SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT
PF İZOLEN-P 5% DEXTROSE SOLUTION FOR IV INFUSION

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Active ingredients:
Each 100 ml of solution:

Dextrose monohydrate	: 5 g
Sodium lactate	: 0.26 g
Potassium chloride	: 0.13 g
Magnesium chloride hexahydrate	: 0.031 g
Dibasic potassium phosphate	: 0.026 g

Excipients:
Each 100 ml of solution

Sodium bisulfate	: 0.021 g

See 6.1 for inactive ingredients.

3. PHARMACEUTICAL FORM
Sterile apyrogen solution for intravenous infusion

4. CLINICAL PARTICULARS
4.1 Therapeutical indications
PF İZOLEN-P 5% DEXTROSE ELECTROLYTE SOLUTION FOR IV INFUSION is generally indicated as water source as electrolytes, calories and as alkalinization.

It is preferred in the following cases.

- The maintenance of Daily fluid and electrolyte balance in infants and small children
- Treatment of children with acute diarrhea
- Excessive fluid loss
- Prevention and treatment of complications of diabetes acidosis

4.2 Posology and method of administration
Posology/ Frequency and period of administration
The dosage to be administered must be decided individually for each patient by the doctor based on the age, body weight, and laboratory values. Laboratory and clinical evaluation must be repeated in order to monitor blood, glucose and electrolyte concentrations and fluid-electrolyte balance during prolonged parenteral therapy.

The amount of fluid to be administered must be decided individually for each patient taking into consideration the patient's fluid requirements for maintenance or replacement.

Generally 1300 ml per 24 hours for each square of body surface in adults meets minimum fluid and electrolyte requirements. In cases needed extremely dose can be increased to 3000 ml per square meter per 24 hours.
Daily 40 mEq/1 potassium is sufficient to meet potassium requirement during normal fluid losses in adults. Infusion rate must not exceed 10 mEq at hour and 120 mEq on day for potassium.

Administration rate:
It will always be administered as 120-240 ml per square meter of the body area.

Route of administration:
Administration is made through the peripheral or central veins with sterile pyrogen sets intravenously.

Administration will be made intravenously.

With the purpose of minimizing the venous irritation during the peripheral administration of a hypertonic solution, the needle with the smallest diameter possible must be introduced to the largest vein possible, and infusion must be given with the slowest rate possible. Care must be taken to prevent the leakage of the administered fluid outside the vein.

Please see section 6.6 for details of 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. However, since this drug is largely excreted through the kidneys, the risk of appearance of toxic effects will increase in cases where the renal functions are impaired. Therefore, care must be taken when selecting the dosage in renal failure (See: section 4.3).

Paediatric population:
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. It is generally recommended in the dosage range of 20-100 ml/kg /24 hours for this population.

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.

Since the reduction of liver, kidney or cardiac functions is more frequent in the elderly population and possibilities of concomitant diseases or use of other drugs are more frequent in the elderly population, care must be taken in selecting dosage in this population, and the dose must be at the lower limit.

Since this drug is largely excreted through the kidneys, the risk of appearance of toxic effects will increase in cases where the renal functions are impaired. The reduction of renal functions is greater in the elderly; therefore, care must be taken in this population when selecting the dosage. Follow-up of the renal functions can be helpful in this population.

Patients in postoperative period:
The fluid-electrolyte requirements of the patients in the postoperative period must be calculated according to the daily electrolyte treatment principles. The following information can be used when calculating these requirements:

When replacing the fluid loss, the contents of the fluid lost must be taken into consideration (gastric, gastrointestinal fistula, bile, small intestines, etc.), and suitable standard solutions must be selected or supplementing the solution with additional electrolytes, vitamins or minerals must be considered.

- The requirements of the patients must be calculated for each 24 hours.

- The formula "basal requirement + additional loss" will be used in calculations. The fluid amount calculated according to this formula will be divided into 3 equal portions and each portion must be administered through the intravenous route within periods of 8 hours.

- The basal fluid requirement is the amount of fluid and electrolytes required by a healthy individual within 24 hours under normal conditions. It can be calculated as follows:
  Adults: 35ml/kg (around 2500 ml in an adult weighing 70 kg)
  In infants and children:
  - 100 ml/kg for the first 10 kg of the body weight
  - 75 ml/kg for the second 10 kg of the body weight
  - 50 ml/kg for the third 10 kg of the body weight

- Basal electrolyte requirements is 1 mEq/kg/day for sodium and chloride (60-80 mEq in adults), and 0.5 mEq/kg/day for potassium (30-40 mEq in adults).

-The following information can be used in calculating the additional losses:
- The amounts of fluids taken and excreted by the patient must be calculated meticulously.

- Long procedures in adults will require fluid transfusion of 10 ml/kg (500-700ml in the average) for each our spent in the operation room.

- It will be considered that an individual that had sweated in volumes enough to wet the bed sheets had lost at least 1 liter of fluid.

- Nasogastric aspiration or fistula discharge fluids and urine must be collected for 24 hours.

- Gauze soaked with blood, diarrhea diapers, and gauze used to dress the fistula area must be weighed and possible fluid content must be estimated.

- Furthermore, the previous clinical experience and impressions must be taken into consideration.

Patients with burns:
Special formulas must be used for burns

4.3 Contraindications

This solution is contra-indicated in anuria, severe oliguria, renal failure, crush syndrome, severe hemolysis, adrenal gland failure, hypoparathyroidism, cardiac block and high levels of plasma potassium.

Furthermore, it is contra-indicated in the patients with hypersensitivity against sulfite and corn-derived products.

4.4 Special warnings and precautions for use

Warnings

Administration of the intravenous solutions can lead to dilution of the serum electrolyte concentrations, over-hydration, and overloading of fluid and/or solute to cause congestive conditions and/or pulmonary edema.

The risk of dilution is inversely proportional with the electrolyte concentration. The risk of developing congestive conditions that lead to peripheral or pulmonary edema, however, is directly proportional with the electrolyte concentrations in the solution.

The ion concentrations of the solution is as follows:

Sodium (Na^+)	25 mEq/liter (25mmol/liter)
Chloride (Cl^-)	20,5 mEq/liter (20,5 mmol/liter)
Potassium (K^+)	20,5 mEq/liter (20,5 mmol/liter)
Magnesium (Mg^{++})	3 mEq/liter (1.5 mmol/liter)
Phosphate	3 mEq/liter (1.5 mmol/liter)
Lactate	23 mEq/liter (23 mmol/liter)
Sulphide	2 mEq/liter (2.0 mmol/liter)

Careful clinical observation is required at the beginning of all the intravenous infusions. Hypervolemia of intravenous administration must be implemented carefully in patients having renal failure, urinary tract obstruction, apparent or potential cardiac decompensation. Administration must be implemented under regular and careful observation; clinical and biologic parameters and particularly the serum electrolyte must be monitored.

When parenteral treatment extends or the general condition of the patient requires, clinical and biologic evaluation and appropriate laboratory measurement may require. In case of significant deviations from normal values, electrolytes and other vitamins and minerals must be added to the treatment.

In case of excessive loss of electrolysis such as excessive nasogastric irrigation, vomiting, diarrhea or gastrointestinal fistula drainage tube, additional electrolytes, vitamins or minerals may be administered.

Solutions containing sodium or potassium must be used with care in patients using corticosteroids or corticotropin, in cases with other sodium deposition together with congestive heart failure, severe renal failure and edema.

Administration of solutions containing sodium or potassium ions in patients with reduced renal function can be resulted with sodium and potassium deposition.

Solutions containing potassium ions must be used meticulously in case of hyperkalemia, severe renal impairment and potassium deposition.

Solutions containing potassium and magnesium must be used meticulously in cardiac patients, especially in patients having renal disease.

While administering potassium treatment, especially if patient receive a treatment with drugs from digital group, treatment must be treated by receiving the serial electrocardiograms.

Solutions containing magnesium must be used meticulously due to its additive central depressive effect to the patients taking barbiturates, narcotics, hypnotics or systemic anesthetic.

Patients with severe hypokalemia and acidosis may also need to be given potassium and lactate.

PF İZOLEN-P 5% DEXTROSE ELECTROLYTE SOLUTION FOR IV INFUSION does not contain magnesium to recover magnesium deficiency.

In order to avoid phosphate intoxication, infusion of solution containing phosphate must be administered rather slowly. Administering of phosphate at high concentrations may cause to hypocalcemia and tetany. Serum phosphorus and calcium levels must be monitored closely.

One liter of solution provides 170 kcal. Solutions containing dextrose must be administered meticulously in patients that they are already known to be diabetes mellitus or subclinical diabetes and have carbohydrate intolerance for any reason

In order to reduce an incompatibility risk that may be with any other drugs added to the solution, immediately after stirring, before administration or during administration, control must be carry out whether any blurring or precipitation occurs in the last stirring of which infusion is made at defined intervals

If this drug will be administered through controlled infusion pump, it must be ensured that the operation of the pump stops before complete emptying of the bottle, otherwise air embolism may occur.

The solution is administered intravenously through sterile sets.
Use only if the solution is clear and if the packaging and caps are intact.

Laboratory tests:
Clinical evaluations and periodic laboratory tests must be performed to monitor changes in the fluid balance, electrolyte concentrations and acid-base balance in long-term parenteral administrations or whenever the status of the patient requires. Such values must be returned to normal with sodium chloride solutions containing dextrose or with alternative solutions when significant deviations from the normal values are seen.

Due to it contains 0,021 g sodium bisulfite in each 100 ml as a preservative, it can cause rarely severe hypersensitivity reactions and bronchospasm

4.5 Interactions with other medical products and other forms of interaction

Some drugs or other solutions can be incompatible with the solution. Like all the other parenteral solutions, compatibility with the added drugs must be evaluated by a doctor before use.

If other substances will be added to the solution, aseptic technique must be used and shaken till the substance is mixed. It must be made sure that there are no color changes, not dissolving particles or crystallization following the addition of drugs.

Corticosteroids and carbenoxolone may cause to sodium and water retention, care must be taken when using with PF İZOLEN-P 5% DEXTROSE ELECTROLYTE SOLUTION FOR IV INFUSION

Care must be taken when using the potassium-containing solutions with drugs that increase the potassium level in blood (potassium retaining solutions, ACE inhibitors, cyclosporine and drugs containing potassium salts like penicillin).

PF İZOLEN-P 5% DEXTROSE ELECTROLYTE SOLUTION FOR IV INFUSION can make the urine alkaline drugs, it increases renal clearance of acidic drugs such as salicylic acid and barbiturate. Sympathomimetic and stimulant may cause to increase in toxicity by increasing some drugs half-life.

Interactions in relation with sodium that solution contains:

-Corticoids/steroids and carbenoxolone (with edema and hypertension) in relation with sodium and water retention

Interactions in relation with potassium that solution contains

- Potassium retaining diuretics (amiloride, spironolactone or triamterene singly or in combination).
- Angiotensin converting enzyme inhibitors and possible angiotensin II receptor antagonists.
- Tacrolimus and cyclosporine (these drugs increase the potassium concentration in the plasma and can potentially cause fatal hyperkalemia in renal failure conditions, in which the hyperkalemic effects will increase).

Interactions in relation with lactate (it is metabolized to bicarbonate) that solution contains

- Bicarbonate resulted in lactate metabolism makes the urine alkaline, the excretion of acidic drugs such as salicylates, barbiturates and lithium from the renal increase.
- resulting bicarbonate is made alkaline urine salicylates, barbiturates and increase the renal excretion of acidic drugs such as lithium

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 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.

PF İZOLEN-P 5% DEXTROSE ELECTROLYTE SOLUTION FOR IV INFUSION must not be used during pregnancy unless it is required for vitally important conditions.

Pregnancy
Studies on animal reproduction with dextrose solutions containing sodium chloride have not been carried out.

Whether or not PF İZOLEN-P 5% DEXTROSE ELECTROLYTE SOLUTION FOR IV INFUSION causes fetal damage if used in pregnant women, or if it causes impairment on ability of fertility are not known.
PF İZOLEN-P 5% DEXTROSE ELECTROLYTE SOLUTION FOR IV INFUSION must be used in pregnant women only when it is absolutely necessary.

Labor:
It has been reported in the literature that solutions containing dextrose and saline have been used during labor. It must be considered when required by the fluid balances of the mother and fetus, glucose or electrolyte concentrations and acid-base balance, or when required by the conditions of the mother or fetus.

Lactation
It is not known whether or not this drug is excreted to human milk. Since it is known that many drugs are excreted to human milk, PF İZOLEN-P 5% DEXTROSE ELECTROLYTE SOLUTION FOR IV INFUSION must be used carefully in breastfeeding mothers.

4.7 Effects on ability to drive and use 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 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)

Blood and lymphatic system disorders
Unknown: Acute hemolytic anemia (related to phosphorus deficiency)

Metabolism and nutrition disorders
Unknown: edema (related to hypernatremia); deterioration of congestive cardiac failure (related to hypernatremia); acidosis (related to hyperchloremia), deterioration of tissue oxygenation (related to phosphorus deficiency)

Psychiatric disorders
Unknown: Hyperirritability, psychotic behaviors (related to hypomagnesemia)

Nervous system disorders
Unknown: Mental confusion (related to hyperkalemia); reducing of the central nervous system functions (related to hypernatremia)

Cardiac disorders
Unknown: Arrhythmias, cardiac block, electrocardiographc abnormalities, cardiac arrest (related to hyperkalemia); reducing of the cardiac functions (related to hypermagnesemia); Tachycardia (related to hypomagnesemia).

Vascular disorders
Unknown: Hypotension (related to hyperkalemia); circulation collapse (related to hypermagnesemia); hypertension (related to hypomagnesemia).

Respiratory, thoracic and mediastinal disorders
Unknown: Respiratory arrest (related to hyperkalemia); respiratory depression (related to hypermagnesemia).

Gastrointestinal disorders
Unknown: Nausea, vomiting, diarrhea, abdominal cramps, diarrhea (related to potassium contained in the solution), Intestinal dilation and ileus (related to hypokalemia).

Skin and subcutaneous tissue disorders
Unknown: Hot flush and sweating (related to hypermagnesemia).

Musculoskeletal and connective tissue disorders
Unknown: Paresthesa in extremities, loss of reflexes, paralysis in extremities (related to hyperkalemia); deterioration of neuromuscular functions (related to hypokalemia); cramps, tetanus, hyperexcitability in muscles (related to phosphorus taken in excessive amounts as compared to calcium)

General disorders and administration site conditions
Unknown: Fatigue (related to hyperkalemia);

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

4.9 Overdose and treatment
If fluid or electrolyte overload related to excessive infusion is seen during the parenteral treatment, the patient must be re-evaluated and proper corrective treatments must be started.

Infusion must be stopped in case of overdose of solutions containing potassium, and the following measures will be taken to decrease potassium in serum:

- 10 or 25% dextrose solution in water with 10 units of crystallized insulin added for each 20 grams of dextrose will be administered with a rate of 300-500 ml per hour.
- Potassium absorption and exchange can be applied using sodium or ammonium cation exchange resins in the form of oral or retention enemas.

- Hemodialysis or peritoneal dialysis will be applied if required. Foods and drugs containing potassium must be stopped. However, it must be kept in mind that rapid lowering of the plasma potassium in digitalized patients can cause digital intoxication.

Administration of phosphorus replacement in excessive amounts can cause hypocalcemic tetanus. Administration of phosphorus must always be accompanied by calcium support.

In case overdose is related to the drugs added to the solution, the signs and symptoms related to overdose will depend on the added drug. If the dosage is inadvertently exceeded during the treatment, administration must be stopped and the patient must be followed for the signs and symptoms of the administered drug. Symptomatic and supporting treatments must be administered if required

5. PHARMACOLOGICAL PARTICULARS

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Intravenous solutions/ Solutions that affect the electrolyte balance
ATC code: B05BB02

PF İZOLEN-P 5% DEXTROSE ELECTROLYTE SOLUTION FOR IV INFUSION is a sterile, stable and without pyrogen a multiple electrolytic solution intended for intravenous use. It includes no bacteriostatic substances

PF İZOLEN-P 5% DEXTROSE ELECTROLYTE SOLUTION FOR IV INFUSION is formulated to meet the maintenance of daily fluid and electrolyte balance in children, and the requirement of the liquid, electrolyte, calorie losses; it contains electrolytes in sufficient quantity to meet daily needs of infants and small children. It can be used in cases where water loss occurred in elders or urine concentration decreases.

Multiple electrolyte solutions are used for electrolytes and body's hydration as water source. If solutions containing bicarbonate precursor can be used as alkalinizing (acetate, lactate, citrate), solutions containing carbohydrates (dextrose, fructose, etc.) can be used as calorie source.

Dextrose (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.

Lactate included in the composition of solution causes to alkalizing effect by forming bicarbonate in the body.

Sodium is the main cation of the extracellular fluid. Level of normal sodium in serum is from 135 to 145 mEq. Level of sodium, which is the main regulator of body fluids is kept relatively constant through a number of mechanisms at these levels. For example, when serum sodium level increases, sodium excretes from kidneys by decreasing to excrete antidiuretic hormones; when sodium levels are low, excreting hormones increase so it tries to protect the serum sodium level

Sodium shows its effect as primary through distribution of water in body, fluid balance and controlling the osmotic pressure of body fluids. Sodium is also in relation with the regulation of acid-base balance of body fluid together with chloride and bicarbonate.
Chloride is the main anion of the extracellular fluid of which normal level is 10-106 mEq/l in serum monitors sodium metabolism closely and changes which are in acid-base balance of body are reflected changes in the concentration of chloride.

Potassium is the main cation of the intracellular fluid, and it is essential for the maintenance of the acid-base balance, isotonicity, and the electrodynamics characteristics of the cell. Normal potassium level is 3-4-5.When potassium levels increase, kidneys excrete this ion rapidly. Potassium is important activator for many enzymatic reactions; it is vital for many physiological processes such as transmission of nerve impulses, contractility of heart and skeletal muscle, gastric secretions, renal functions, tissue synthesis and carbohydrate metabolism. Potassium deficiency reveals itself through impairment of neuromuscular function, bowel dilatation and ileus.

Magnesium is the main intracellular cation of the soft tissues, and is mainly involved in the enzymatic reactions of the carbohydrate and protein metabolism as a co-factor. Furthermore, magnesium is also plays a role in the neurochemical transmission and neuromuscular excitability. Tachycardia, hypertension, over nervous sensibility and psychotic behaviors can be seen in magnesium deficiency. There is regulatory effect on calcium levels, there is buffer effect on acid-base balance and it plays primary role in the excretion of hydrogen ions from kidneys. Normal serum level of phosphorus which is the most important component of phosphate assuming the buffer role for protection acid-base balance of the body is about 0.3-0.45 mg/l.

5.2 Pharmacokinetic properties
General properties
Pharmacokinetic properties of PF İZOLEN-P 5% DEXTROSE ELECTROLYTE SOLUTION FOR IV 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 into cells in related with insulin in organism.

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 in the extracellular fluid enters the cell with active transport until it reaches 40 times of the extracellular concentration. Glucose, insulin and oxygen make the entry of potassium into the cell easier. pH changes in extracellular liquid causes changing of plasma potassium concentration

Magnesium is mainly distributed in the intracellular fluid (particularly within the soft tissue cells)

Phosphate is mainly distributed in the intracellular fluid. Normal serum level of phosphorus, which is the most important component of phosphate is about 0.3-0.45 mg/l.

Biotransformation:
Dextrose is rapidly metabolized and converted to carbon dioxide and water
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 the glomerules, reabsorbed in the proximal tubules and secreted in the distal tubules with Na-K exchange. Tubular secretion of potassium is affected from hydrogen ion exchange, acid-base balance and adrenal hormones.

Plasma phosphate is filtered from the glomerulus and more than 80% is absorbed from the tubules

Lactate included in the composition of solution is metabolized mainly in the liver both though in oxidation and glukonegenaz. Time over 1-2 hours requires for forming bicarbonate through both ways.

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.

Potassium is excreted through the kidneys in a rate of 80-90%. The remaining portion is excreted through feces, and a very small amount is excreted through sweating

Phosphate is excreted through renal. Phosphorus which is the most important component of phosphate and its normal serum level is up to 0.3-0.45 mg/l, is not known the excreted mechanism from the kidneys exactly as well as it is accepted that after phosphate is filtrated, reabsorbed from tubules at the rate of %85-90 and D vitamin increases this rate.

Linearity/ nonlinear conditions:
The electrolytes and glucose in the composition of PF İZOLEN-P 5% DEXTROSE ELECTROLYTE SOLUTION FOR IV INFUSION display linear pharmacokinetic behavior if administered in rates adequate for the supplementation of the deficiencies in the body, that is, in therapeutical dosages.
When any drug is added to PF İZOLEN-P 5% DEXTROSE ELECTROLYTE SOLUTION FOR IV INFUSION, the pharmacokinetics of these drugs will depend on the drug added

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 PF İZOLEN-P 5% DEXTROSE ELECTROLYTE SOLUTION FOR IV 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

Sodium bisulfite
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.

Decision of whether or not the added drug is compatible by checking any color change and/or precipitation, or presence compounds that have not been dissolved or crystallization are the responsibility of the doctor making the administration. The decision for the compatibility of the drug to be added to the solution must be made according to the instructions for use of the drug and solubility and stability of the drug to be added to PF İZOLEN-P must be decided on by making use of the instructions for use of the drugs to be added to the solution.

Before adding any drug to the solution, it must be confirmed that the drug is soluble and stable at the pH of PF İZOLEN-P, PF İZOLEN-P must be used immediately after the addition of any compatible drug. Drugs known to be incompatible must not be added.

6.3 Shelf life

24 months.

Shelf-life after addition of drugs:

- As regards microbiology, the drug must be used immediately after preparation for administration. In cases where it is not used immediately, determining the conditions for and period of storage is the responsibility of the person who had added/diluted the drug; and this period is no longer than 24 hours under 2-8°C temperature if this procedure is not performed under validated aseptic conditions.

6.4 Special precautions for storage

There are no special conditions 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 500 and 1000-ml glass bottles
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

The unused or waste products must be discarded according to the “Regulation Related to the Control of Medical Waste” and the “Regulation Related to the Control of Packaging and Packaging Waste”.

Instruction for use:

The solution must be checked before use.
Application will be made through the intravenous route using sterile apyrogen sets.

Only clear solutions not containing any particles within intact packaging must be used.
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 bottle, 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 an 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.

It is for single use.

Partially used solutions must not be stored.
Partially used bottles must not be re-connected to systems administered 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 bottle stopper will be disinfected.
2. The drug to be added will be added into the bottle using an injector with a 19-22 gauge tip.
3. The solution with the added drug will be mixed thoroughly.
Caution: Bottles with added drugs must not be stored.

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

7. MARKETING AUTHORISATION HOLDER
POLİFARMA İLAÇ SAN. VE TİC. A.Ş.
Vakıflar OSB Mah. Sanayi Cad. No:22/1
Ergene/TEKİRDAĞ/TURKEY
Tel: +90 282 675 14 04
Fax: +90 282 675 14 05

8. MARKETING AUTHORISATION NUMBER(S)
208/81

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Renewal of the Authorisation:

10. DATE OF REVISION OF THE TEXT
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