PATIENT INFORMATION LEAFLET

POLİFLEKS 5% DEXTROSE – 0.2% SODIUM CHLORIDE SOLUTION FOR I.V. INFUSION
Used intravenously.
Sterile

Active ingredients: Each liter of the solution includes 2 grams of sodium chloride (salt) and 50 grams of glucose (dextrose anhydrous).

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 POLİFLEKS 5% DEXTROSE – 0.2% SODIUM CHLORIDE and what is it used for*?*

POLİFLEKS 5% DEXTROSE– 0.2% SODIUM CHLORIDE is a solution that contains sodium and chloride ions and glucose, which are fundamental for the body and it is administered intravenously.

POLİFLEKS 5% DEXTROSE – 0.2% SODIUM CHLORIDE is available in PVC and PP bags with volumes 100, 150, 250, 500 and 1000 ml with or without sets.

It is used to treat or prevent deprivation of water and salt in the body (dehydration). In addition, it meets a portion of the energy requirement of the body. Particularly, it is preferred as preoperative and postoperative care as a drug that can initiate renal functions.

POLİFLEKS 5% DEXTROSE– 0.2% SODIUM CHLORIDE is also used to dilute before intravenous administration some concentrated drugs suitable for intravenous administration.

2. Before you are given POLİFLEKS 5% DEXTROSE – 0.2% SODIUM CHLORIDE

POLİFLEKS 5% DEXTROSE – 0.2% SODIUM CHLORIDE 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 – 0.2% SODIUM CHLORIDE 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 – 0.2% SODIUM CHLORIDE, that is, if you have experienced sudden stopping of breath, wheezing, skin rashes, itching or swelling in your body, DO NOT USE this drug.

In addition, if you are allergic against corn products, DO NOT USE THIS DRUG.

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

USE POLİFLEKS 5% DEXTROSE – 0.2% SODIUM CHLORIDE CAREFULLY under the following conditions:

This drug must be administered to you carefully if you have any of the following:

- congestive cardiac insufficiency,
- significant renal failure,
- obstruction of the urinary tract,
- Swelling (edema) in your body or extremities, particularly if you are in immediate postoperative period or if you are elderly.

If you have the following conditions, this drug must be administered to you carefully:

- If you are diabetic,

- If you are intolerant against carbohydrates for any reason.

If this drug will be administered to you through an electronic pump,
- It must be ensured that the operation of the pump stops before complete emptying of the bag.

Administration of this drug requires changing of the pipes (sets) every 24 hours.
Furthermore, this drug must be used only if the bag is intact and the contained solution is clear.
Please consult your doctor if these warnings are valid for you, even at any time in the past.

Use of POLİFLEKS 5% DEXTROSE – 0.2% SODIUM CHLORIDE with foods or drinks
POLİFLEKS 5% DEXTROSE – 0.2% SODIUM CHLORIDE is a drug administered intravenously; and it 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 – 0.2% SODIUM CHLORIDE 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 baby, inform your doctor about this. Do not use POLİFLEKS 5% DEXTROSE – 0.2% SODIUM CHLORIDE during pregnancy unless specifically recommended by your doctor.

Driving and use of machines
POLİFLEKS 5% DEXTROSE – 0.2% SODIUM CHLORIDE has no effects on driving or using machines.

Important information about some ingredients of POLİFLEKS 5% DEXTROSE – 0.2% SODIUM CHLORIDE
No adverse effects are expected related to the inactive ingredients included in the contents of POLİFLEKS 5% DEXTROSE – 0.2% SODIUM CHLORIDE 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 – 0.2% SODIUM CHLORIDE is incompatible with some drugs. The drugs known to be incompatible must not be added to the solution, and other solutions must be preferred to dilute such drugs. The following are drugs known to be incompatible:

- Ampicilin sodium
- Mitomycin
- Amphotericin B
- Erythromicin lactobinate

With the purpose of minimizing the potential incompatibility risk with any other drugs that might be added to the solution, the healthcare personnel will check if there is any turbidity or sedimentation right after mixing, just before administration and with certain intervals during administration.

The solution should not be administered from the same set together with blood.

POLİFLEKS 5% DEXTROSE – 0.2% SODIUM CHLORIDE must be used carefully in patients using carbenoxolone (used to protect the gastric surface in peptic ulcer), corticosteroids (a drug used intravenously in allergic conditions, through the respiratory route in allergic respiratory track diseases and topically on the skin in various allergic conditions) or corticotrophin (a hormone secreted by the brain and used as a drug in case of deficiency).

POLİFLEKS 5% DEXTROSE – 0.2% SODIUM CHLORIDE solutions must be used by adding potassium in sufficient amount in fasting patients with good renal functions particularly is the patient is under treatment with digitalis-type drugs.

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 – 0.2% SODIUM CHLORIDE 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 – 0.2% SODIUM CHLORIDE. 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 you vein through a proper plastic pipe (set).

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

Use in the elderly:
Since decrease of the liver, renal and cardiac functions are more frequent in the elderly and the frequency of co-morbidities or using other drugs concomitantly is also higher, dose selection generally requires more attention by choosing the possible lowest limit of the dose range.

Since this drug is largely eliminated through the kidneys, the risk of adverse effects of the drug will increase where the renal functions are impaired. Since the decrease in renal functions is greater in the elderly, care must be given in the selection of dosage and renal functions must be monitored during treatment.

Conditions of special use:
Renal/ hepatic impairment
Your doctor can prefer not to use this drug on you in cases of renal or liver insufficiency, depending on the severity of your condition; if s/he decides to use the drug, s/he will follow you up carefully.

If you have the impression that the effects of POLİFLEKS 5% DEXTROSE – 0.2% SODIUM CHLORIDE *is too powerful or too weak, consult your doctor or pharmacist.*

In case you had used POLİFLEKS 5% DEXTROSE – 0.2% SODIUM CHLORIDE in an amount more than you should:
Consult a doctor or a pharmacists if you had used POLİFLEKS 5% DEXTROSE – 0.2% SODIUM CHLORIDE in an amount more than you should.

In case you forget to take POLİFLEKS 5% DEXTROSE – 0.2% SODIUM CHLORIDE:
Do not take double dosage to balance the skipped dosage.

Possible effects related to the termination of the treatment with POLİFLEKS 5% DEXTROSE – 0.2% SODIUM CHLORIDE:
None

4. Possible side effects
Like all drugs, POLİFLEKS 5% DEXTROSE – 0.2% SODIUM CHLORIDE can cause adverse effects in individuals who are sensitive to the contents.

In case you encounter any of the following, stop using POLİFLEKS 5% DEXTROSE – 0.2% SODIUM CHLORIDE and inform your doctor immediately or apply to the emergency room of the nearest hospital:

Widespread or local (urticaria) wheezing, sense of compression on your chance, drop of blood pressure, fever, feeling of being unwell, gastric pain or tremors/ flu-like signs.

These are all very serious adverse effects.

Having any of the above means that you are seriously allergic against POLİFLEKS 5% DEXTROSE – 0.2% SODIUM CHLORIDE. Emergent medical intervention or hospitalization can be necessary.

All of these very serious adverse effects are seen rather rarely.

Inform your doctor immediately or apply to the emergency room of the nearest hospital in case you encounter any of the following:

- Fluid accumulation in the body, swelling (edema) and congestive (related to fluid accumulation) heart failure becoming more severe
- Decrease in the fluid amount in your body and water deficiency in your body (dehydration)
- Decrease in the amounts of substances called ions in your body (including potassium, magnesium, phosphate, etc.)
- Increase in your blood sugar (hyperglycemia)
- Shifting the body fluids to the acidic side (acidosis)
- Headache
- Vertigo
- Irritability
- Excessive excitability
- Contractions
- Coma and death
- Palpitation (tachycardia)
- Increase of blood pressure
- Increase in the volume of the circulating blood (hypervolemia)
- Fluid accumulation in lungs (edema)
- Slowing down of breathing
- Respiratory arrest
- Nausea, vomiting, diarrhea, abdominal cramps, thirst, reducing of saliva amount
- Reducing of sweating

- Fasciculation and hardening of muscles
- Renal failure
- Increase in urinary output
- Fever, fatigue
- Extravasation in application site
- Pain, redness and swelling in the application site
- Inflammation in the application site
- Irritation in the application site
- Inflammation in the application site starting from the application site and spreading
- Formation of clots in the veins starting from the application site
- Inflammation in the application site
- Hardness, redness or swelling starting from the application site and spreading

All of the above are serious adverse effects that might require emergent medical intervention.

In case you encounter any adverse effects not mentioned in these PATIENT INFORMATION LEAFLET, please inform your doctor or pharmacists.

5. How to store POLİFLEKS 5% DEXTROSE – 0.2% SODIUM CHLORIDE

Keep POLİFLEKS 5% DEXTROSE – 0.2% SODIUM CHLORIDE 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 the drug according to the expiry date.

Do not use POLİFLEKS 5% DEXTROSE – 0.2% SODIUM CHLORIDE after the expiry date shown on the packaging.

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

The solution must be checked before administration.

Administration must be made intravenously using sterile/non-pyrogen 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.

This drug is intended for single use.

Partially used solutions should not be kept.

Partially used drugs must not be connected to systems applied to patients again.

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. 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.
4. 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 which are mixed with additional drugs must not be kept.

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.
5. 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.
6. The bag will be brought to the previous position and administration will be continued.