PATIENT INFORMATION LEAFLET

PF 1/3 POLİDEKS (3.33% DEXTROSE-0.3% SODIUM CHLORIDE) Solution for I.V. Infusion

For intravenous administration.

Sterile

Active substances: Each solution contains 3 g sodium chloride (salt) and 33.3 g glucose (dextrose monohydrate) in 1 liter.

Excipients: 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 PF 1/3 POLİDEKS is and what it is used for?

PF 1/3 POLİDEKS is a clear, odorless and sterile solution free from particles given intravenously, containing sodium, chloride ions, which are vital for the body, with glucose.

PF 1/3 POLİDEKS belongs to the drug group 'Solutions affecting electrolyte balance / Carbohydrate electrolyte solutions'.

PF 1/3 POLİDEKS is supplied in 500 and 1000 ml glass bottles. Product comes in two forms: with and without set.

It is used to treat the deficit of water and sodium (dehydration) of the body and to prevent this condition from occurring. It is preferred in cases where the loss of a substance called chlorine is equal to or greater than the loss of a substance called sodium, because of the stomach fluids being removed, especially in cases such as sweating, vomiting, and surgery, in patients who need fluid along with blood transfusion, in the pre- and post-operative care, as first medicine to initiate renal function.

PF 1/3 POLİDEKS is also used for the dilution of certain intravenous medicines in concentrated form before intravenous administration.

2. Before you are given PF 1/3 POLİDEKS?

PF 1/3 POLİDEKS 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.

DO NOT USE PF 1/3 POLİDEKS if you have the following circumstances

Do not use this medicine if you have had an allergic reaction, e.g. symptoms such as sudden shortness of breath, wheezing, rash, itching or swelling when you were given PF 1/3 POLİDEKS or drugs containing its active substance and any of the excipients.

Do not use this medicine if you also have the following:

- Excess fluid and salt accumulation in your body and associated swelling (edema).
- Severe kidney failure (you cannot urinate or only in very small quantities).
- Heart failure that is severe and not responding to treatment.
- Elevated levels of sodium, chloride and lactate in your blood (hypernatremia, hyperchloremia and hyperlactatemia).
- Cirrhosis (fluid accumulation in the abdomen).
- Coma (coma due to diabetes or increased blood density)
- Excessive blood sugar and sugar intolerance in cases such as starvation or trauma (metabolic stress conditions).
- If you are allergic to corn products (consult your doctor if you are not sure that are allergic).

USE PF 1/3 POLİDEKS with CAUTION if

If you have one of the following conditions:

- Diabetes or intolerance to carbohydrates,
- Heart failure,

- Severe renal failure,
- Urinary tract obstruction,
- Water retention (oedema) in your body or arms or legs,
- And especially if you are old and you have recently been operated on.

If this medicine will be administered by an electronic pumping device, care must be taken to discontinue pumping action before the bottle is fully empty.

It is recommended that the tubing used for administration be replaced once every 24 hours. Use only if the bottle is intact and not leaking and the solution is clear.

Please consult your doctor if these warnings are valid for you, even at any time in the past.

Using PF 1/3 POLİDEKS with food and beverages
PF 1/3 POLİDEKS 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 PF 1/3 POLİDEKS 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.

It is not known whether PF 1/3 POLİDEKS is excreted via human milk. You should seek the advice of your doctor before breastfeeding your baby.

Tell your doctor if you are breastfeeding. Do not use PF 1/3 POLİDEKS during breastfeeding unless it is specifically deemed appropriate by your doctor.

Ability to drive and use machines
It is practically not possible to drive vehicles during the use of infusion solutions. PF 1/3 POLİDEKS has no effect on the use of vehicles or machinery.

Vital information regarding some of the excipients contained in PF 1/3 POLİDEKS
If you do not have hypersensitivity to the excipients of PF 1/3 POLİDEKS, no adverse effect due to these substances is expected.

Use in combination with other drugs

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.

PF 1/3 POLİDEKS is incompatible with some of the following medications. 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: Following drugs are known to be incompatible.

- Ampicillin sodium
- Mitomycin
- Amphotericin B
- Erythromycin lactobionate

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.

PF 1/3 POLİDEKS should be used in caution in patients using carbenoxolone (a drug that is used to protect the stomach surface in stomach ulcers), corticosteroids (a drug that is used by intravenous routes in various allergic conditions, by inhalation during allergic respiratory diseases such as asthma, and by topical application on skin in various allergic conditions) or corticotropin (hormone secreted from the brain, used as a drug in the absence of hormone).

In fasting patients with good renal function, POLYFLEX 1/3 POLYDEKS should be administered with adequate potassium, especially when the patient is being treated with digitalis type heart medicines.

If you are currently taking or recently took any prescribed or over-the-counter drugs, please inform your physician or pharmacist.

3. How you will be given PF 1/3 POLİDEKS

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, condition and the reason for treatment. Follow these instructions unless otherwise recommended by your doctor.

Do not forget to take your medication on time.

Your doctor will inform you on the duration of your treatment with PF 1/3 POLİDEKS. 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:
For children, the size of the dose and set of administration is decided by the doctor who recommends applying it. PF 1/3 POLIDEKS should be used with caution in children, newborns and low birth weight infants.

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.

PF 1/3 POLİDEKS should be used with caution in elderly

Special conditions of use:
Renal / Hepatic failure:
In case of kidney and liver failure, your doctor may not treat you with this medicine depending on the severity of your illness; if he/she decides to administer, he/she will follow you carefully during application.

If you have the impression that the effect of PF 1/3 POLİDEKS is too strong or weak, talk with your doctor or pharmacist.

If you have taken more PF 1/3 POLİDEKS than you should have:
If you have used PF 1/3 POLİDEKS more than you should have or more than prescribed, consult a physician or a pharmacist.

If you forget to take PF 1/3 POLİDEKS:
Do not double-dose to make up for forgotten doses.

Possible effects once PF 1/3 POLİDEKS treatment is concluded
Not applicable.

4. Possible side effects
Like all medicines, PF 1/3 POLİDEKS may cause side effects in patients sensitive to its ingredients.

Side effects are listed as shown in the categories below.

Very common: It can be seen in at least 1 of 10 patients.

Common: Less than one in 10 patients, but more than one in 100 patients.

Uncommon: Less than one in 100 patients, but more than one in 1000 patients.

Rare: Less than one in 1,000 patients, but more than one in 10,000 patients.

Very rare: Less than one in 10,000 patients can be seen.

Unknown: It cannot be estimated from the available data.

If any of the following reactions happen, stop taking PF 1/3 POLİDEKS and tell your doctor immediately or contact the emergency department at your nearest hospital:

- Itchy redness / blisters, burning sensation at the application site;
- Respiratory distress, wheezing, chest pain;
- Feeling of extreme heat or cold in the body;
- Swelling in hands, feet, lips, face or whole body;
- Dizziness, fainting sensation;
- Heart palpitations.
- Hypernatremia (the sodium level in the blood rises above normal)
- Increase in blood glucose level
- High blood pressure
- Difficulty breathing
- The amount of phosphate in the blood goes below normal

These are all very serious side effects.

If you experience one of these side effects, it means that you are severely allergic to PF 1/3 POLİDEKS. You may need urgent medical attention or to be hospitalized.

In addition, if symptoms such as fever, shivering occur (febrile reaction) in your body while the application is going on, tell your doctor IMMEDIATELY; in which case the doctor may stop the treatment and give emergency medical attention.

These very serious side effects are all rare.

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

Very common:

- Cardiac failure (in patients with heart disease)
- Excessive fluid load in your body (with or without an increase in urine volume)
- Fluid accumulation in the lungs (pulmonary edema)
- Asymptomatic disturbances in the balance of substances in your blood called ions

Uncommon:

- Decrease in the blood level of ion called sodium (hyponatremia)

Unknown:

- (These side effects are related to the technique of administration and the incidence of which is unknown):
- Pain, redness, swelling around the application site
- Inflammation of the application site
- Irritation of the veins at the application site
- Vascular infiltration from the vein at the application site
- Increased circulating blood volume (hypervolemia)
- Inflammation that spreads through the veins starting from the application site
- Formation of clots blocking the veins from the application site
- Fever, weakness
- Inflammation at the injection site
- The drug leaking out of the vein
- Water retention and edema
- Nausea, vomiting, diarrhea;
- Stiffness in the muscles
- Headache, dizziness
- Restlessness
- Aggravation in congestive heart failure (respiratory failure due to heart failure, edema, enlarged liver disease and pronounced disease)
- Abdominal cramps
- Feeling thirsty
- A decrease in the amount of saliva
- Kidney failure
- Polyuria (excessive urination)
- Tachycardia (acceleration of the heart beat)
- Hypertension (high blood pressure)
- Respiratory arrest
- Decreased sweating
- Hyponatremia (low sodium level in the blood below normal)
- Acidosis (excessive accumulation of acid in the blood)
- Hyperglycaemia (increase in blood sugar levels)
- Fluid loss

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 PF 1/3 POLİDEKS

Store PF 1/3 POLİDEKS in original packaging and keep out of the reach and sight of children.

Store below 25°C.

It is disposable. Partially used bottles should not be stored; they must be disposed of in accordance with the medical waste procedure of the health facility where the application is made.

Each bottle 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 PF 1/3 POLİDEKS after the expiry date which is stated on the packaging..

Do not throw away drugs that have expired or are not used! Deliver to the collection system determined by the Ministry of Environment and Urbanism.

Marketing Authorization Holder:

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This patient leaflet was approved on ……..

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 apyrogen 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.

Serial connections with other infusion fluids should not be made to prevent an air embolism that may occur due to residual air in the bottle.

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 bottles to the administration systems.

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.

Attention! Do not store bottles mixed with additional medication.

Adding medication during administration
1. Close the clamp.
2. Disinfect the drug applicator.

3. The drug to be added is applied into the bottle with a 19-22 gauge needle with a syringe.
4. Remove the solution from IV pole and invert.
5. In this position, tap gently both ports to allow mixing of solution and medication.
6. Return bottle to its former position and open the clamp and continue administration.