PATIENT INFORMATION LEAFLET

POLİFLEKS 0.9% ISOTONIC SODIUM CHLORIDE Solution for IV infusion
For intravenous administration.
Sterile

Active substances: Each 100 mL solution contains 900 mg sodium chloride (salt) (sodium 154 mmol/L, chloride 154 mmol/L).
***Excipient(s)*:** Sterile water for injection

Before using this medicine, read all of this PATIENT INFORMATION LEAFLET carefully. Because, this leaflet includes important information for you.

- *Keep this PATIENT INFORMATION LEAFLET. You may need to read it again.*
- *If you have any further questions, ask your doctor or pharmacist.*
- *This medicine has been prescribed for you. Do not pass it on to others.*
- *During the use of this medicine, tell that you are using this medicine when you go to a doctor or hospital.*
- *Follow the written instructions exactly. Do not use **higher or lower** dose than the recommended dose.*

The following subjects are covered herein:

1. What is POLİFLEKS 0.9% ISOTONIC SODIUM CHLORIDE and what is it used for?

POLİFLEKS 0.9% ISOTONIC SODIUM CHLORIDE is an **intravenous solution** containing sodium and chloride ions which are the building blocks of the body. It works to replace fluids and salt lost from the body.
POLİFLEKS 0.9% ISOTONIC SODIUM CHLORIDE comes in 25 ml and 5000 ml (only PVC bag), 50, 100, 150, 250, 500, 1000 and 3000 ml PVC and PP bags. Product comes in two forms: with and without set.
The medicine is given through a plastic set only into a vein.

POLİFLEKS 0.9% ISOTONIC SODIUM CHLORIDE is used to treat the deficit of water and salt (dehydration) of the body and to prevent this and condition from occurring.
POLİFLEKS 0.9% ISOTONIC SODIUM CHLORIDE is also used for the dilution of certain intravenous medicines in concentrated form before intravenous administration.

2. Before you are given POLİFLEKS 0.9% ISOTONIC SODIUM CHLORIDE?

DO NOT USE POLİFLEKS 0.9% ISOTONIC SODIUM CHLORIDE under the following circumstances

- If you had an allergic reaction, e.g. symptoms such as sudden shortness of breath, wheezing, rash, itching or swelling when you were given POLİFLEKS 0.9% ISOTONIC SODIUM CHLORIDE or drugs containing its active substance and any of the excipients.
- If you have a clinical condition where the application of sodium or chloride is detrimental,
- If you have sodium elevation (hypernatremia) or chlorine elevation (hyperchloremia).

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

Take special care with POLİFLEKS 0.9% ISOTONIC SODIUM CHLORIDE in following conditions

POLİFLEKS 0.9% ISOTONIC SODIUM CHLORIDE is a safe drug for many patients. However, your doctor may decide not to use this medicine if you have cardiac, renal, hepatic or lung problems, if you are diabetic or there are swellings (oedema) due to excessive accumulation of sodium in your body.

If you have one of the following conditions:

- Congestive heart failure,
- Severe renal failure,
- Urinary tract obstruction,
- Excessive secretion of aldosterone
- Water retention (oedema) in your body or arms or legs,

This medicine should be administered to you carefully.

If,

- This medicine will be administered by an electronic pumping device, care must be taken to discontinue pumping action before the bag is fully empty. An air plug may otherwise occur.

It is recommended that the tubing (sets) used for administration be replaced once every 24 hours.

In addition, use only if the bag is intact and the solution is clear.

If these warnings were experienced by you, even at any time in the past, please contact your doctor.

Use of POLİFLEKS 0.9% ISOTONIC SODIUM CHLORIDE with food and drink

POLİFLEKS 0.9% ISOTONIC SODIUM CHLORIDE is administered intravenously; there is no interaction with food and drinks in terms of its route of administration.

Pregnancy

Before using this medicine consult your doctor or pharmacist.

Do not use POLİFLEKS 0.9% ISOTONIC SODIUM CHLORIDE during pregnancy unless it is specifically deemed appropriate by your doctor.

If you notice that you have been pregnant during treatment, tell your doctor or pharmacist immediately.

Breastfeeding

Before using this medicine consult your doctor or pharmacist.

Tell your doctor if you are breastfeeding. Do not use POLİFLEKS 0.9% ISOTONIC SODIUM CHLORIDE during breastfeeding unless it is specifically deemed appropriate by your doctor.

Driving and using machinery

POLİFLEKS 0.9% ISOTONIC SODIUM CHLORIDE has no effect on driving and use of machinery.

Important information on some excipients present in POLİFLEKS 0.9% ISOTONIC SODIUM CHLORIDE

If you are not sensitive to excipients of POLİFLEKS 0.9% ISOTONIC SODIUM CHLORIDE, a negative effect due to these substances is not expected.

Taking with other medicines

Please tell your doctor if you are planning to take or have recently taken any other medicines, including over-the-counter medicines, vaccines and herbal medicines.

POLİFLEKS 0.9% ISOTONIC SODIUM CHLORIDE is incompatible with some drugs. These drugs, which are known to be incompatible, should not be added to the solution and other solutions should be preferred for diluting these drugs.

To minimize the risk of possible incompatibilities arising from mixing any of these solutions with other additives that may be prescribed, the final mixture should be inspected by the health staff for cloudiness or precipitation immediately after mixing, prior to administration and periodically during administration.

POLİFLEKS 0.9% ISOTONIC SODIUM CHLORIDE should be given with caution due to the risk of sodium and water build-up in case of concomitant use with carbenoxolone, corticosteroid or corticotropin.

If you are taking or have recently taken any other medicines, with or without a prescription, tell your doctor or pharmacist.

3. How you will be given POLİFLEKS 0.9% ISOTONIC SODIUM CHLORIDE?

Instructions regarding correct use and dosage/administration frequency:

Your doctor will decide on how much you need and when it is to be given. This will depend on your age, weight and the reason for treatment. Follow these instructions unless otherwise recommended by your doctor.

Your doctor will inform you on the duration of your treatment with POLİFLEKS 0.9% ISOTONIC SODIUM CHLORIDE. Do not stop your treatment early because you cannot get the desired result.

- **Route and method of administration:**

It is given through a plastic tube (set) suitable to your vein.

- **Different age groups**

Use in children:

In children, the dose and the size of the application set is decided by the treating physician.

Care must be exercised in treatment of babies, especially in pre-term neonates, whose renal function may be immature and whose ability to excrete fluid and solute loads may be limited. Fluid intake, urine output, and serum electrolytes should be monitored closely.

Elderly:

Care should be taken in selecting the dose, generally because the decrease in liver, kidney or cardiac function is more frequent in elderly and is likely to be accompanied by other illnesses or other medications and should be usually based on the lowest possible limit of dose range.

The risk of adverse drug effects is increased in cases of impaired kidney functions since this drug is mainly excreted through the kidneys. Care should be taken in selecting doses and renal function should be monitored during treatment as there is a greater decline in renal function in the elderly.

- **Special conditions of use:**

There is no special condition of use.

If you have the impression that the effect of POLİFLEKS 0.9% ISOTONIC SODIUM CHLORIDE is too strong or weak, talk with your doctor or pharmacist.

If you have taken more POLİFLEKS 0.9% ISOTONIC SODIUM CHLORIDE than you should have:

Tell your doctor or pharmacist if you use more POLİFLEKS 0.9% ISOTONIC SODIUM CHLORIDE than you should.

If you forget to take POLİFLEKS 0.9% ISOTONIC SODIUM CHLORIDE?

Do not take double dose to make up the dose you have missed.

Effects that may occur if you stop taking POLİFLEKS 0.9% ISOTONIC SODIUM CHLORIDE

There is no known effect.

4. Possible side effects

Like all medicines, POLİFLEKS 0.9% ISOTONIC SODIUM CHLORIDE may cause side effects in patients sensitive to its ingredients.

Side effects may be associated with the deficit or excess of the ions contained in solution and occurrence of side effects is not expected under normal treatment conditions.

Following side effects are those observed depending on the technique of administration and their frequency is unknown.

If you notice any of the following side effects, tell your doctor immediately or contact the emergency department at your nearest hospital:

- Formation of a clot in the vessel

- Bleeding
- Build up of salt (sodium) in the body
- Build up of water, swelling (edema) and aggravation of heart failure due to fluid accumulation (congestive)
- Acidification of body fluids (acidosis)
- Headache
- Dizziness
- Restlessness
- Severe irritability
- Fits
- Coma and death
- Heart palpitation (tachycardia)
- Increase in pressure
- Build up of fluid in the lungs (edema)
- Slowing of respiration
- Respiratory arrest
- Nausea, vomiting, diarrhea, abdominal cramps, feeling of thirst, decreased salivation
- Decrease in sweating
- Muscle twitching and rigidity
- Kidney failure
- Fever, fatigue
- Pain at the site of infusion
- Inflammation at the site of infusion
- Stiffness, redness or swelling spreading through the vein from the site of infusion

These are all serious side effects. You may need urgent medical attention.

Tell your doctor or pharmacist if you notice any other effects not listed in this leaflet.

5. How to store POLİFLEKS 0.9% ISOTONIC SODIUM CHLORIDE?

Store POLİFLEKS 0.9% ISOTONIC SODIUM CHLORIDE in original packaging and keep out of the reach and sight of children.

Store at temperature below 25°C.

For single use only.

Each bag has an expiration date on its label. If this date is past, you will not be given this medicine.

Use in compliance with the expiry date.

Do not use POLİFLEKS 0.9% ISOTONIC SODIUM CHLORIDE after the expiry date on the packaging.

Marketing Authorisation Holder and Manufacturing Site:

POLİFARMA İLAÇ SAN. VE TİC. A.Ş.
Vakıflar OSB Mahallesi,
Sanayi Caddesi, No:22/1
Ergene/TEKİRDAĞ/TURKEY
Tel: +90 282 675 14 04
Fax: +90 282 675 14 05

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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 apyrogenic 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 bag, 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.

It is disposable. **Do not store partly used solutions**

Do not reconnect partly used bags to the administration systems.

To open:

1. Check the integrity of the outer packaging and check for leaks; Do not use if the packaging is damaged.
2. Tear off the protective outer packaging.

3. Check for robustness by squeezing the inner bag firmly. Check the clarity of the solution in the bag and that is free of foreign substances.

Preparation for administration:

1. Suspend the bag.
2. Remove the protective cover from the application port.
3. Stick the spike of the application set firmly in the application tip.
4. The instructions for use of the set must be followed for the administration of the solution.

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. Disinfect the drug applicator.
2. Inject the drug to be added using syringe with 19 to 22 gauge needle.
3. Mix the solution and the added drug thoroughly. For high density medication such as potassium chloride, tap gently to the ports of the bag, while ports are upright to allow mixing.

Attention: Do not store bags mixed with additional medication.

Adding medication during administration

1. Close the clamp.
2. Disinfect the drug applicator.
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 both ports to allow mixing of solution and medication.
6. Return bag to its former position and open the clamp and continue administration.