PATIENT INFORMATION LEAFLET

POLIFLEKS 0.45% Sodium Chloride Solution for IV Infusion
It is administered into a vein.
Sterile

- ***Active ingredient:*** Each 1000 ml solution contains 4.5 g sodium chloride.
- ***Excipients:*** Sterile water for injections

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 POLIFLEKS 0.45% Sodium Chloride Solution for IV Infusion is and what is it used for?

POLIFLEKS 0.45% Sodium Chloride Solution for IV Infusion is a solution administered intravenously and contains sodium and chloride ions that are the basic building blocks of the body.

POLIFLEKS 0.45% Sodium Chloride Solution for IV Infusion is introduced in 100, 150, 250, 500 and 1000 ml PP bags. There are two forms of with/without set.

The product is used for replacement treatment of sodium and chloride.

POLIFLEKS 0.45% Sodium Chloride Solution for IV Infusion is used for prophylaxis and treatment of dehydration, chlorine loss due to pulled out gastric juices in cases such as sweating, vomiting, and surgery etc. is equal or more than sodium loss, along with blood transfusion in patients who need fluid replacement, pre-and post-operative care, it is used as first hydration fluid that initiate kidney functions.

POLIFLEKS 0.45% Sodium Chloride Solution for IV Infusion is also used before the diluting process of some concentrated medicines that are suitable in intravenous infusion.

2. Before you are given POLIFLEKS 0.45% Sodium Chloride Solution for IV Infusion

POLIFLEKS 0.45% Sodium Chloride Solution for IV Infusion is a safe medicine in many patients. But if you have problems in your heart, kidneys, liver, lungs or edema your doctor may decide not to administer to you.

DO NOT USE POLIFLEKS 0.45% Sodium Chloride Solution for IV Infusion in the following conditions:

Do not use this medicine if you are allergic to POLIFLEKS 0.45% Sodium Chloride Solution for IV Infusion, its active substance or any of the other ingredients, you have symptoms such as sudden breathlessness, wheezing, skin rash, pruritus or swelling of the body.

This medication should not be used for you in the following cases:

- Increased blood volume (hypervolemia)
- Decreased chloride of blood (hypocalcemia)
- Decreased sodium of blood (hyponatremia)
- Heart Failure
- Retention of water and sodium
- Cirrhosis
- Retention of fluid in the patient with kidney, liver, or heart failure

In addition, if you are allergic to corn products DO NOT USE this medicine.

If you are not sure whether you have an allergy, consult your physician.

USE POLIFLEKS 0.45% SODIUM CHLORIDE CAREFULLY UNDER THE FOLLOWING CONDITIONS

If,

- You have edema,
- You have heart failure,
- You have severe renal failure and you are elder or in the postoperative period, this medicine should be administered carefully.

If administration is done with a controlled infusion pump, work of the pump should be stopped before the bag is fully discharged, otherwise air embolism may occur.

It is recommended to replace used pipes (sets) every 24 hours while this medicine is administered to you.

Also, the bag can be used only if it is steady and the solution is clear.

Use of POLIFLEKS 0.45% Sodium Chloride with food and drinks

POLIFLEKS 0.45% Sodium Chloride is an intravenously administered medicine, so food and drink does not affect your treatment.

Pregnancy

Consult your doctor or pharmacist before using this drug.

POLIFLEKS 0.45% Sodium Chloride SHOULD NOT be used during pregnancy unless it is especially deemed suitable 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, tell your doctor this situation. POLIFLEKS 0.45% Sodium Chloride SHOULD NOT be used during breast-feeding unless it is especially deemed suitable by your doctor.

Driving and using machines

POLIFLEKS 0.45% Sodium Chloride does not affect your ability to drive or use machines.

Important information about some of the ingredients in POLIFLEKS 0.45% Sodium Chloride Solution for IV Infusion
If you are nor allergenic to ingredients in POLIFLEKS 0.45% Sodium Chloride Solution for IV Infusion, it is not expected to have a negative impact on the substances.

Taking with other medicines
Please tell your doctor if you are planning to take, taking or have recently taken any other medicines including medicines obtained without a prescription, vaccines and herbal medicines.

POLIFLEKS 0.45% Sodium Chloride Solution for IV Infusion is incompatible with certain medicines. These drugs known to be incompatible with this product should not be added to the solution, and other solutions should be preferred for the dilution of these drugs.

To minimize the incompatible risk that may be possible with any drugs added to the solution, the final mixture will be controlled by the health officer, just after mixing, before administration and during administration, if there is any turbidity or sedimentation should be administered with caution in patients.

POLIFLEKS 0.45% SODIUM CHLORIDE should be used with caution in patients using carbenoxolone (used to protect the surface of the stomach in gastric ulcer), corticosteroid (a drug used by inhalation in various allergic conditions, intravenously, asthma, etc., in respiratory diseases of the respiratory tract and in various allergic conditions) or corticotropin (a hormone secreted from the brain; used as a medicine in its deficiency)

POLIFLEKS 0.45% Sodium Chloride Solution for IV Infusion should be administered by adding sufficient potassium in patients that the renal functions are good and especially that use digitalis.

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 POLIFLEKS 0.45% Sodium Chloride Solution for IV Infusion will be given?

Instructions for use and dose/ frequency of administration:
Your doctor will decide what quantities you need this drug or when it should be administered. He/she will decide this according to your age, body weight and the cause of administration. Please follow these instructions unless your doctor advises you separate.
Do not forget to take your medicine on time.

Your doctor will report how long your treatment with POLIFLEKS 0.45% Sodium Chloride Solution for IV Infusion continues. Do not give up the treatment early because you cannot get the desired results you expected.

Route and method of administration:
It is administered to vein with a suitable plastic pipe (set).

Different age groups
Pediatric use:
For children, the size of the dosage and administration set is determined by the doctor who advised the administration.

Geriatric use:
Should be carefully selected dosage for elderly patients and doses of treatment for elders should be started at the bottom of the range of dosage because liver, renal or cardiac functions may be reduced, other drugs also be used with or other diseases can be found.

This product is predominantly excreted by the kidney so the risk of toxic reactions increases in patients with impaired renal function. Decrease in renal function occurs more frequent in elders so should be carefully selected dosage for elderly patients and monitored renal functions.

Special use cases:
Renal / hepatic impairment:
Your doctor cannot administer to you according to the severity of your disease in cases with renal and liver failure; if your doctor decides to administer, he/she will monitorize carefully during administration.

If you have an impression that the effect of POLIFLEKS 0.45% Sodium Chloride Solution for IV Infusion is very strong or weak, please tell your doctor or pharmacist.

If you use more POLIFLEKS 0.45% Sodium Chloride Solution for IV Infusion:
If you use more POLIFLEKS 0.45% Sodium Chloride Solution for IV Infusion than you should, talk to a doctor or pharmacist.

If you forget to use Polifleks 0.45% Sodium Chloride:
Do not take a double dose to compensate forgotten dose.

Effects that may occur after the treatment of POLIFLEKS 0.45% Sodium Chloride Solution for IV Infusion:
There are no effects.

4. Possible side effects
Like all other medicines, POLIFLEKS 0.45% Sodium Chloride may cause side effects in patients with sensitivity to any component content.

Do not use POLIFLEKS 0.45% Sodium Chloride Solution for IV Infusion, tell your doctor immediately or contact nearest emergency department of a hospital if any of the followings happened:

- Common rash or a local (urticaria), wheezing, chest tightness, drop in the blood pressure, high fever, malaise, stomachache or chill/ flu-like symptoms

All of these are the serious side effects.

If you have any of these that means you have a serious allergy to POLIFLEKS 0.45% Sodium Chloride Solution for IV Infusion. You may need urgent medical attention or hospitalization.

These all very serious side effects are rare.

Tell your doctor immediately or contact nearest emergency department of a hospital if you notice any of the following:

- Water retention, swelling (edema), and increased (congestive) heart failure is due to retention of fluid
- Decreased in the amount of liquid in the body and dehydration
- Decrease of blood ions (potassium, magnesium, phosphate, etc.) levels
- Acidosis
- Headache
- Dizziness
- Anxiety
- Excessive excitability
- Spasms
- Coma and death
- Rise in blood pressure
- Hypervolemia
- Edema
- Respiratory slowing
- Respiratory arrest
- Nausea, vomiting, diarrhea, abdominal cramps, thirst sensation, decrease in the amount of saliva
- Decrease in sweating
- Muscle twitching and hardening
- Kidney failure
- Increase in urine
- Fever, malaise
- Penetration out of the vein from the injection site

- İnflammation at the injection site
- İrritation of the vein
- Starting from the site of injection and spreading throughout the veins inflammation
- Clotting that starting from the site of injection and spreading throughout the veins
- Starting from the site of injection and spreading throughout the veins rigidity, redness or swelling

All of these are the serious side effects. You may need urgent medical attention.

If you encounter with any side effects that are not mentioned in this leaflet, please inform your doctor or pharmacist.

5. How to store Polifleks 0.45% Sodium Chloride Solution for IV Infusion

Keep Polifleks 0.45% Sodium Chloride out of the reach and sight of children and store in the original container.

Store below 25°C.

It is for single use only. Partly used containers should not be stored and they must be disposed in accordance with the procedures of medical waste of healthcare organization where the injection is made.

Expiration date is written on the label of each bag. If this date passes, you will not be given this medicine.

Use in accordance with the expiration date.

Do not use Polifleks 0.45% Sodium Chloride after the expiration date which is stated on the package.

Do not dispose of expired or unused drugs! Give to the collection system determined by the Ministry of Environment and Urbanization.

Do not use Polifleks 0.45% Sodium Chloride if you notice defects in product and / or packaging.

Marketing Authorization Holder & Manufacturer:

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These PATIENT INFORMATION LEAFLET have been approved on 02/10/2019

THE FOLLOWING INFORMATION IS INTENDED FOR MEDICAL OR HEALTHCARE PROFESSIONALS ONLY.

The solution should be checked.

This medical product is prepared for intravenous administration with non-pyrogenic sterile device and sets. It should be administered aseptically by intravenous infusion only.
It is for single use only. Partly used containers should not be stored and they must be disposed in accordance with the procedures of medical waste of healthcare organization where the injection is made.

Parenteral drugs should be inspected visually before use; only clear, particle-free and packaging intact products should be used.

Do not remove the guard until just before use; start the administration immediately after removing the guard. Protective outer sheath protects the product from decrease in the water content by evaporation. Inner bag ensures that the product is sterile.

Caution: To prevent the air embolism may occur depending on the residual air in the bag, serial connection with another infusion fluid should be avoided.

To open:

- Remove the outer guard immediately before use. Protective is opened by tearing and the bag is revealed. Start the administration immediately after removing the protector.
- Opaque depending upon a sterilization process can be seen in the bag. This is normal, and it does not effect the quality and reliability of the solution. Opacity gradually disappears.
- Check for leaks by squeezing the bag after removing the protective package firmly. If leaks are found, discard solution, as sterility may be compromised.

Preparation for administration:

1. Hang the bag.
2. Remove the protector from outlet port of administration.
3. Attach the administration set to the bag by firmly dipping the spike of administration set to the end of an administration.
4. The instructions of set should be followed for the implementation of solution to the patient.

Injection of additive medications:

Warning: As in all parenteral solutions, all the substances to be added to the product must be compatible with the product. If adding is to be made to the product, compatibility should be checked in final mix before applying to the patient.

To add medication before administration:

1. Disinfect medication site.
2. Medicine is administered using syringe with 19 (1.10 mm) to 22 (0.70 mm) gauge needle.
3. Mix solution and medication thoroughly. For high-density medication such as potassium chloride, tap the ports gently while ports are upright and mix.

Caution: Do not store bags containing added medications.

To add medication during administration:

1. Close clamp on the set.
2. Disinfect medication site.
3. Medicine is administered using syringe with 19 (1.10 mm) to 22 (0.70 mm) gauge needle.
4. Remove container from IV pole and/or turn to an upright position.
5. Evacuate both ports by tapping gently while the container is in an upright position to mix solution and medication thoroughly.
6. Return container to in use position, re-open the clamp and continue administration.