SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

POLİFLEKS 5% DEXTROSE, 0.45% SODIUM CHLORIDE, 0.3% POTASSIUM CHLORIDE SOLUTION FOR I.V. INFUSION

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredients

Each 100 ml solution contains:
Dextrose monohydrate 5 g
Sodium chloride 0.45 g
Potassium chloride 0.30 g

Ionic concentrations of the solution:

	mEq/L	mmol/L
• Sodium	77	77
• Potassium	40	40
• Chloride	117	117

Excipients:

See section 6.1 for excipients

3. PHARMACEUTICAL FORM

Sterile apyrogen solution for intravenous infusion
Clear and non-particle solution

4. CLINICAL PARTICULARS

4.1 Therapeutical indications

Indicated in order to provide sodium, chloride and potassium which are essential electrolytes, a small amount of calories and the following situations:

• Treatment of hyponatremia (serum sodium content of <135 mEq / L) (occurs in excessive sweating, excessive water intake, the excess of application of the liquid electrolyte, gastrointestinal aspiration and adrenal insufficiency commonly.)
• Treatment of hypochloremia (serum chloride amount <100 mEq / L) (occurs in diarrhea, excessive sweating or endocrine disorders commonly.)

Treatment of hypokalemia (serum potassium levels <3,5 mEq / L) (occurs in the long-term use of potassium-free intravenous fluids, severe vomiting, diarrhea, fistula drainage, chronic debilitating disease, the long-term cortisone treatment, diuretic therapy, diabetes acidosis, primary hyperaldosteronism and metabolic acidosis commonly. Severe cases of vomiting, chloride lost more than sodium, and the table could result hypochloremic alkalosis).

4.2 Posology and method of administration

Posology/ Frequency and period of administration

In adults, geriatric and pediatric population

The dosage to be administered must be decided individually for each patient by the doctor based on the age, body weight, and biological conditions and the concomitant treatments given.

General posology

Recommended dose for treatment of sodium, carbonhydrate and fluid loss:

- Adults: 500 mL- 3 liters per 24 hours
- Babies and children:
  - 0-10 kg: 100 mL/kg/24 hours
  - 10-20 kg: 1000 mL/kg/24 hours + (50 ml for each kg over 10 kg)
  - More than 20 kg: 1500 mL/kg/24 hours + (20 ml for each kg over 20 kg)

With the purpose of preventing the development of hyperglycemia, the infusion rate must not exceed the glucose oxidation capacity of the patient. Therefore, the maximum glucose administration rate must be 5 mg/kg for adults, 10-18 mg/kg for babies and children.

Posology in prevent and treatment to lack of potassium

Typical doses of potassium for the prevention of hypokalemia may be up to 50 mmol daily and similar doses may be adequate in mild potassium deficiency (POLİFLEKS 5% DEXTROSE, 0.45% SODIUM CHLORIDE, 0.3% POTASSIUM CHLORIDE SOLUTION FOR I.V. INFUSION contains 40 mmol potassium).

The maximum recommended dose of potassium is 2 to 3 mmol/kg/24h.

Patients with renal impairment should receive lower doses.

Maximum rate of administration shouldn't exceed 15-20 mmol / h. In any case, the dosage given under "General Posology" should not be exceeded.

Route of administration:

Administration will be made intravenously using sterile apyrogen sets.

Intravenous potassium should be administered in a large peripheral or central vein to diminish the risk of causing sclerosis. If infused through central vein, be sure the catheter is not in the atrium or ventricle to avoid localized hyperkalemia. Solutions containing potassium should be administered slowly. (It is recommended to administer at a speed of less than 15-20 mmol / h)

Monitoring

Adequate urine flow must be ensured and careful monitoring of plasma-potassium and other electrolyte concentrations is essential. High dosage or high speed infusion must be performed under ECG control.

See Section 6.6 for detailed informations about administration.

Special populations:
Renal/ hepatic impairment:
Since there are no studies performed specifically on this population, there are no special dosages recommended for this patient group. Patients with renal impairment should receive lower doses.

Pediatric population:
The dosage to be administered and the infusion rate will be adjusted according to the weight and clinical and biological status of the infant and also according to the treatment to be administered concomitantly.

Geriatric population:
Like in the adults, the dosage to be administered and the infusion rate will be adjusted according to the weight and clinical and biological status of the patient and also according to the treatment to be administered concomitantly.

4.3 Contraindications
- Hyperchloremia and hyperkalemia that are not related to the concentration effect associated to a volume depletion
- Severe renal insufficiency (with oliguria/anuria)
- Uncompensated heart failure
- Addison's disease
- Head trauma (first 24 hours)
- Uncompensated diabetes
- Other known glucose intolerances (such as metabolic stress situations)
- Hyperosmolar coma
- Hyperglycemia
- Hyperlactatemia

Contraindicated in patients with known corn allergies.

4.4 Special warnings and precautions for use
High volume infusion must be used under specific monitoring in patients with cardiac, pulmonary or renal failure.

Potassium loss from the body usually occurs accompanied necessarily result in loss of chloride in hypochloremic metabolic alkalosis. In such cases, treatment of the underlying causes and intravenous administration of potassium chloride requires.

The patient's fluid, electrolyte and acid-base balance should be evaluated with long-term parenteral fluid treatments, when necessary, by clinical and laboratory evaluations, and additional electrolytes or dextrose solutions without electrolyte should be added to the

treatment when necessary. It may be necessary to support the treatment with additional electrolytes, especially in cases of prolonged nasogastric aspiration, vomiting, diarrhea or gastrointestinal fistula drainage. Close monitoring is required especially for plasma potassium levels in patients at risk of hyperkalaemia.

Administration of intravenous solutions may result in fluid and / or solute loading at dilution of serum electrolyte, overhydration, congestive conditions, or pulmonary edema. Dilution risk is inversely proportional to electrolyte concentration. The risk of developing congestive conditions that can lead to peripheral and pulmonary edema is directly proportional to the electrolyte concentration in the solution.

Ionic concentrations of the solution mEq/L(mmol/L):

- Sodium 77 (77)
- Chloride117(117)
- Potassium 40 (40)

Solutions containing sodium chloride should be used with caution in cases of hypertension, heart failure, peripheral or pulmonary edema, or other conditions and treatments (patients receiving corticosteroids or corticotropin therapy) with preeclampsia, aldosteronism or sodium deposition.

In patients receiving more potassium supplements than maintenance doses, frequent measurement of serum potassium levels and serial electrocardiography follow-up are recommended.

Solutions containing potassium should be used with caution in heart patients. Especially in patients receiving digital therapy, close physician supervision, frequent electrocardiographic inspections, and serum potassium determinations should be guiding in parenteral potassium treatments.

Solutions containing potassium should also be used with caution in situations that tend to hyperkalemia, such as acute dehydration and excessive tissue destruction in severe burns.

Kidney diseases or adrenal insufficiency can cause potassium intoxication. Therefore, solutions containing potassium salts should be used with caution in kidney or adrenal insufficiency. In order not to develop potassium intoxication, the infusion rate of the solution should not be high.

Rapid or excessive dextrose administration in newborns with low birth weight can lead to an increase in serum osmolarity and bleeding in the brain.

When serum sodium and calcium levels decrease, moderate elevation of serum potassium may have toxic effects on the heart and skeletal muscle. Respiratory stress and dysphagia can be seen as late symptoms following weakness and late paralysis in voluntary muscles. High plasma potassium levels can cause cardiac depression, arrhythmia, and cardiac arrest, which can result in death. Therefore, patients should be monitored by continuous or serial ECG monitoring, if possible, during administration of solutions containing potassium.

Infusion of glucose-containing solutions can cause hyperglycemia. It is recommended not to use glucose-containing solutions in acute ischemic stroke situations, as hyperglycemia will increase ischemic brain damage and delay recovery. Caution should be exercised when using this solution in diabetics.

Potassium salts should never be administered by bolus injection.

Solutions containing dextrose can be contraindicated for the first 24 hours following head trauma and close monitoring of glucose concentration in the blood during periods of intracranial hypertension.

In order to minimize the risk of incompatibility with any other medication to be added to the solution, it should be checked whether there is any turbidity or precipitation in the final mixture to be infused periodically, prior to and during application, after mixing.

In case the administration will be made through a controlled infusion pump, it must be checked is the operation of the pump has been stopped before the complete emptying of the bag; otherwise, air embolism can result.

The solution is administered intravenously through sterile sets. It is recommended that sets used for intravenous administrations will be replaced every 24 hours.

4.5 Interactions with other medical products and other modes of interaction

Interaction related to the presence of sodium:

Solutions containing sodium can cause sodium and water retention (edema and hypertension) in patients taking corticosteroids or carbenoxolone.

Interaction related to the presence of potassium:

- Potassium-sparing diuretics (amiloride, spironolactone, triam terene, alone or in combination).
- Angiotensin converting enzyme inhibitors and possibly angiotensin II receptor antagonists.
- Tacrolimus, cyclosporine (they increase the concentration of potassium in plasma and can potentially cause fatal hyperkalaemia in cases of renal failure where hyperkalaemic effects will increase).
- Other drugs that increase blood potassium level (other drugs from the digitalis group and drugs such as penicillin containing potassium salts)

Solutions containing dextrose should not be administered with blood transfusion, they may cause hemolysis and erythrocyte agglomeration.

Special populations:
No interaction studies have been performed.

Paediatric population:
No interaction studies have been performed.

4.6 Pregnancy and lactation

General recommendations
Pregnancy category: C.

Women of childbearing potential /Contraception
Adequate data related to the use of dextrose solutions containing sodium chloride and potassium chloride in pregnant women are not available.

Studies carried out on animals are inadequate as regards the effects on pregnancy and/or embryonic /fetal development and/or natal/ postnatal development (see: Section 5.3). Potential risks on humans are not known.

Pregnancy
Hypokalemic and hypokalemic serum levels lead to impaired cardiac function of the maternal and fetal hearts. Therefore, maternal electrolyte levels must be controlled regularly.

It has been suggested that if used during labour, the glucose load on the mother may lead to fetal hyperglycemia, hyperinsulinaemia, and acidosis, with subsequent neonatal hypoglycemia and jaundice. Others have found no evidence of such an effect.

POLİFLEKS 5% DEXTROSE, 0.45% SODIUM CHLORIDE, 0.3% POTASSIUM CHLORIDE SOLUTION FOR I.V. INFUSION is not considered a potential risk if serum electrolyte is held at the physiological level during pregnancy. Whether or not POLİFLEKS 5% DEXTROSE, 0.45% SODIUM CHLORIDE, 0.3% POTASSIUM CHLORIDE SOLUTION FOR I.V. INFUSION causes fetal damage if used in pregnant women, or if it causes impairment on ability of fertility are not known. POLİFLEKS 5% DEXTROSE, 0.45% SODIUM CHLORIDE, 0.3% POTASSIUM CHLORIDE SOLUTION FOR I.V. INFUSION must be used in pregnant women only when it is absolutely necessary.

Lactation
It is not known whether or not this drug is excreted to human milk. POLİFLEKS 5% DEXTROSE, 0.45% SODIUM CHLORIDE, 0.3% POTASSIUM CHLORIDE SOLUTION FOR I.V. INFUSION is not considered a potential risk if serum electrolyte is held at the physiological level during lactation. Since it is known that many drugs are excreted to human milk, POLİFLEKS 5% DEXTROSE, 0.45% SODIUM CHLORIDE, 0.3% POTASSIUM

CHLORIDE SOLUTION FOR I.V. INFUSION must be used carefully in breastfeeding mothers.

When a medicinal product is added, the nature of the drug and its use during pregnancy and lactation have to be considered separately.

Fertility
There are no known effects.

4.7 Effects on driving and using machines
Driving is practically impossible during the use of solutions administered through infusion. It has no known effects on driving or use of machines.

4.8 Undesirable effects
Adverse effects can be related to the deficiency or abundance of the ions and dextrose in the solutions; therefore, sodium, potassium and chloride levels must be monitored closely. Also, one should be cautious that additional drugs administered after diluting can cause adverse effects. In this case, the product characteristics of the additional drug must be referred to.

Infusion must be stopped upon any adverse effects seen during the administration, status of the patient must be evaluated and proper treatment measures must be taken.

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), and unknown (available data do not allow deciding)

Metabolism and nutrition disorders
Unknown: Water retention and edema; deterioration of congestive cardiac failure (related to hypernatremia); acidosis (related to hyperchloremia), fluid and electrolyte imbalance; dehydration and hyperglycemia (due to the long-term use of solutions containing dextrose)

Nervous system disorders
Unknown: Headache, vertigo, uneasiness, irritability, convulsions, coma and death (related to hypernatremia), areflexia, mental confusions (related to hyperkalemia)

Cardiac disorders
Unknown: Tachycardia (related to hypernatremia), aggravation congestive heart failure due to water retention, edema (related to hypernatremia); cardiac arrhythmias, heart block, ECG abnormalities and cardiac arrest (related to hyperkalemia)

Vascular disorders
Unknown: Hypertension (related to hypernatremia), hypotension (related to hyperkalemia).

Respiratory, thoracic and mediastinal disorders

Unknown: Pulmonary edema, respiratory depression and respiratory arrest (related to hypernatremia).

Gastrointestinal disorders
Unknown: Nausea, vomiting, diarrhea, abdominal cramps, thirst, and reducing the saliva amount (related to hypernatremia).

Skin and subcutaneous tissue disorders
Unknown: Reducing of sweating (related to hypernatremia).

Musculoskeletal and connective tissue disorders
Unknown: Fasciculation and hardening of muscles (related to hypernatremia), paresthaesia in the extremities, muscular weakness, flaccid paralysis, paralysis, weakness and feeling of heaviness in the legs (related to hyperkalemia)

Renal and urinary disorders
Unknown**:** Renal failure (related to hypernatremia), hyperglycosuria and osmotic diuresis (due to hyperglycemia)

General disorders and administration site conditions
Unknown: Fever; fatigue (related to hypernatremia)

Surgical and medical procedures*
Unknown: Febrile reactions; infection in the injection site; local pain or irritation; venous irritation; venous thrombosis or phlebitis starting the injection site and spreading; extravasation and hypervolemia

* Adverse effects that can be seen as a result of application technique

4.9 Overdose and treatment
Overdose or rapid administration may lead to water and sodium loading, especially in cases where sodium excretion is impaired, causing risk of edema. In this case, renal dialysis treatment may be needed.

Excessive administration of potassium may lead to the development of hyperkalemia, especially in patients with renal impairment. Symptoms include paresthesia of the extremities, muscle weakness, paralysis, cardiac arrhythmias, heart block, cardiac arrest, and mental confusion.

One of the important indicators of potassium toxicity are ECG changes including tall, peaked T-waves, depression of S-T segment, disappearance of the P-wave, prolongation of the Q-T interval, and widening and slurring of the QRS complex.

Treatment of hyperkalaemia involves the administration of calcium, insulin or sodium bicarbonate, and exchange resins or dialysis.

Administration of chloride-containing salts at over doses may lead to bicarbonate loss that causes acidizing effects.

Administration of dextrose-containing solutions for longer periods or fast administration may cause hyperglycemia and associated hyperosmolarity, dehydration, hyperglucosary and osmotic diuresis.

If an overdose is due to the drugs added to the solution, the signs and symptoms of an overdose depend on the properties of this added drug.

If during the treatment the dose is exceeded mistakenly, the administration must be stopped and the patient must be monitored for the signs and symptoms associated with the drug. If necessary, symptomatic and support treatments must be applied for such symptoms.

5. PHARMACOLOGICAL PARTICULARS

5.1 Pharmacodynamic properties

Pharmacotherapeutical group: Solutions affecting the electrolyte balance / Electrolyte solutions containing carbohydrates

ATC code: B05BB02

Pharmacokinetic properties of POLİFLEKS 5% DEXTROSE, 0.45% SODIUM CHLORIDE, 0.3% POTASSIUM CHLORIDE SOLUTION FOR I.V. INFUSION consist of the properties of its components (dextrose, sodium, potassium and chloride).

POLİFLEKS 5% DEXTROSE, 0.45% SODIUM CHLORIDE, 0.3% POTASSIUM CHLORIDE SOLUTION FOR I.V. INFUSION contains 5% dextrose, 0,45% sodium chloride and 0,3% potassium chloride. Potassium amount is about 10 times (40 meq/l) compaired with plasma. Also 77 mEq/L sodium and 117 mEq/L chloride.

Glucose is the main energy source in the cellular metabolism. Such solutions can stimulate diuresis depending on the clinical conditions of the patients. Glucose is fully metabolized and decreases the protein and nitrogen losses in the body, and increases glycogen storage. It decreases or prevents ketosis when administered in adequate dosages. POLİFLEKS 5% DEXTROSE, 0.45% SODIUM CHLORIDE, 0.3% POTASSIUM CHLORIDE SOLUTION FOR I.V. INFUSION provides a caloric intake of 170 kcal/L.

The electrolytes in POLİFLEKS 5% DEXTROSE, 0.45% SODIUM CHLORIDE, 0.3% POTASSIUM CHLORIDE SOLUTION FOR I.V. INFUSION composition, on the other hand, provide a suitable treatment for patients who need sodium, chloride and potassium.

In cases of excessive sweating, excessive water intake, liquid electrolyte of application of the excessive gastrointestinal aspiration and adrenal insufficiency; hyponatremia (serum sodium content in the milliequivalents than 135 liters is down) will appear.

Diarrhea, excess sweating or in endocrine disorders, hypocalcemia with excessive sodium loss (an indication of the amount of chloride in the serum under 100 milliequivalent per liter) is observed.

The loss of more chloride than sodium in vomiting and would result in hypochloremic alkalosis.

Sodium is the main cation of extracellular fluid. The normal sodium level in serum is 135-145 mEq / L. Sodium levels, which are the basic regulators of body fluids, are kept at a very constant level with many mechanisms, for example, when serum sodium levels increase, antidiuretic hormone secretion decreases and sodium excretion from kidneys; When sodium levels decrease, antidiuretic hormone secretion increases and serum levels of sodium are tried to be maintained. Ions like sodium pass through the cellular membrane using various transport mechanisms include sodium pump (Na-K-ATPase). Sodium plays an important role in neurotransmission, cardiac electrophysiology and renal metabolism. Sodium shows its effect primarily by the distribution of water in the body, fluid balance and control of the osmotic pressure of body fluids. Sodium is also associated with the regulation of the acid-base balance of body fluids, along with chloride and bicarbonate.

Chloride, the main anion of extracellular fluid with normal levels of 100-106 mEq / L in serum, closely monitors sodium metabolism, and changes in the acid-base balance of the body are reflected by changes in chloride concentration. Chloride is found in low amounts in bone tissue and high amounts in some components of connective tissue, for example collagen tissue. It is regulated with kidneys in the balance of anions and cations. Chloride reabsorption usually follows sodium reabsorption.

Potassium is the main cation of intracellular fluid, it is necessary for the maintenance of the acid-base balance of the cell, isotonicity and electrodynamic properties. Potassium is an important reactor for many enzymatic reactions; Conduction of nerve impulses is vital for many physiological processes, such as contractility of the heart and skeletal muscles, gastric secretions, renal functions, tissue synthesis, and carbohydrate metabolism.

A normal concentration of potassium in plasma is about 3.5 to 5.0 mmol per liter. Potassium is predominantly an intracellular action. When potassium levels increase, kidneys quickly remove this ion from the body. Potassium deficiency is manifested by impaired neuromuscular function, intestinal dilatation and ileus.

Under normal conditions, the intracellular metabolic activity, kidneys and homeostatic mechanism provides high potassium extracellular and low intracellular levels remain. Potassium infiltrates the outer part of cells in disease states are thrown out by the kidneys. In

the long-term use of potassium-free intravenous fluids, severe vomiting, the diarrhea, the fistula drainage, chronic debilitating disease, the long-term cortisone treatment, the diuretic therapy, diabetes acidosis, primary hyperaldosteronism and metabolic acidosis hypokalemia (in the amount of potassium in plasma liter 3.5 milliequivalents than being down) it can be seen.

In clinical cases, potassium deficiency is more common than excess potassium. Should be initiated intracellular potassium in preventive or therapeutic treatment where no likelihood of potassium loss. To resolve this deficiency is located in solutions containing potassium in parenteral fluid nowadays therapy. Milliequivalents of potassium per day for adults 40-50 is sufficient. In case of lack of potassium, 70-80 milliequivalents potassium (or more) per day must be given.

5.2 Pharmacokinetic properties

General properties

Pharmacokinetic properties of POLİFLEKS 5% DEXTROSE, 0.45% SODIUM CHLORIDE, 0.3% POTASSIUM CHLORIDE SOLUTION FOR I.V. INFUSION consist of the properties of its components.

Absorption:

The active ingredients in the drugs administered through the intravenous route reach the maximum plasma concentrations immediately after the administration.

Distribution:

Glucose passes rapidly into cells associated with insulin on organisms.

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

Chloride is distributed mainly in the extracellular fluids.

Potassium goes through via active transport into cells until reaches 40 times the concentration outside the cell. Glucose, insulin and oxygen facilitates the entry into cells of potassium. It causes a change of extracellular pH changes in the liquid plasma potassium concentration.

Biotransformation:

Dextrose is metabolized into carbon dioxide and water rapidly.

The half-life following radioactive-labeled sodium (^{24}Na) injection is 11 to 13 days for 99% of the injected sodium, and one year for the remaining 1%.

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

Potassium is filtered in glomeruli is reabsorbed from the proximal tub, and is secreted by the Na-K exchange in the distal tubule. Potassium tubular secretion is affected by hydrogen ion exchange, acid-base balance and adrenal hormones.

Elimination:

Sodium is excreted mainly through the renal route; however, majority is absorbed back with the renal route. A small amount of sodium is excreted through feces and sweat.

Since chloride follows sodium in the metabolic sense, it is mainly excreted through the renal route, and with feces and sweat in small amounts.

80-90% of the potassium is excreted mainly by the kidneys. The rest is excreted in faeces and only a small part of the perspiration.

Linearity/ nonlinear conditions:
The electrolytes and glucose in the composition of POLİFLEKS 5% DEXTROSE, 0.45% SODIUM CHLORIDE, 0.3% POTASSIUM CHLORIDE SOLUTION FOR I.V. INFUSION display linear pharmacokinetic behavior if administered in rates adequate for the supplementation of the deficiencies in the body, that is, in therapeutical dosages.

5.3 Pre-clinic safety data
Since the components of the solutions are physiological components of the human and animal plasma, and since no toxic effects are expected from clinical administrations, no studies have been performed on POLİFLEKS 5% DEXTROSE, 0.45% SODIUM CHLORIDE, 0.3% POTASSIUM CHLORIDE SOLUTION FOR I.V. INFUSION to evaluate its carcinogenic or mutagenic potentials and its effects on fertility.

Safety of the drugs added to the solution must be handled separately.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Water for injection

6.2 Incompatibilities
Compatibility of the drug to be added to the solution must be evaluated in advance. Any drug without compatibility data must not be added to the solution.

When a compatible medication is added to POLİFLEKS 5% DEXTROSE, 0.45% SODIUM CHLORIDE, 0.3% POTASSIUM CHLORIDE SOLUTION FOR I.V. INFUSION, the solution must be administered immediately.

It is the responsibility of the physician to judge the incompatibility of an additive medication with POLİFLEKS 5% DEXTROSE, 0.45% SODIUM CHLORIDE, 0.3% POTASSIUM

CHLORIDE SOLUTION FOR I.V. INFUSION by checking for eventual colour change and/or eventual precipitate, insoluble complexes or crystals apparition. The Instructions for Use of the medication to be added must be consulted. Before adding a drug, verify it is soluble and/or stable in water at the pH of POLİFLEKS 5% DEXTROSE, 0.45% SODIUM CHLORIDE, 0.3% POTASSIUM CHLORIDE SOLUTION FOR I.V. INFUSION (pH: 3.5 to 6.5).

In addition, POLİFLEKS 5% DEXTROSE, 0.45% SODIUM CHLORIDE, 0.3% POTASSIUM CHLORIDE SOLUTION FOR I.V. INFUSION should not be administered from the same Infusion set with massive blood transfusions as it may cause pseudoagutination due to its glucose content.

6.3 Shelf life
24 months
In-use shelf life: From a microbiological point of view, the diluted product must be used immediately unless dilution has taken place under controlled and validated aseptic conditions. If not used immediately, in-use storage times and conditions are the responsibility of the user.

6.4 Special precautions for storage
It must be kept at room temperature under 25 °C away from direct light.

6.5 Nature and contents of the packaging
In 250, 500 and 1000-ml PVC and PP bags
It has two forms, namely the forms with and without sets.

6.6 Destruction of the residual materials human medicinal product and other special precautions

It is for single use. **Partially used solutions must not be stored.**
Partially used bags must not be re-connected to systems applied to the patient.

The solution must be checked before use. **Only clear solutions not containing any particles within intact packaging must be used.**

Application will be made through the intravenous route using sterile apyrogen sets.

Administration must be started within the shortest time possible after the application set is attached to the product.

With the purpose of preventing air embolism because of the residual air in the bag, serial connection to other infusion liquids must not be made.

The solution must be administered through the sterile application set using the aseptic technique. Fluid must be passed through the application set to prevent entry of air to the system.

Additional drug can be added with the help of a injector under aseptic conditions before or during the infusion. Isotonicity of the final products must have been determined before the parenteral administration.

The added drug must be mixed thoroughly before administering to the patient. Solutions containing additional drugs must be used immediately after the addition of the drug, and must not be kept to be used later.

Addition of drugs to the solution or erroneous application technique can cause febrile reaction depending on the contamination of the product with pyrogens. Infusion must be stopped immediately in case adverse reactions are seen.

How to open:
1. Check the intactness of the outer packaging and if there is any leakage; do not use the packaging if the packaging is damaged.
2. Tear off the protective outer packaging.
3. Check if the bag within the protective packaging is intact.
4. Check the clarity of the solution within the bag and there is no foreign material within.

Preparations for the administration:
1. Hang the bag.
2. Remove the protective cap at the application tip.
3. Stab the spike of the application set to the application tip tightly. The instructions of use of the set must be followed when administering the solution to the patient.

Addition of drugs before administration
Caution: Like in all the parenteral solutions, all the substances to be added to the product must be compatible with the product. If any drug will be added to the product, compatibility must be checked before administration to the patient.

Adding drugs before administration:
1. The administration end will be disinfected.
2. The drug to be added will be added into the bag using and injector with a 19-22 gauge tip.
3. The solution with the added drug will be mixed thoroughly. (For drugs with high density like potassium chloride, mixing will be ensured by tapping the application outlet of the bag gently when it is in the upside position.)

Caution: Bags with added drugs must not be stored.

Mixing drugs during administration

1. The clamp of the set will be closed.
2. The administration end will be disinfected.
3. The drug to be added will be added into the bag using and injector with a 19-22 gauge tip.
4. Solution is removed from the hanger and turned upside down. In this position, mixing of the added drug and the solution will be ensured by tapping the administration end and the injection input gently of the bag.
5. The bag will be brought to the previous position and administration will be continued.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER(S)

207/88

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date Of First Authorisation: 27.07.2006
Renewal Of The Authorisation: ----------

10. DATE OF REVISION OF THE TEXT