PATIENT INFORMATION LEAFLET

BIOFLEKS 0.9% ISOTONIC SODIUM CHLORIDE SOLUTION

50-100-150-250-500-1000 and 3000 ml PVC Bag

For intravenous administration.

Active ingredients: Every liter of the solution contains 9 g sodium chloride (salt).

Excipients: Sterile water for injection

Read all of this PATIENT INFORMATION LEAFLET carefully before you start taking this medicine because it contains important information for you.

- *Keep this leaflet. You might need to read it again.*
- *For further questions, please refer to your physician or your pharmacist.*
- *This medication is prescribed solely for you, do not offer it to others.*
- *If you visit a doctor or a hospital during the use of this medicine, tell your doctor that you use this medicine.*
- *Follow the recommendations on this leaflet exactly as described. Do not use **higher or lower** dose except the dose you have been recommended for the medicine.*

In this Information Leaflet:

Headings are included.

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

BIOFLEKS 0.9% ISOTONIC SODIUM CHLORIDE SOLUTION is an **intravenously administered** solution which contains sodium and chloride, essential constituents for the body. It compensates the fluid and salt loss of the body.

BIOFLEKS 0.9% ISOTONIC SODIUM CHLORIDE SOLUTION is presented in 50-100-150-250-500-1000 and 3000 ml PVC Bag with two outputs, with protective HDPE Overpouch. The product is available with and without a set. This drug can only be administered inside a vein via a plastic tube (set) designed for this purpose.

BIOFLEKS 0.9% ISOTONOC SODIUM CHLORIDE SOLUTION is used for the treatment and prevention of the lack of water and salt (dehydration) in the body.

BIOFLEKS 0.9% ISOTONIC SODIUM CHLORIDE SOLUTION, can be used to dilute some intravenous concentrated drugs before intravenous administration.

2. What you need to know before you use BIOFLEKS 0.9% ISOTONIC SODIUM CHLORIDE SOLUTION

DO NOT USE *BIOFLEKS 0.9% ISOTONIC SODIUM CHLORIDE SOLUTION* if,

You previously had an allergic reaction to BIOFLEKS 0.9% ISOTONIC SODIUM CHLORIDE SOLUTION or any of it's active ingredients or excipients, i.e. sudden shortness of breath, wheezing, skin rash, itching or swelling of the body.

If you are unsure if you are allergic or not, refer to your physician.

USE *BIOFLEKS 0.9% ISOTONIC SODIUM CHLORIDE SOLUTION* WITH CAUTION if,

BIOFLEKS 0.9% ISOTONIC SODIUM CHLORIDE SOLUTION is a safe medication for most of the patients. However if you have heart, kidney, liver or lung problems, if you are diabetic or have swellings (edema) due to over-accumulation of salts on your body your physician may decide not to use this medication on you.

If you have one of these disorders;

- Congestive heart failure
- Severe kidney failure,
- Urinary tract obstruction,
- Retention of water on your body or on your arms and legs (edema), this medicine should be administered carefully.

If,

- you are going to use this medication via an electronic pump, make sure that the pump will stop before the bag is entirely empty.

It is advised to change the tubes (sets) every 24 hours while using this drug. Additionally, it should only be used if the bag is intact and the solution is clear.

Use of *BIOFLEKS 0.9% ISOTONIC SODIUM CHLORIDE SOLUTION* with food and drinks

BIOFLEKS 0.9% ISOTONIC SODIUM CHLORIDE SOLUTION is an intravenously administered medication, due to it's mode of administration, no interaction with food or drinks should be expected.

Pregnancy

Consult your physician or your pharmacist before using this medication.

If not especially found suitable by your doctor, avoid using BIOFLEKS 0.9% ISOTONIC SODIUM CHLORIDE SOLUTION during pregnancy.

If you find out about your pregnancy during your treatment, consult your physician or your pharmacist.

Breast-feeding

Consult your physician or your pharmacist before using this medication.

If you are breast feeding inform your doctor about it. If not especially found suitable by your doctor, avoid using BIOFLEKS 0.9% ISOTONIC SODIUM CHLORIDE SOLUTION during breast feeding.

Using machinery and vehicles

BIOFLEKS 0.9% ISOTONIC SODIUM CHLORIDE SOLUTION has no effect on driving or using machines.

Important information on some of the excipients found in the composition of BIOFLEKS 0.9% ISOTONIC SODIUM CHLORIDE SOLUTION

Unless you have a hypersensitivity to the excipients that are found in BIOFLEKS 0.9% ISOTONIC SODIUM CHLORIDE SOLUTION, no negative reactions should be expected from the excipients.

Use with other medicines

If you are planning to or have recently used any other medications including non-prescription drugs, vaccinations or herbal medicines please inform your physician.

BIOFLEKS 0.9% ISOTONIC 0.9% SODIUM CHLORIDE SOLUTION is incompatible with some medications. The drugs known to be incompatible should not be added to the solution, other solutions should be chosen to dilute these drugs.

To reduce any risk of incompatibility with drugs added to the solution to a minimum, the final mixed solution should be observed for blurriness and precipitation right after mixing and before and during administration in regular intervals by the healthcare professional.

BIOFLEKS 0.9% ISOTONIC SODIUM CHLORIDE SOLUTION should be used with caution in patients using carbenoxolone, corticosteroid or corticotropin.

If you are using or have recently used any type of prescription or non-prescription drugs, please inform your physician or your pharmacist.

3. How to use BIOFLEKS 0.9% ISOTONIC SODIUM CHLORIDE

Instructions for appropriate use and dose/administration frequency:

Your physician will decide the dosage you need and timing of your medication Parameters like your age, body weight and the reason why you need to use this medication will be taken into account. Unless recommended otherwise by your physician, follow these instructions.

Do not forget to take your medicine on time.

Your physician will tell you how long your treatment is going to continue with BIOFLEKS 0.9% ISOTONIC SODIUM CHLORIDE SOLUTION. Do not stop your treatment prematurely as you may not see the desired effect.

- **Method and route of administration:**

  It is administered in your veins via a plastic tube (set).

- **Various age groups:**

  Use in children:

For pediatric patients, the dosage and the size of administration set should be decided by the physician.

Use in elderly:

The dosage selection should be made with caution and generally should be kept at the lowest effective dose as possible in elderly patients since the risk of having impaired renal, hepatic or cardiac functions is higher and also concurrent illnesses and drug use is more common.

Since this drug is mainly excreted via kidneys, in case of impaired renal function the risk of being exposed to its harmful effects is higher. The dose should be chosen with caution in elderly patients since they are more likely to have impaired renal function and the renal functions should be monitored closely during treatment.

- **Special conditions of use:**

  No special conditions.

If you have the impression that the efficacy of BIOFLEKS 0.9% ISOTONIC SODIUM CHLORIDE SOLUTION is too strong or too weak, talk to your doctor or pharmacist.

If you have used more BIOFLEKS 0.9% ISOTONIC SODIUM CHLORIDE than you should:

If you have used more BIOFLEKS 0.9% ISOTONIC SODIUM CHLORIDE SOLUTION than recommended, consult a doctor or a pharmacist.

If you forget to take *BIOFLEKS 0.9% ISOTONIC SODIUM CHLORIDE SOLUTION*:

Do not take a double dose to make up for forgotten doses.

Effects which may occur when treatment with *BIOFLEKS 0.9% ISOTONIC SODIUM CHLORIDE SOLUTION* is discontinued:

None.

4. **Possible side effects**

Like all medicines, side effects may occur in people sensitive to ingredients of BIOFLEKS 0.9% ISOTONIC SODIUM CHLORIDE SOLUTION.

Side effects might originate from the deficiency or excessiveness of ions in the solution and under normal treatment conditions no side effects should be expected.

The side effects mentioned below may occur due to overdosing or administration technique and their frequencies are unknown.

If you notice any of the following, inform your doctor immediately, or apply to the emergency service of the nearest hospital:

- Clot formation inside the blood vessels
- Bleeding
- Salt (sodium) retention in the body
- Water retention in the body, swelling (edema) and exacerbation of (congestive) heart failure

due to fluid retention

- Increase in the acidity of body fluids (acidosis)
- Headache
- Dizziness
- Restlessness
- Irritability
- Contractions
- Coma and death
- Heart palpitations (tachycardia)
- Hypertension
- Water retention in the lungs (edema)
- Slow breathing
- Respiratory arrest
- Nausea, vomiting, diarrhea, abdominal cramps, thirst, decreased amount of saliva
- Decreased sweating
- Muscle stiffness and twitches
- Kidney failure
- Fever, malaise
- Pain on administration site
- Inflammation on administration site
- Stiffness, redness or swelling (thrombophlebitis) originating from the administration site and expanding through the veins.

All of these are serious side effects. Urgent medical treatment might be necessary.

If you experience any side effect not mentioned in this patient information leaflet, inform your doctor or your pharmacist.

5. How to store BIOFLEKS 0.9% ISOTONIC SODIUM CHLORIDE SOLUTION

Keep BIOFLEKS 0.9% ISOTONIC SODIUM CHLORIDE SOLUTION out of reach of children and in its packaging.

Store at temperatures below 25°C.

For single use. Partially used bags should not be stored; should be disposed of in line with medical waste procedures at the healthcare center where administration was performed.

Expiration date is found on the label of each bag. If the expiration date has passed, the bag will not be used.

Use in compliance with the expiry date.

Do not use BIOFLEKS 0.9% ISOTONIC SODIUM CHLORIDE SOLUTION after the expiration date stated on the packaging.

Marketing authorization holder and manufacturer:

Osel İlaç San. ve Tic. A.Ş.

Akbaba Mah Maraş Cad. No:52, 34820

Beykoz / İSTANBUL/ TURKEY

This patient information leaflet has been approved on 03/02/2015

INFORMATION BELOW IS FOR THE HEALTHCARE PROFESSIONAL WHO WILL BE ADMINISTERING THIS MEDICINAL PRODUCT

Administration should be started immediately after the administration set is attached to the product.

In order to prevent air embolism resulting from residual air in the bag, it should not be connected in series to other infusion fluids.

Pressurizing intravenous solutions contained in flexible plastic bags to increase flow rates can result in air embolism if the residual air in the bag is not fully evacuated prior to administration.

The solution should be administered with aseptic technique via a sterile administration set. In order to prevent air entry into the system, fluid should be passed through the administration set before use.

Additional medications may be added before or during infusion through the injection port with a needle under aseptic conditions. The isotonicity of the final product should be determined before parenteral administration.

The added medication should be completely mixed with the solution before administration to the patient. The solutions containing additional medication should be used immediately after the addition of the medication; it should not be kept for later use.

Adding an additional medication to the solution or incorrect administration technique may result in fever reaction due to pyrogenic contamination of the product. In case of any adverse reaction, infusion should be stopped at once.

For single use.

Partially-used solutions should not be stored.

Partially-used bags should not be reconnected to the systems administered to patient.

To open it:

1. Check the integrity of outer packaging and whether there is any leakage; if the packaging is damaged do not use it.
2. Tear and open the protective outer packaging.
3. Check if the bag inside the protective packaging is intact by squeezing. Check the clarity of the solution and if there are any foreign substances inside the solution.

Preparation for administration:

1. Hang the bag.

2. Remove the protective cap on the administration port.
3. Firmly insert the spike of the administration set to the administration port.
4. Follow the instructions for use of the set to administer the solution to the patient.

Adding additional medication:

Caution: As with all parenteral solutions, all substances that will be added to the product should be compatible. If a medication is to be added to the product, the compatibility of the final mixture should be checked before administration to the patient.

Adding a drug before administration

1. Disinfect the medication administration port.
2. Administer the medication through the medication administration port via a syringe with a 19-22 gauge needle.
3. Mix the solution and the medication well. For dense medications such as potassium chloride, gently tap the administration port when it's on upright position to ensure that it is mixed.

Caution: The bags which were mixed with other medications should not be stored.

Adding medication during administration

1. Close the clamp of the set.
2. Disinfect the medication administration port.
3. Administer the medication through the medication administration port via a syringe with a 19-22 gauge needle.
4. Take the solution from the hanger and bring it to an inverted position.
5. At this position, gently tap the administration port and injection port to ensure that the solution and the additional medication are mixed.
6. Invert the bag to its original position, open the clamp and continue the administration.