SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:
Each 100 ml of solution contains:
Dextrose anhydrous 3.33 g
Sodium Chloride 0.3 g

Ionic concentrations of solution:
- Sodium: 51.3 mEq/L
- Chloride: 51.3 mEq/L

Excipient(s):
For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Sterile, apyrogen solution for intravenous infusion.
This is a colorless, clear, particle-free, odorless and sterile solution. Its pH is 3.2-6.5, total osmolarity 270.6 mOsm/L, electrolyte concentration of sodium is 51.3 mEq/L, electrolyte concentration of chloride 51.3 mEq/L.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

- Cases such as sweating, vomiting and gastric aspiration, where the loss of chloride is equal to or greater than the loss of sodium
- Patients who need fluid along with blood transfusion
- In the pre- and post-operative care, as the first hydration solution to initiate renal function by compensating extracellular fluid losses

4.2 Posology and method of administration

Posology/frequency and duration of administration
Dosage and infusion rate are directed by a physician depending on age, weight, clinical and biological condition (acid-base balance) of the patient and the concomitant treatment.

In general, 500 to 3000 mL per 24 hours for adults, adolescents and elderly and 20 to 100 mL/kg per 24 hours for infants and children is recommended unless otherwise prescribed by the doctor.

The frequency of administration is adjusted by the physician according to the clinical condition of the patient. Usually an infusion rate of 40 mL/kg/24 hours in adults and elderly, an average of 5 mL/kg/hour in pediatric cases is recommended (6-8 ml/kg in infants, 4-6 mL/kg in children aged 1-6 and 2 to 4 mL/kg/day for children older than 6 and adolescents).

To prevent the development of hyperglycemia, the rate of infusion should not exceed the patient's glucose oxidation capacity. The maximum infusion rate of dextrose should therefore be 500-800 mg/kg/hour.

Method of administration:
The administration is by intravenous route with sterile apyrogen sets.

Patients should be carefully monitored in terms of urine output and serum sodium and electrolyte concentrations during the administration of PF 1/3 POLİDEKS.

See also section 6.6 for details on the administration.

Additional information on special populations:

Renal/Hepatic failure:
There is no specific dosage recommendation for this group of patients, as there is no specific study for this population. It is recommended to be used with caution in these patients due to decreased kidney or liver function.

Pediatric population:
As in adults, dosage and infusion rate are directed by a physician depending on weight, clinical and biological condition of the patient and the concomitant treatment.

In children, the dose varies depending on the child's age, fluid and energy needs. The dose may vary between 100-1000 mL in infants and 200-2000 mL in infants. Multiple electrolyte solutions should be preferred in long-term maintenance treatments.

Serum glucose concentration monitarization is required in newborns and low birth weight infants.

In low birth weight infants, excessive or rapid dextrose infusion may increase serum osmolality, which may cause intracerebral hemorrhage.

In this population, a dose of 20-100 ml/kg/24 hours is generally recommended and this dose is adjusted according to body weight as follows:

- 0-10 kg : 100 mL/kg/day
- 10-20 kg : 1000 mL + 50 mL/day for every kg over 10 kg
- 20 kg : 1500 mL + 20 mL/day for every kg over 20 kg

Geriatric population:
As in adults, dosage and infusion rate are directed by a physician depending on weight, clinical and biological condition of the patient and the concomitant treatment.

No clinical trials have been conducted that show response differences between older and younger patients.

As the reduction in liver, kidney or cardiac functions is more common in the elderly and there is a higher probability of seeing other illnesses or using other medicines in general, care should be taken in dose selection in the elderly and should be done by taking the lowest possible limit of the dose range.

4.3. Contraindications
These solutions are contraindicated where the administration of sodium or chloride could be clinically detrimental:

- Extracellular hyperhidration or hypervolemia
- Fluid and sodium retention, general edema
- Severe renal insufficiency (oliguria or anuria)
- Uncompensated cardiac failure
- Hypernatremia
- Hyperchloraemia
- Cirrhosis (ascitic)
- Glucose intolerance such as metabolic stress situations
- Uncompensated diabetic coma
- Hyperosmolar coma
- Hyperlactatemia
- Cases with extremely high blood glucose (hyperglycaemia)

Solutions containing dextrose may be contraindicated in patients with hypersensitivity to corn products.

Kidney failure; It is contraindicated in patients with edema associated with heart, kidney or liver disease.

4.4 Special warnings and precautions for use
The administration of intravenous solutions can cause fluid and/or solute overload resulting in dilution of serum electrolyte concentrations, overhydration, congested states or pulmonary edema.

The risk of dilution is inversely proportional to the electrolyte concentration. The risk of congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentration. If necessary, these electrolytes (Ca^{++}, Mg^{++}, PO^{4-}, K^{+}) should be

given separately. Treatment can result in hypokalemia, hypophosphatemia, and hypomagnesaemia.

The solution contains 51.3 mmol/l (51.3 mEq/l) sodium (Na^+) and 51.3 mmol / l (51.3 mEq/l) chloride (Cl^-); the osmolarity is about 270.6 mOsm/L.

In patients with diminished renal function, administration of solutions containing sodium ions may result in sodium retention. Sodium-containing solutions should be administered with caution to patients receiving corticosteroids or corticotrophin, or to other salt-retaining patients.

Care should be exercised in administering solutions containing sodium to patients with renal or cardiovascular insufficiency, with or without congestive heart failure, particularly if they are postoperative or elderly.

Sodium containing solutions should be used with care in patients with hypervolemia, hypertension, pre-eclampsia, heart failure, peripheral or pulmonary edema, renal dysfunction, urinary tract obstruction, aldosteronism or disease states associated with sodium accumulation.

As pre-term or neonates do not have full renal function, excessive sodium cannot be excreted. Monitoring of serum sodium concentrations is therefore required when sodium chloride infusions are administered.

While infusion of solutions containing glucose is not contraindicated in the first 24 hours following head trauma, blood glucose concentration should be closely monitored during intracranial hypertension episodes.

Water given to efforts to quickly restore hypernatremia and hyperosmolarity to normal can lead to brain edema.

Infusion of solutions containing dextrose may lead to hyperglycaemia. Solutions containing dextrose are not recommended in cases of acute ischemic strokes as hyperglycaemia has been implicated in increasing cerebral ischemic brain damage and impairing recovery. To prevent the development of hyperglycemia, the rate of infusion should not exceed the patient's glucose oxidation capacity (see section 4.2). The infusion rate must be adjusted or insulin administered if hyperglycaemia occurs.

Glucose tolerance may be impaired in patients with diabetes or renal impairment. When administered to such patients, blood glucose levels should be monitored closely and insulin and/or potassium administration should be considered if necessary.

Dextrose containing solutions should be administered with caution to patients with known diabetes mellitus or with geriatric and post-operative patients with subclinical diabetes and carbohydrate intolerance for any reason.

Hypokalaemia may develop during parenteral administration of hypertonic dextrose solutions. Excessive administration of potassium-free dextrose solutions may result in significant hypokalemia. Serum potassium levels should be maintained and potassium supplemented as required.

Additional electrolyte may be needed in case of excessive loss of electrolytes such as excessive nasogastric irrigation, vomiting, diarrhea or drainage from the gastrointestinal fistula.

Solutions containing 0.20%, 0.30% or 0.33% sodium chloride together with dextrose should not be administered from the same infusion line as it can lead to clustering in erythrocytes.

Prolonged infusion can lead to increased extracellular fluid and water intoxication.

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 for cloudiness or precipitation immediately after mixing, prior to administration and periodically during administration.

If administration is controlled by a pumping device, care must be taken to discontinue pumping action before the container runs dry or air embolism may result.

Solution is intended for intravenous administration using sterile equipment. It is recommended that intravenous administration apparatus be replaced at least once every 24 hours.

Use only if solution is clear and container and seals are intact.

Laboratory tests:
Clinical evaluation and periodic laboratory determinations are necessary to monitor changes in fluid balance, electrolyte concentrations, and acid-base balance during prolonged parenteral therapy or whenever the condition of the patient warrants such evaluation. Significant deviations from normal concentrations may require tailoring of the electrolyte pattern, in these or alternative solutions.

Warnings and precautions for pediatric use:
Safety and efficacy of Dextrose and Sodium Chloride solution in pediatric patients have not been established by adequate and well-controlled studies.

Dextrose is safe and effective for the stated indications in pediatric patients (see Indications). As reported in the literature, the dosage selection and infusion rate of intravenous dextrose must be selected with caution in pediatric patients, particularly neonates and low birth weight infants, because of the increased risk of hyperglycemia/hypoglycemia. Frequent monitoring of serum glucose concentrations is required when dextrose is prescribed to pediatric patients, particularly neonates and low birth weight infants.

In neonates or in very small infants even small volumes of fluid may affect fluid and electrolyte balance. Care must be exercised in treatment of neonates, especially 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.

Warnings and precautions for use in elderly:
Clinical studies of Dextrose and Sodium Chloride solutions did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between elderly and younger patients.

In general, dose selection for an elderly patient should be cautious. Starting at the low end of the dosing range is recommended in elderly considering the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

These drugs are known to be substantially excreted by the kidney, and the risk of toxic reactions to these drugs may be greater in patients with impaired renal function.

Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function (See “Warnings”).

4.5 Interaction with other medicinal products and other forms of interaction
Sodium containing solutions can cause sodium and water retention (edema and hypertension) in patients receiving corticosteroids and carbenoxolone.

Solvents containing dextrose should not be co-administered with blood transfusions if they do not contain sufficient electrolyte, which may lead to hemolysis and erythrocyte agglomeration.

Attention should be paid to ensure that the drug added during a mandatory addition is stable at the pH of the solution and is compatible with the substances in the solution, and this decision must be made by the doctor.

Additional information on special populations
No interaction study has been performed.

Pediatric population

No interaction study has been performed.

4.6 Pregnancy and lactation

General recommendation
Pregnancy category: C

Women with childbearing potential/Contraception
There is no special recommendation regarding the use of POLYFLEX 1/3 POLİDEKS in women with childbearing potential, pregnancy and birth control.

Studies on animals are insufficient in terms of effects on pregnancy / and-or / embryonal / fetal development / and-or / birth / and-or / postpartum development (see Section 5.3). The potential risk for humans is unknown.

PF 1/3 POLIDEKS should not be used during pregnancy unless it is necessary for conditions of vital importance.

Pregnancy
Animal reproduction studies have not been performed with sodium chloride solutions of dextrose.

It is also not known whether PF 1/3 POLİDEKS can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. PF 1/3 POLİDEKS should be given to a pregnant woman only if clearly needed.

Delivery:
The effects of PF 1/3 POLİDEKS on the duration of labor or delivery, on the possibility that forceps delivery or other intervention or resuscitation of the newborn will be necessary, and on the later growth, development, and functional maturation of the child are unknown.

Administration of sodium and dextrose containing solutions during labor and delivery have been reported in the literature. Caution should be exercised, and the fluid balance, glucose and electrolyte concentrations, and acid-base balance, of both mother and fetus should be evaluated periodically or whenever warranted by the condition of the patient or fetus.

Lactation
It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when PF 1/3 POLİDEKS are administered to a nursing woman.

Fertility
It has no effect on reproduction capacity/fertility.

4.7 Effects on ability to drive and use machines
Driving is not practically possible during infusion of solutions. There is no known effect on driving and the use of machine after it has been used.

4.8 Undesirable effects
Undesirable effects may result from an excess or deficit of one or more of the ions or dextrose present in the solution; therefore, frequent monitoring of sodium and chloride levels is required.

The physician should also be alert to the possibility of adverse reactions to drug additives diluted and administered. In such case, prescribing information for drug additives to be administered should be consulted.

The reported undesirable effects associated with the use of PF 1/3 POLİDEKS are given below. The frequency of occurrence of adverse events is classified according to the following criteria:

Very common (≥ 1/10); Common (≥ 1/100 to < 1/10); Uncommon (≥ 1/1.000 to < 1/100); Rare (≥ 1/10.000 to < 1/1.000); Very rare (< 1/10.000); Not known (cannot be estimated from the available data)

Metabolism and nutritional diseases
Not known: water retention and edema; Aggravation in congestive heart failure (due to hypernatremia); Acidosis (due to hyperchloremia); Fluid and electrolyte imbalances *; Hyperglycaemia and dehydration **

Nervous system disorders
Not known: headache, dizziness, restlessness, irritation, convulsions, coma and death (due to hypernatremia).

Cardiac disorders:
Very common: Cardiac failure (in patients with heart disease)
Not known: tachycardia (due to hypernatremia)

Vascular disorders:
Very common: Hyperhydration (with or without polyurea)
Not known: hypertension (due to hypernatremia)

Respiratory, thoracic and mediastinal disorders:
Very common: Pulmonary edema
Not known: respiratory depression and respiratory arrest (due to hypernatremia)

Gastrointestinal diseases

Not known: nausea, vomiting, diarrhea, abdominal cramps, feeling of thirst, decreased saliva (due to hypernatremia)

Skin and subcutaneous tissue disorders
Not known: decreased sweating (due to hypernatremia)

Musculoskeletal and Connective Tissue Disorders
Not known: Twitching and stiffness in muscles (due to hypernatremia)

Kidney and urinary diseases
Not known: renal failure (due to hypernatremia); polyuria

General disorders and diseases related to the application site
Not known: fever, malaise (due to hypernatremia)

Investigations
Very common: Asymptomatic electrolyte imbalance
Uncommon: Hyponatremia

Surgical and medical procedures***
Not known: Febrile reactions; Infection at the site of injection; Local pain or reaction; Ven irritation; The development of venous thrombosis and phlebitis, starting from the injection site; Intravenous infiltration; hypervolemia

* Hypokalaemia, hypomagnesemia and hypophosphatemia etc.

** Adverse effects usually seen as a result of incorrect parenteral administration.

*** Adverse effects that can be seen depending on the application technique

The physician should be alert to the possibility of adverse reactions to drug additives diluted and administered. In such case, prescribing information for drug additives to be administered should be consulted.

If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate therapeutic countermeasures, and save the remainder of the fluid for examination if deemed necessary.

4.9 Overdose and therapy
If fluid or solute loading due to excessive infusion is observed during parenteral treatment, the patient should be re-evaluated and appropriate corrective treatments should be initiated.

In cases where renal sodium excretion is impaired, excessive ruse or rapid infusion may result in water and sodium overload, which can lead to peripheral edema and pulmonary edema. Dialysis may be required in such cases.

Hypernatremia may rarely develop at therapeutic doses. The most important effects of hypernatremia are somnolence, confusion, convulsion, coma, respiratory failure and brain dehydration, which can result in death. Other symptoms include thirst, decreased saliva and tear, fever, tachycardia, hypertension, headache, dizziness, fatigue, irritability and weakness.

Overload of chloride salts can cause a loss of bicarbonate with an acidifying effect.

Rapid or long-term administration of solutions containing dextrose may result in hyperosmolarity, dehydration, hyperglycaemia, hyperglucosuria and osmotic diuresis due to hyperglycemia.

In cases of accidental excessive infusion, treatment should be terminated and the patient should be monitored to observe signs and symptoms of the administered drug. Where necessary, supportive treatment should be given against the relevant signs and symptoms.

5. PHARMACOLOGICAL PROPERTIES

Pharmacodynamic and pharmacokinetic properties of PF 1/3 POLİDEKS are dependent upon its dextrose, sodium and chloride content.

Each ml of solution contains 33.3 g dextrose, 51.3 mEq sodium and 51.3 mEq chloride.

Solution pH is within the range of 3.5 - 6.5.

5.1 Pharmacodynamic properties

Pharmacotherapeutic Group: Solutions affecting electrolyte balance / Electrolyte solutions with carbohydrates

ATC Code: B05BB02

Ions, such as sodium, circulate through the cell membrane, using various mechanisms of transport, among which is the sodium pump (Na+/K+-ATPase) Sodium plays an important role in neurotransmission, cardiac electrophysiology, and also in renal metabolism.

Chloride is mainly an extracellular anion. Intracellular chloride is in high concentration in red blood cells and gastric mucosa. Reabsorption of chloride follows reabsorption of sodium.

Dextrose is the principal source of energy in cellular metabolism. These solutions are capable of inducing diuresis depending on the clinical condition of the patient. Dextrose is fully metabolized and may decrease losses of body protein and nitrogen, promotes glycogen deposition. It decreases or prevents ketosis if sufficient doses are provided.

Carbohydrate in sodium chloride solutions have been developed to meet a portion of the caloric need with fluid and electrolyte deficiencies in the body. These solutions have beneficial results in cases where chlorine loss is equal to or greater than sodium due to conditions such as sweating, vomiting and gastric aspiration.

In addition, pseudoagglutination occurs in erythrocytes during the transfusion of blood, on the one hand, and dextrose solutions, on the other hand, by means of a Y-shaped intravenous infusion device. They may lead to transfusion reactions, even if they do not result in hemolysis. To resolve this incompatibility between blood and aqueous dextrose solutions, it is necessary to add some electrolyte to solutions containing dextrose. Dextrose solutions containing 0.3% sodium chloride can be given concomitantly with the blood.

In pre- and post-operative period, renal functions need to be initiated before potassium solutions are given to patients. Dextrose solutions with 0.2% or 0.3% sodium chloride are the most valuable as the first hydration solution that can initiate renal function in response to extracellular fluid losses.

Fluid therapy for surgical patients:

Before surgery, the most important fluid-electrolyte metabolism complication seen in patients is dehydration due to extracellular fluid loss. This is caused by vomiting, diarrhea, gastrointestinal drainage, stuffing of fluid into blocked intestinal compartments, or leakage of fluids out of the veins in traumatized tissues. In addition, in the case of nausea and loss of appetite, fluid intake is generally decreased. The catabolic reactions and the inability to feed caused by the disease can often lead to loss of fluid and potassium from the tissues. This is exacerbated by hunger catabolism and ketosis. Severe intracellular dehydration may reduce so much fluid volume in the bloodstream that hypovolemic shock may develop in patients without significant bleeding or loss of plasma.

Such patients need to be prepared for surgery with an effective parenteral treatment. In order to initiate renal function, a dextrose hydration solution containing sodium chloride at 0.3% (0.2% in patients with severe intracellular loss) is first administered within 45 minutes. If the patient does not have enough urine or if the amount of urine taken by the catheter is not enough, the application rate of the solution is lowered by four and the application is continued after one hour. If there is not enough urine at the end of this period, the kidney function of the patient is further deteriorated; the clinical condition should be reviewed again.

After the patient begins to urinate, fluid and electrolyte losses are calculated based on body weight, serum electrolyte levels and anamnesis. Multiple electrolyte solutions are used to meet extracellular losses. In severe acidosis, sodium lactate, bicarbonate or acetate should be given. In order to meet the intracellular potassium deficiency, this fluid should also contain potassium chloride, acetate or phosphate.

After replacing the fluid and electrolyte losses in the patients, the daily fluid and electrolyte requirements are met by resolved electrolyte solutions. In patients with further impairment of nutrition, hypertonic dextrose solutions provide the necessary energy, amino acids and amino acids necessary for protein synthesis and electrolytes.

Hypovolemia (loss of colloid) due to blood loss, solutions with dextran or starch, albumin or whole blood should be used.

The need for parenteral fluid in the postoperative period varies according to the patient's fluid-electrolyte balance prior to the operation and the surgical procedure. If the patient is well prepared, all previous losses have been replaced. Postoperative fluid therapy is intended to replace daily fluid losses and those caused by gastrointestinal drainage etc. There is always some water and salt retention in the post-operative period. There is also some fluid release due to the catabolism of fat and tissues.

For this reason, immediately after the operation, the volume of fluid delivered should be low until the stress reaction is over. In general, post-operative fluid therapy can be summarized as follows:

1. Uncomplicated recovery period: An average of 1.5 liters of maintenance electrolyte solution in patients with body fluids balanced, well fed, renal function normal, elective indications and moderate surgical trauma and meets the first postoperative day needs. Oral feeding is the next step.

   Patients who have the same characteristics as the above patients, but who undergo post-operative drainage or aspiration, require long-term replacement and maintenance therapy. The parenteral fluid treatment program in these patients should be as follows: Maintenance fluid therapy for the first post-operative day is the same as above (item a). This fluid should also be supplemented with fluid and specific electrolytes that are lost by drainage and aspiration. (If the patient receives adequate fluid, postoperative water and electrolyte retention can lead to oliguria. To avoid fluid overload to the patient, the fluid balance should be checked by daily weighing).

2. Complicated healing period where normal homeostatic mechanisms are extremely impaired: For patients who have undergone urgent major surgery and whose cardiovascular function is normal before surgery, 1.5 liters of dextrose solution in 0.2% sodium chloride is applied on the first day so that the patient is not loaded with excess fluid due to post-operative water and sodium retention. In addition, pre- and post-operative fluid losses from the gastrointestinal tract are met with appropriate solutions. Once the amount of urine of the patient has reached adequate levels, maintenance solutions are used for maintenance fluid therapy.

If the patient cannot take oral fluid on the second post-operative day, parenteral fluid and electrolyte treatment is continued. The 1.3 liter of maintenance electrolyte solution per square meter of body surface is often enough to meet the fluid - electrolyte deficit.

In order to prevent protein catabolism, some calories may be obtained from hypertonic dextrose solutions. Amino acids required for tissue repair are provided with solutes containing amino acid combinations.

In patients who have undergone major surgery urgently and whose cardiovascular function is impaired prior to surgery, each patient should be monitored individually and supervised by a specialist physician in order to prevent unnecessary metabolic complications.

5.2 Pharmacokinetic properties

General properties:
Pharmacokinetic properties of PF 1/3 POLİDEKS are those of its components (glucose, sodium and chloride).

Absorption:
Active substances in drugs administered intravenously reach their maximum plasma concentrations immediately after administration.

Distribution:
Dextrose can be administered at doses up to 0.5 g/kg hour without causing glucosuria. At the highest infusion rate of 0.8 g/kg/h, approximately 95% of dextrose administered remains in the body.

Sodium distribution varies according to tissues: it is fast in muscles, liver, kidney, cartilage and skin; it is slow in erythrocytes and neurons; it is very slow in the bone.

Chloride is mainly distributed in extracellular fluids.

Biotransformation
Dextrose provides energy by fully metabolizing in the body by pyruvic acid or lactic acid, and is largely transformed into water with carbon dioxide.

The half-life after radioactively labeled sodium ($_{24}Na$) injection is 11-13 days for 99% of injected sodium and one year for the remaining 1%.

Chloride closely monitors sodium metabolism and changes in the acid-base balance of the body are reflected by changes in chloride concentration.

Elimination:

Carbondioxide resulted from dextrose biotransformation is excreted in the lungs, and the water formed is mainly excreted through the kidneys and in small amounts in the sweat, feces and tidal air.

Sodium is excreted primarily by the renal route, but at the same time the vast majority is reabsorbed by the renal route. A small amount of sodium is excreted with feces and sweat.
Since chloride metabolically monitors sodium, it is mainly excreted by the renal route but also in lesser amounts in feces and sweat.

Linearity/Non-linearity:
Electrolytes and dextrose in the PF 1/3 POLİDEKS composition show a linear pharmacokinetic behavior when administered to the body at therapeutic doses to complete their deficiency.

5.3 Preclinical safety data
Because the components of the solution are physiological components of human and animal plasma and are not expected to show toxic effects in clinical practice, studies with PF 1/3 POLİDEKS have not been performed to evaluate the effects of carcinogenic, mutagenic potential and fertility.
The safety of medications added into the solution must be considered separately.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients
Water for injection

6.2 Incompatibilities
Incompatibility of the medicinal product to be added with the solution must be assessed before addition. In the absence of compatibility studies, this solution must not be mixed with other medicinal products.

Solution pH is within the range of 3.5 - 6.5. Before adding a drug, verify it is soluble and stable in water at the pH of PF 1/3 POLİDEKS which is 3.5 to 6.5.

Some of the following medications are incompatible with PF 1/3 POLİDEKS:

- Ampicillin sodium
- Mitomycin
- Amphotericin B
- Erythromycin lactobionate

Those additives known to be incompatible should not be used.

6.3 Shelf Life

24 months

6.4 Special precautions for storage
No special precautions for storage. Store at room temperature below 25°C, protect from direct light.

6.5 Nature and contents of container
In 500 and 1000 ml glass bottles.
Product has in two forms: with and without set.

6.6 Special precautions for disposal and other handling
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.

Directions for use
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.

In order to prevent an air embolization that may occur due to the residual air in the bottle, 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 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. For high density medication such as potassium chloride, tap gently to the ports of the bottle, while ports are upright to allow mixing.

Attention! Do not store bottles 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 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.

7. MARKETING AUTHORISATION HOLDER

POLİFARMA İLAÇ SAN. VE TİC. A.Ş.
Address: Vakıflar OSB Mahallesi, Sanayi Caddesi, No: 22/1
Ergene/TEKİRDAĞ
Tel: 0 282 675 14 04
Fax: 0 282 675 14 05

8. MARKETING AUTHORISATION NUMBER
208/71

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Date of first authorization: 14.08.2006
Date of renewal of the authorization: 20.06.2013

10. DATE OF REVISION OF THE TEXT
06.04.2017