotic diuresis (abundant urination due to high blood sugar)
  - Inflammation in the vein where the application is performed
  - Stiffness, redness, or swelling starting from where the application was made, spreading across the veins

These are all very critical side effects. Emergent medical intervention may be required.

*If you see any side effect not mentioned in this PATIENT INFORMATION LEAFLET, inform your physician or pharmacist.*

**5. How to store POLİFLEKS 5% DEXTROSE, 0.45% SODIUM CHLORIDE, 0.3% POTASSIUM CHLORIDE SOLUTION FOR I.V. INFUSION**

*Store POLİFLEKS 5% DEXTROSE, 0.45% SODIUM CHLORIDE, 0.3% POTASSIUM CHLORIDE SOLUTION FOR I.V. INFUSION in places out of sight and reach of children and within the original packaging.*

Store at below 25°C.

It is for single use only. The bags used partially should not be stored, should be destroyed according to the medical waste procedures of the healthcare institution where administration is made.

The expiry date is written in the label of each bag. If this date is passed, this medicine will not be given to you.

**Use is consistently with the expiry date.**

*Do not use POLİFLEKS 5% DEXTROSE, 0.45% SODIUM CHLORIDE, 0.3% POTASSIUM CHLORIDE SOLUTION FOR IV INFUSION after the expiry date indicated on the packaging.*

***Marketing Authorisation Holder and Manufacturer:***

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**THE INFORMATION BELOW IS FOR THE HEALTHCARE PERSONNEL WHO WILL ADMINISTER THIS MEDICINE.**

The solution should be administered by using aseptic technique through sterile administration set. Liquid should be passed from administration set before usage for air not entering the system.

Additional drugs may be added before and during the infusion by means of a needle from the edge of the injection under aseptic conditions. Isotonicity of the final product formed should be determined before parenteral administration.

It is required that the added medicine is completely mixed before administering the patient. The solutions containing additional medicine should be used just after the addition of the medicine. They should not be stored for using afterwards.

Adding additional drug to the solution or wrong administration technique may cause fever reaction based on pyrogenic contamination to the product. Infusion should be immediately stopped in case that adverse reaction is seen.

It is for single usage. **The solutions partially used should not be stored.**

The bags partially used should not be attached to the systems administered to the patient again.

**To open:**

1. Check the solidity of the external package and whether there is leakage or not; if the package is damaged, don't use.
2. Open the protective external package by tearing.
3. Check whether the bag inside the protective package is solid or not by squeezing.
4. Check the clearness of the solution inside the bag and whether it contains foreign substances or not.

**Application preparations:**

1. Hang the bag.
2. Remove the protective cover at the administration edge.
3. Tightly insert the spike of the administration set to the administration edge. The usage directive of the set should be followed to administer the solution to the patient.

**Adding additional medicine:**

**Caution:** All substances to be added to the product should be incompatible with the product, like for all parenteral solutions. If adding will be made to the product, the incompatibility should be checked in the final mixture before administering the patient.

***Adding medicine before application***

1. The medicine administration edge is disinfected.
2. The medicine to be added is added inside the bag with an injector which has a needle with a thickness of 19 – 22 gauge.
3. Solution and the medicine added inside is mixed thoroughly. (It is ensured that the medicine is mixed by slightly tapping to the administration exit when it is up position for the dense drugs like potassium chloride.)

**Attention:** The bags additional drug is applied inside should not be stored.

***Adding medicine during administration***

1. Clamp of the set is closed.
2. The medicine administration edge is disinfected.
3. The medicine to be added is applied from the medicine administration edge with an injector which has a needle with a thickness of 19 – 22 gauge.
4. The solution is removed from the hanger and turned upside down. It is ensured that the medicine is mixed by slightly tapping to the administration exit and injection input of the bag when it is in this position.
5. The bag is brought to the old position; clamp is opened and administration is continued.