PATIENT INFORMATION LEAFLET

POLİFLEKS 3% HYPERTONIC SODIUM CHLORIDE SOLUTION FOR I.V. INFUSION
Used intravenously.
Sterile

Active ingredients: Each 100 milliliters of solution contains 3 grams (30 mg/ml) of sodium 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 this 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 3% HYPERTONIC SODIUM CHLORIDE and what is it used for?

POLİFLEKS 3% HYPERTONIC SODIUM CHLORIDE is a solution which can be administered intravenously.
Each milliliter of solution contains 30 milligrams of salt called as sodium chloride. The sodium chloride solution contains sodium and chloride ion which are from the primary elements of the body. The solution which is ready for use and is clear is available in transparent plastic infusion bags wrapped by a thicker protective cover.

POLİFLEKS 3% HYPERTONIC SODIUM CHLORIDE is offered in PVC and PP bags with the volumes of 100, 150, 250, 500 and 1000 milliliters (These bags contain respectively 3 grams, 4.5 grams, 7.5 grams, 15 grams and 30 grams of salt.).

The drug is administered only in the vein and through an appropriate plastic pipe (set).

POLİFLEKS 3% HYPERTONIC SODIUM CHLORIDE is used in the following cases:

- In case of loss of liquid or electric loaded ions (agents called electrolyte) from your body, if you were treated with sodium-free solutions and sodium and chloride levels in your blood decreased (cases of hyponatremia and hypochloremia)
- Excessive dilution of water in your body due to administration of enema to you or excessive volumes of wash waters used during a closed method prostate operation (transurethral prostate resection operation) penetrated in your body.
- In case of critical loss of salt due to excessive perspiration, vomiting, diarrhea and other reasons and if this condition is desired to be treated rapidly.

2. Before you are given POLİFLEKS 3% HYPERTONIC SODIUM CHLORIDE

DO NOT USE *POLİFLEKS 3% HYPERTONIC SODIUM CHLORIDE* under following conditions:

If:

- You have allergy (excessive sensitivity) to sodium, chloride or the auxiliary agents contained in the product, do not use the POLİFLEKS 3% HYPERTONIC SODIUM CHLORIDE. These allergic reactions may be in the form of itch, redness on your skin or stertorous respiration or similar difficulty in breathing. If you are not sure about them, consult with your doctor.
- The potassium levels in your blood (an electric-loaded ion) are lower than the normal level (hypokalemia), do not use the POLİFLEKS 3% HYPERTONIC SODIUM CHLORIDE.
- Your blood is in an acid structure more than the normal level (acidosis), do not use the POLİFLEKS 3% HYPERTONIC SODIUM CHLORIDE.

- If the electrolyte (electric-loaded sodium, potassium, chloride and similar agents) levels in your blood are high, normal or slightly low, do not use the POLİFLEKS 3% HYPERTONIC SODIUM CHLORIDE.
- In cases of congenital heart failure, edema and sodium retention, high tension and heart failure, it must not be used.

Use POLİFLEKS 3% HYPERTONIC SODIUM CHLORIDE under following conditions CAREFULLY:

- In the event of a past inflammation related to your veins (In this case, your doctor shall administered the drug from a large vein of you to reduce the possibility of a further inflammation in your veins, shall replace your vein administered in every 24 hours and shall make the administration as slow as possible).
- If you have an untreated heart failure,
- If your tension is high,
- If there is bloating (edema) in your arms, legs and body,
- If you take the drugs called as steroid or drugs increasing secretion of this hormone on the body,
- If you have serious kidney failure,
- If you are a cirrhosis disease,
- If you use cortisone,
- If you are old or are in the post-surgery period,
- If your physical condition is weak or if your alcoholic (as administration of the hypertonic sodium chloride solution in an excessive speed or in an excessive volume may cause critical effects related to your nervous system in particular for those who have a poor physical condition or those having taken alcohol for a long period, your doctor shall make sure that the sodium level in your blood not to be higher than a certain value and shall ensure the administration to be as slow as possible).

If these warnings are applicable to you even for a part period, consult with your doctor.

Use of POLİFLEKS 3% HYPERTONIC SODIUM CHLORIDE together with foods and drinks

It is not practically possible to use it with foods and drinks in the course of administration. If you have taken alcohol for a long period, administration of the drug in an excessive speed or in an excessive volume may cause critical effects related to your nervous system (See Section 2: Conditions requiring CAREFUL USE)

Pregnancy

Consult your doctor or pharmacist before using this drug.

There is no sufficient data for use of the drug in pregnant women. Do not use it in the pregnancy period unless it is found expressly required by the 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.

As POLİFLEKS 3% HYPERTONIC SODIUM CHLORIDE contains high level of sodium, it must not be used in the breastfeeding period unless it is very required considering the fact that it may cause dehydration due to high increase in the sodium volume in blood of newborns.

Driving and use of machines
Driving and use of machine is not practically possible during the administration. It has no known effect on driving and use of machine after the administration.

Important information about some ingredients of POLİFLEKS 3% HYPERTONIC SODIUM CHLORIDE
If you are not sensitive to excipients in POLİFLEKS 3% HYPERTONIC SODIUM CHLORIDE, a negative effect due to these substances is not expected.

Taking other medicines
Injection of another drug in the solution is not recommended unless it is compulsory. During a compulsory addition, attention must be paid to ensure the added drug must be stable in pH of the solution and compatible with the agents in the solution and this decision must be made by the doctor.

There is no known drug interaction. However, if you use the drug named steroid or drugs increasing secretion of this hormone on the body, the POLİFLEKS 3% HYPERTONIC SODIUM CHLORIDE must be carefully used to prevent increase in your tension and dropsy on your body (See Section 2: CAREFUL USE CONDITIONS)
If you take any of the drugs above, your doctor may change dose of these drugs or give you another drug or adjust dosage of the POLİFLEKS 3% HYPERTONIC SODIUM CHLORIDE.

Please tell your doctor or pharmacist if you are taking or have recently taken any other prescription or non-prescription medicines.

3. How POLİFLEKS 3% HYPERTONIC SODIUM CHLORIDE will be given?

Your doctor shall decide volume of the drug you need and period of your treatment.
Volume of the drug that you shall take depends on your age, weight, current clinical condition, other drugs being used by you and type and severity of the disease to be treated.

Instructions for appropriate use and dose/administration frequency:
Your doctor shall determine dose of the drug based on your disease and administer it to you accordingly.
In general, 100 ml of solution shall be administered to you for a period longer than one hour.
For continuing the treatment, your doctor shall measure electrolyte intensities in your blood and shall decide to continue or not to continue treatment accordingly.

Route and method of administration:
POLİFLEKS 3% HYPERTONIC SODIUM CHLORIDE is a solution ready for administration and administered in the vein (intravenous). It is given in the vein by a specialized healthcare officer (doctor or nurse) in a period longer than 60 minutes.

This medical product may be blended with another drug before administration in the vein or during administration (See section titled "DETAILS OF THE HEALTHCARE PERSONNEL TO ADMINISTER THE DRUG" at the end of this User manual).

Different age groups:
Use in children
POLİFLEKS 3% HYPERTONIC SODIUM CHLORIDE may also be used for children. Your doctor shall determine dose of your drug depending on your disease and shall administer it accordingly.

Use in the elderly:
Do not use POLİFLEKS 3% HYPERTONIC SODIUM CHLORIDE for elderly.

Conditions of special use:
Renal / hepatic impairment:
Your doctor shall determine dose of your drug depending on your disease and shall administer it accordingly in case of kidney failure and liver failure.

In case you have the impression that the effect of POLİFLEKS 3% HYPERTONIC SODIUM CHLORIDE is too strong or too weak, consult your doctor or pharmacist.

In case you had used POLİFLEKS 3% HYPERTONIC SODIUM CHLORIDE in an amount more than you should:
If you have used POLİFLEKS 3% HYPERTONIC SODIUM CHLORIDE more than the required volume, your doctor shall measure performance of your kidney and intensity of electrolytes in your blood and shall decide use of a diuretic drug or requirement of dialysis accordingly.
If you used POLİFLEKS 3% HYPERTONIC SODIUM CHLORIDE more than you should have used, please consult a doctor or pharmacist.

In case you forget to take POLİFLEKS 3% HYPERTONIC SODIUM CHLORIDE:
Do not take a double dose on the same day to make up for a forgotten dose

Possible effects upon finalization of treatment with POLİFLEKS 3% HYPERTONIC SODIUM CHLORIDE:
No effect occurs when treatment with POLİFLEKS 3% HYPERTONIC SODIUM CHLORIDE is finalized.

4. Possible side effects
Like all other drugs, POLİFLEKS 3% HYPERTONIC SODIUM CHLORIDE may also cause side effects but all patients may not be affected.

The following side effects can be seen due to excessive use of POLİFLEKS 3% HYPERTONIC SODIUM CHLORIDE, and their incidence is unknown. Therefore, they are listed in the order of severity:
− Coma and death
− Conditions arising from bleeding in brain (hemorrhagic encephalopathy)
− Convulsion
− Delirium with shakes and shocks
− Functionless kidneys (kidney failure)
− Increase in blood acidity
− Difficulty in breathing or hard breathing (deteriorated congestive heart failure)
− Increase in heartbeat (tachycardia)
− Low tension (hypotension) or high tension (hypertension)
− Decrease in urine volume
− Distention in hands, arms, feet, legs or whole body (edema)
− Vomiting blood
− East excitability, twitch and stiffening in muscles
− Unrest
− Fever
− Headache
− Dizziness
− Drowsiness
− Diarrhea
− Abdominal cramps
− Vomiting
− Nausea
− Doziness
− Decrease in perspiration, decrease in salivation
- Increase in the blood volume
- Increase in the blood sodium level

In addition, the following side effects may also be seen due to intravenous administration:
− Inflammation in the places of administration and veins.

− Leakage out of vein.
- Infection in the injection area
- Grume formation in vein

In case you experience any adverse effect not mentioned in this PATIENT INFORMATION LEAFLET, immediately inform your doctor or pharmacist.

5. How to store POLİFLEKS 3% HYPERTONIC SODIUM CHLORIDE

Keep POLİFLEKS 3% HYPERTONIC SODIUM CHLORIDE out of the sight and reach of children and store within its packaging.

This medical product has been prepared only for administration intravenously by sterilized devices. Each infusion bag has been designed in a **disposable** form. Once it is opened, its unused portion must be disposed.

Use according to the expiry date.

Do not use POLİFLEKS 3% HYPERTONIC SODIUM CHLORIDE after the expiry date indicated on the package.

If you notice disorders in the product and/or its package, do not use POLİFLEKS 3% HYPERTONIC SODIUM CHLORIDE.

Do not throw away any expired or unused medicines! Give to the collection system determined by the Ministry of Environment and Urbanization.

Marketing Authorisation Holder and Manufacturing Site:

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This patient leaflet was approved on 02.10.2019

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

This medical product has been prepared only for intravenous administration by sterile device and sets. It must be administered only through intravenous infusion aseptically.
It is disposable. Partially used solutions must not be stored; they must be destroyed according to the medical waste procedures of the healthcare institution where intravenous administration is performed.
Visual control must be performed before use of parenteral drugs; only clear, particle-free products in an integral package must be used.
Do not remove the outer protector up to immediately prior to use; start administration immediately after removal of the protector. The protective outer case protects the product by preventing evaporation and loss of water ingredient. The inner bag ensures the product to remain sterile.
Caution: Do not make serial connection with other infusion liquids to prevent air emboli which may arise from residual air in the bag.

How to open:

- Remove the outer protector immediately before use. The protector is opened by tearing and the bag is taken out. Start administration immediately after removal of the protector.
- A slight opacification may be seen due to the sterilization process in the bag. It is normal and does not affect quality and reliability of the solution. Opacification would disappear gradually.
- Compress the bag to control its soundness after removal from its protective package. If leakage is found, the product must not be used; its sterility might be disordered.

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 in which additional drug was administered 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.
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.

CONFORMITY WITH OTHER INTRAVENOUS DRUGS

This product must not be mixed with other drugs until its compatibility is proven.

POST-ADMINISTRATION

Unused products or waste agents must be destroyed according to the instructions.