

PATIENT INFORMATION LEAFLET

PF 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.*

In this leaflet:

- 1. What is PF 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 PF 5% DEXTROSE, 0.45% SODIUM CHLORIDE, 0.3% POTASSIUM CHLORIDE SOLUTION FOR I.V. INFUSION**
 - 3. How you will be given PF 5% DEXTROSE, 0.45% SODIUM CHLORIDE, 0.3% POTASSIUM CHLORIDE SOLUTION FOR I.V. INFUSION?**
 - 4. Possible side effects**
 - 5. How to store PF 5% DEXTROSE, 0.45% SODIUM CHLORIDE, 0.3% POTASSIUM CHLORIDE SOLUTION FOR I.V. INFUSION**
- headlines are included.**

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

PF 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.

PF 5% DEXTROSE, 0.45% SODIUM CHLORIDE, 0.3% POTASSIUM CHLORIDE SOLUTION FOR I.V INFUSION is presented in PVC and PP bottles, 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. PF 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 PF 5% DEXTROSE, 0.45% SODIUM CHLORIDE, 0.3% POTASSIUM CHLORIDE SOLUTION FOR I.V. INFUSION

PF 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 PF 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 PF 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 (hyponatremia),
- 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 PF 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 PF 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 PF 5% DEXTROSE, 0.45% SODIUM CHLORIDE, 0.3% POTASSIUM CHLORIDE SOLUTION FOR I.V. INFUSION with foods or drinks

PF 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 PF 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 PF 5% DEXTROSE, 0.45% SODIUM CHLORIDE, 0.3% POTASSIUM CHLORIDE SOLUTION FOR I.V. INFUSION during breastfeeding period.

Driving and use of machines

PF 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 PF 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 PF 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.

PF 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 PF 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 11 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 PF 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 PF 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 PF 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 PF 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 PF 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 PF 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 PF 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 PF 5% DEXTROSE, 0.45% SODIUM CHLORIDE, 0.3% POTASSIUM CHLORIDE SOLUTION FOR I.V. INFUSION can acidify your blood.

If you have used more PF 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 PF 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 PF 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 PF 5% DEXTROSE, 0.45% SODIUM CHLORIDE, 0.3% POTASSIUM CHLORIDE SOLUTION FOR I.V. INFUSION:

None

4. Possible side effects

Like all drugs, PF 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 PF 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 PF 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 PF 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, hyponatremia, 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
- 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 PF 5% DEXTROSE, 0.45% SODIUM CHLORIDE, 0.3% POTASSIUM CHLORIDE SOLUTION FOR I.V. INFUSION

Store PF 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 bottles 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 bottle. If this date is passed, this medicine will not be given to you.

Use is consistently with the expiry date.

Do not use PF 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 FOLLOWING INFORMATION IS INTENDED FOR MEDICAL OR HEALTHCARE PROFESSIONALS ONLY

Solution should be inspected visually before use.

The administration is by intravenous route with sterile, apyrogen sets.

Only products that are clear, particle-free and intact in packaging integrity should be used.

The administration should be started as soon as possible after the application set is attached to the product.

In order to prevent an air embolisation that may occur due to the residual air in the bottle, no serial connection should be made with other infusion fluids.

The solution should be applied using the aseptic technique through the sterile application set. In order to prevent air from entering the system, liquid must be passed through the application set before use.

Additional medication may be added before and during infusion with the aid of Injection a needle in aseptic conditions. The final product's isotonicity should be determined before parenteral administration.

The added drug must be completely mixed with the solution before application to the patient. Solvents containing additional drug should be used immediately after drug addition; it should not be stored for later use.

Addition of additive or wrong application technique may result in a fever reaction due to pyrogen contamination of the product. If an adverse reaction occurs, the infusion should be terminated immediately.

For single use only.

Do not store partly used solutions.

Do not reconnect partly used bottles to the administration systems.

Addition of additional drug:

Attention: As with all parenteral solutions, all substances to be added to the product must be compatible with the product. If an addition is to be made, compatibility should be checked in the final mixture before administration to the patient.

Adding medication before administration

1. Stopper of the bottle is disinfected.

2. Inject the drug to be added to the bottle by using syringe with 19 to 22 gauge needle.
3. Mix the solution and the added drug thoroughly.

Attention: Do not store the bottles which mixed with additional medication.

Adding medication during administration

1. Close the clamp.
2. Stopper of the bottle is disinfected.
3. Inject the drug to be added using syringe with 19 to 22 gauge needle.
4. Remove the solution from the hanger and invert.
5. In this position, tap gently the bottle to allow mixing of solution and medication.
6. Return the bottle to its former position and open the clamp and continue administration.