SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

PF LACTATED RINGER SOLUTION FOR IV INFUSION
Sterile

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredients:
Each 100 ml solution contains the following:
Sodium lactate: 0,30 g
Sodium chloride: 0,60 g
Potassium chloride: 0,04 g
Calcium chloride dehydrate: 0,03 g

Electrolyte concentrations in the solution mEq/l (mmol/l):
- Sodium: 130 (130)
- Calcium: 4 (2)
- Chloride: 112 (112)
- Potassium: 5 (5)
- Lactate: 27 (27)

Total osmolar concentration: 275,52 mOsm/L

Excipients:
See section 6.1 for excipients.

3. PHARMACEUTICAL FORM

Sterile, apyrogen solution for intravenous infusion and sterile irrigation

4. CLINICAL PARTICULARS

4.1. Therapeutical indications

-In cases where isotonic concentration of electrolyte therapy is sufficient to correct extracellular fluid volume and electrolyte balance or to replace extracellular fluid losses.
-In the treatment of short-term volume replacement in cases of hypovolemia or hypotension (alone or in combination with a colloid solution).
-Regulation or maintenance of acid-base balance and/or treatment of mild to moderate metabolic acidosis (except lactic acidosis).

4.2 Posology and method of administration

Posology/ Frequency and period of administration
Administration for intravenous infusion
The dose to be administered, the rate of infusion and duration of administration should be adjusted by the physician according to the indication using the solution, the age of the patient,

body weight and clinical condition, the treatment administered with the solution to the patient, the clinical and laboratory response to the treatment.

In order to ensure normal blood volume in blood losses, 3-5 times the amount of blood lost is required by PF LACTATED RINGER.

In general, doses of 500 - 3,000 mL per day are recommended in adults, and 20 - 100 mL per kg of body weight per day in children.

The rate of administration in adults is usually 40 mL per kg of body weight per day.

Route of administration:
Administration will be made with sterile apyrogen sets intravenously.
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.

Since the lactate metabolism can be impaired in patients with liver insufficiency, PF LACTATED RINGER may not show its alkalizing effect.

Pediatric population:
The efficacy and safe use of PF LACTATED RINGER in children has not been investigated by appropriate and well-controlled studies; however, there is information in the medical literature that shows the use of electrolytic solutions in the pediatric population. Lactate-containing solutions should be applied with special care in newborns and infants younger than 6 months.

Although the infusion rates in the pediatric population are on average 5 mL / kg per hour, it varies according to age as follows:

- 6-8 mL/kg/hour in infants older than 1 month
- 4-6 mL/kg/hour in 1-2 years old children
- 2-4 mL/kg/hour in children older than 2 years

In children with burns, it is recommended to apply at an average dose of 3,4 mL/kg/burn rate in the first 24 hours and at the dose of 6,3 mL/kg/burn rate on the second day.
The average dose in children with severe head injury is 2.850 mL/m^2.

Infusion may be faster during surgery or, if necessary, or greater than the total volume administered.

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

- Patients with known hypersensitivity to sodium lactate.
- Extracellular hyperhydration or hypervolemia.
- Severe kidney failure (with oliguria / anuria)
- Decompensated heart failure
- Hyperkalemia.
- Hypercalcemia.
- Metabolic alkalosis.
- Acid cirrhosis.
- Severe metabolic acidosis.
- When lactate levels are elevated (hyperlactaemia), including when lactate use is impaired, such as lactic acidosis or severe liver failure.
-Use with digital therapy (see section 4.5.).
-In newborn babies younger than 28 days of age, the use of PF LACTATED RINGER, like other calcium-containing solutions, is contraindicated even if it is administered from separate infusion lines (due to the precipitation of the fatal ceftriaxone calcium salt in the bloodstream of the newborn). For the use of PF LACTATED RINGER with ceftriaxone in patients older than 28 days, see "Section 4.4. Special warnings and precautions".

4.4. Special warnings and precautions for use

Hypersensitivity reactions

Infusion should be discontinued immediately if any signs or symptoms suspected of hypersensitivity reaction develop during administration. Appropriate therapeutic interventions should be made when clinically necessary.

Incompatibilities

Ceftriaxone:

In patients older than 28 days, including adults, ceftriaxone should not be used simultaneously from the same infusion line with solutions containing calcium, including PF LACTATED RINGER. If the same application set will be used for sequential applications, the set should be washed thoroughly with compatible solutions prior to application. For the use of PF LACTATED RINGER with ceftriaxone in newborn babies younger than 28 days, see "Section 4.3. Contraindications".

Electrolyte balance

Hypernatremia:

In cases of hypernatremia, PF LACTATED RINGER should only be used after carefully investigating the cause of the underlying disease and when alternative intravenous fluid treatments cannot be applied. In such cases, it is recommended to follow the plasma sodium levels and plasma volume.
PF LACTATED RINGER should be used with special care in conditions that increase susceptibility to hypernatremia (such as adrenocortical insufficiency, diabetes insipidus or extensive tissue damage) and those with cardiac disease.

Hyperchloraemia:

In cases of hyperchloremia, PF LACTATED RINGER should only be used after carefully investigating the cause of the underlying disease and when alternative intravenous fluid treatments cannot be applied. In such cases, it is recommended to follow the plasma chloride levels and the plasma acid-base balance state. In patients who have increased susceptibility to hyperchloremia (such as renal insufficiency and renal tubular acidosis, diabetes insipidus), or

those who take certain diuretics (such as acetazolamide), or steroids that have steroids (androgens, estrogens, corticosteroids) It should be applied with special attention to patients.

Use in patients with potassium deficiency:
Although the amount of potassium in the composition of PF LACTATED RINGER is similar to that of plasma, the solution should not be used for this purpose, since it is not at a level that would have a beneficial effect in cases of severe potassium deficiency.

Use in patients at risk of hyperkalaemia (hyperpotasemia):
Special care should be taken in cases with increased susceptibility to hyperkalaemia (such as severe kidney failure or adrenocortical insufficiency, acute dehydration or extensive tissue damage or burns) and cardiac disease. Close monitoring of plasma potassium levels is recommended in patients at risk of hyperkalaemia.

Use in patients at risk of hypercalcemia:
Calcium chloride is irritant; For this reason, when applying intravenously or intramuscularly, care should be taken not to leave any solution out of the vein. Solutions containing calcium salts should be used with caution in patients with impaired kidney function or high vitamin D levels such as sarcoidosis. In addition, use should be avoided in patients with a history of calcium stone in their kidneys.

Fluid balance/kidney functions
Use in patients with impaired kidney function:
PF LACTATED RINGER should be applied with special attention to patients with impaired kidney function. In such patients, administration of PF LACTATED RINGER can cause sodium and/or potassium accumulation.
Application in patients with risk of fluid and/or solute loading and electrolyte disturbance:
Intravenous administration of the PF LACTATED RINGER depending on the applied volume and the rate of application may cause the following conditions:
- Fluid and / or solute overload and congestive conditions (including pulmonary congestion and edema) causing excessive hydration.
- Clinically relevant electrolyte disturbances and acid-base imbalance.
During long-term parenteral administration, the patient's condition or laboratory condition and laboratory parameters should be monitored at regular intervals whenever the speed required by intravenous fluid administration is required.
High volume infusions should be applied with special monitoring in patients with heart or lung failure.

Use in patients with hypervolemia, overhydration or sodium retention and edema;
In patients with hypervolemia or over hydrated patients, PF RACATED RINGER should be applied with special attention.
In patients with primary hyperaldosteronism, secondary hyperaldosteronism (for example with hypertension, congestive heart failure, renal artery stenosis or nephrosclerosis) or pre-eclampsia, PF lactating RINGER should be applied with special caution due to its sodium chloride content. . (See also Section 4.5.)

Acid-base balance
Use in patients at risk of alkalosis:
PF LACTATED RINGER should be applied with special care in patients at risk of alkalosis. Since lactate is metabolized to bicarbonate, the solution in such patients can cause metabolic alkalosis or aggravate an existing metabolic alkalosis. Although convulsion can be induced in the case of lactate-induced alkalosis, this is not common.

Other warnings
Co-administration of citrate with anticoagulated/stored blood:
Due to the calcium it contains, it is not recommended to add PF LACTATED RINGER to anticoagulated / stored blood with citrate, to be administered simultaneously or to be applied together from the same infusion system.

Use in patients with type-2 diabetes:
Lactate is a substrate for gluconeogenesis. This should be taken into account when using PF LACTATED RINGER in patients with type-2 diabetes.

Application warnings:
Addition of appropriate medication or improper application can lead to fever reactions due to pyrogen contamination. In such a case, infusion should be stopped immediately.
Please refer to Sections 6.2 and 6.6 regarding the compatibility of the solution and the addition of additional medication to the product.

During long-term parenteral treatment, the patient should be given an appropriate nutritional supplement.

4.5. Interactions with other medical products and other modes of interaction
Ceftriaxone:
Please see Sections 4.3 and 4.4 on this subject.

Sodium-related interactions that the solution contains:
- In patients using drugs such as corticosteroids, which may increase the risk of sodium and fluid loading (with edema and hypertension), careful application of PF LACTATED RINGER is recommended.

The potassium-related interactions that the solution contains:
Because PF LACTATED RINGER contains potassium, it is recommended to be used with caution when used with the following medicines that cause hyperkalemia or are known to increase the risk of hyperkalemia:
Potassium-sparing diuretics (amiloride, spironolactone, triamterene, alone or in combination).
Angiotensin converting enzyme inhibitors and angiotensin II receptor antagonists.
- Tacrolimus, cyclosporin

Administration of potassium in patients undergoing treatment with such drugs, especially in severe renal failure, can lead to a condition of severe and potentially fatal hyperkalemia.

Calcium-related interactions that the solution contains:
Calcium administration may increase the effects of digitalis and cause severe or potentially fatal arrhythmias in the heart. Therefore, rapid infusion of the solution in large volumes is not recommended in patients treated with digitalis group drugs.
If the thiazide group that can increase the risk of hypercalcemia is to be used with diuretics or vitamin D, careful application of the PF LACTATED RINGER is recommended.
Absorption (bioavailability decreases) of bisphosphonates, fluoride, some fluoroquinolones and tetracyclines when applied with calcium.

Interactions related to lactate (metabolized to bicarbonate) contained in the solution:
If the renal elimination is to be used with drugs that depend on pH, it is recommended to apply PF LACTATED RINGER carefully: PF LACTATED RINGER may affect the elimination of such drugs, since the bicarbonate urine formed by lactate metabolism makes it alkaline.
- As bicarbonate formed as a result of lactate metabolism makes urine alkaline, excretion of acidic drugs such as salicylates, barbiturates and lithium increases.
- Renal elimination of alkaline drugs such as sympathomimetic drugs (eg ephedrine, pseudoephedrine) and stimulating drugs (eg dexamphetamine sulfate, fenfluramine hydrochloride) slows down.

Additional information on the special population:
No interaction studies have been performed.

Pediatric population:
No interaction studies have been performed.

4.6 Pregnancy and lactation

General advice
Pregnancy category: C.

Women of childbearing potential /Contraception
As long as the electrolyte and fluid balance is kept under control, the PF LACTATED RINGER can be used safely in women with childbearing potential. The interaction with birth control pills is unknown.

Pregnancy
As long as the electrolyte and fluid balance is kept under control, the PF LACTATED RINGER can be used safely in women during pregnancy.
It should be taken into account that calcium passes through the placenta.
If any drugs will be added to the solution, the properties of the drug used and its use during pregnancy should be evaluated separately.

Lactation
As long as the electrolyte and fluid balance is kept under control, PF LACTATED RINGER can be used safely in women during lactation.
It should be taken into account that calcium passes through the placenta and is distributed in breast milk.
If any drugs will be added to the solution, the properties of the drug used and its use during the lactation period should be evaluated separately.

Fertility
There are no known effects.

4.7 Effects on driving and using machines
There is no information about the effects of PF LACTATED RINGER on the ability to drive and use machines.

4.8 Undesirable effects
The adverse reactions reported spontaneously in post-marketing experiences are listed below. Adverse reactions are listed according to MedDRA System Organ Classification. While giving frequency of occurrence, the following terminology was used: 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, including isolated reports (<1/10,000), and unknown (cannot be estimated with the available data).

Immune system disorders
Unknown: Angioedema, chest pain, chest discomfort, decreased heart rate, tachycardia, decreased blood pressure, difficulty breathing, bronchospasm, dyspnea, cough, urticaria, rash, itching, erythema, flushing of the face and / or neck (flushing), irritation in the throat Hypersensitivity / infusion reactions (including anaphylactic / anaphylactoid reactions) that can be seen with one or more of the symptoms of paraesthesia, oral hypoesthesia, dysgeusia, nausea, anxiety, pyrexia and headache.

Metabolic and nutritional disorders
Unknown: Hyperkalemia

General disorders and diseases related to the application site
Unknown: Infusion site reactions that can be seen with one or more of the following symptoms: phlebitis, inflammation at the infusion site, swelling, rash, itching, erythema, pain and burning sensation.

The adverse reactions reported spontaneously during the use of other sodium lactate-containing solutions are listed below:

Immune system disorders
Unknown: Hypersensitivity reactions: Laryngeal edema (Quincke's edema), skin swelling, nasal congestion, sneezing / sneezing.

Metabolic and nutritional disorders
Unknown: Electrolyte disorders

Psychiatric disorders
Unknown: Anxiety

Vascular disorders
Unknown: Hypervolemia

General disorders and diseases related to the application site
Unknown: Other infusion site reactions: infection at the infusion site, extravasation, anesthesia at the infusion site (numbness).

4.9. Overdose and treatment
Administration of overdose or very rapid administration can cause water and sodium overloading in cases where the renal sodium excretion is impaired. Renal dialysis therapy can be required in such cases.

Administration of potassium in excessive amounts can cause hyperkalemia in patients with renal failure. Symptoms of hyperkalemia include paresthesia in extremities, muscular weakness, paralysis, cardiac arrhythmias, cardiac blockage, cardiac arrest and mental confusion. Hyperkalemia can be treated with calcium, insulin (together with glucose), sodium bicarbonate, ion exchanging resins or dialysis.

Administration of excessive calcium can cause hypercalcemia. Symptoms of hypercalcemia include anorexia, nausea, vomiting, constipation, abdominal pain, muscular weakness, mental disorders, polydipsia, polyuria, nephrocalcinosis, and formation of renal stones and in more severe cases, cardiac arrhythmias and coma. Too fast infusion of calcium salts can cause chalk-like taste in the mouth, sudden flushing in the body and particularly in the face and peripheral dilation, as well as many other symptoms of the hypercalcemia. Mild asymptomatic hypercalcemia returns to normal by stopping the administration of calcium and drugs contributing to hypercalcemia including vitamin D. In case hypercalcemia is serious, treatments including loop diuretics, hemodialysis, calcitonin, biphosphonate and trisodium edetate must be started urgently.

Administration of excessive sodium lactate can cause hypokalemia and metabolic alkalosis particularly in patients with renal insufficiency. Symptoms include mood changes, fatigue, stopping of breathing, muscular weakness and irregularity of the heartbeats. Muscular hypertonicity, fasciculation and tetanus can be seen especially in hypocalcemic patients. Treatment of the metabolic alkalosis related to overdose of bicarbonate mainly includes the proper regulation of the fluid and electrolyte balance. Replacement of calcium, chloride and potassium deficiencies is particularly important.

If 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: B05BB01

PF LACTATED RINGER is an isotonic electrolyte solution. The composition and concentration of electrolytes in the PF LACTATED RINGER content are designed to be similar to those of electrolytes in plasma.
The pharmacological properties of PF LACTATED RINGER consist of the pharmacological properties of its components (sodium, potassium, calcium, chloride and lactate). The main effect of PF LACTATED RINGER is the expansion of the fluid in the extracellular compartment, including interstitial and intravascular fluids.
Lactate ions metabolize bicarbonate, mainly in the liver, and have an alkalizing effect on plasma.
Changes in central venous pressure were associated with atrial natriuretic peptide secretion in healthy volunteers given a PF LACTATED RINGER.
PF LACTATED RINGER applied in healthy volunteers decreased serum osmolality, increased the pH of the blood and provided the first urine output in a shorter time than normal saline application.
No significant changes in glucagon, epinephrine, blood glucose and insulin levels were observed in aortic surgery patients undergoing PF LACTATED RINGER.
When a drug is added to the PF LACTATED RINGER, the pharmacodynamic properties of the resulting solution are based on the properties of the added drug.

5.2 Pharmacokinetic properties

General properties:
Pharmacokinetic properties of PF LACTATED RINGER consist of the properties of its components (sodium, potassium, calcium, chloride and lactate).

In hemodynamically stable adults, the infusion of PF LACTATED RINGER does not cause an increase in circulating lactate levels. The pharmacokinetics of D-lactate and L-lactate are similar.

<u>Absorption:</u>
The active ingredients in the drugs administered through the intravenous route reach the maximum plasma concentrations immediately after the administration.

Distribution:
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%. Distribution differs according to tissues: it is fast in the muscle, liver, kidneys, cartilage and skin, slow in erythrocytes and neurons, and very slow in bones.

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 cell easier. The plasma potassium concentration in healthy adults is in 3.5-5 mEq/l range. The plasma level in neonates can reach 7.7 mEq/l. Together with this, since the plasma levels of potassium do not fully reflect the intracellular potassium levels, cellular hypokalemia can be present despite the normal plasma levels. Changes of pH in the extracellular fluid also cause changes in the plasma potassium concentration. A change in the plasma pH of 0.1 units can cause a 0.6 mEq/l reverse change in the plasma potassium concentration.

Chloride is normally found in low amounts in the bony tissue and in large amounts in some components of the connective tissue, for example, in the cartilage. Together with this, it is also found in high concentrations in the erythrocytes and gastric mucosa. The levels of chloride, which is the main anion in the extracellular fluid, in the body are closely related to the changes in the sodium concentration. Abnormalities in the sodium metabolism generally result in changes also in the chloride concentration.

Calcium is an important cation for the maintenance of life both in intracellular and extracellular level. It either stays in the plasma or distributed to tissues based on the requirement. Calcium is also excreted to the placenta or breast milk.

Lactate is transformed into bicarbonate in the serum with oxidation. The lactate distributed to liver will be metabolized in the liver to bicarbonate with gluconeogenesis.

Biotransformation:
Sodium, potassium, calcium and chloride do not undergo any biotransformation. They are either distributed to body fluids and tissues or eliminated.

Lactate however, is metabolized to bicarbonate both with oxidation and gluconeogenesis in the liver within approximately 1-2 hours.

Elimination:
Sodium is mainly excreted through the renal route; the great majority is re-absorbed through the renal route. Small amounts of sodium are excreted with feces and sweat. Excretion through the skin is insignificant unless sweating is excessive.

Chloride, which follows sodium in the metabolic sense, it is mainly excreted through the renal route. Re-uptake of chloride from the kidneys generally which follows the re-uptake of sodium. It is also excreted to sweat in some amount.

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. 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.

Calcium is mainly excreted in the feces; it is excreted with sweat glands in small amounts.

Linearity/ nonlinear conditions:
PF LACTATED RINGER displays linear pharmacokinetic behavior if administered within the recommended dosage range.

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 LACTATED RINGER 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
Ceftriaxone should not be mixed with solutions containing calcium, including PF LACTATED RINGER. Please see Sections 4.3 and 4.4 on this subject.
As with all parenterally administered solutions, additional drugs added to the solution may be incompatible. The compatibility of the drug to be added to the solution with the PF LACTATED RINGER and its bottle should be evaluated before adding the drug. It can be understood whether there is incompatibility by looking for color change and / or precipitation, insoluble compounds or crystallization after adding drug.

For the addition of the drug, the Short Product Information of the drug to be added and the related literature should be consulted.

Before adding any substance or drug to the solution, it should be verified that the pH (pH: 5-7) of the PF LACTATED RINGER is soluble and stable.

Adding drugs to the PF LACTATED RINGER should be done with an aseptic technique. After adding the drugs, the solution should be thoroughly mixed. Solutions containing additional medicines should not be stored.

As a guide, below are some of the incompatible drugs (not an exhaustive list showing all incompatibilities) with the PF LACTATED RINGER:

Some of the drugs incompatible with PF LACTATED RINGER:

- Amino caproic acid
- Amphotericin B
- Metaraminol tartrate
- Cefamandole
- Ceftriaxone
- Cortisone acetate
- Diethylstilbestrol
- Ethamivan
- Ethyl alcohol
- Solutions containing phosphate and carbonate
- Oxytetracycline
- Thiopental sodium
- Versenate disodium

Some of the drugs partially incompatible with PF LACTATED RINGER:

- Tetracycline is stable for 12 hours.
- 2%-3% solutions of ampicillin sodium are stable for 4 hours, while the solutions with concentrations higher than 3% are stable for 1 hour.
- Minocycline is stable for 12 hours.
- Doxycycline is stable for 6 hours

Additional drugs that are known or determined to be incompatible should not be used.

6.3. Shelf-life

24 months

Shelf-life during use:

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.

6.4 Special precautions for storage

It must be kept at room temperature under 25 °C.

6.5 Nature and contents of the packaging

In 500 and 1000 ml glass bottles.

The product has two forms, with and without set.

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

Unused products or waste materials should be disposed of in accordance with the "Medical Waste Control Regulation" and "Packaging and Packaging Waste Control Regulation".

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

Instructions for Use

The solution must be checked before use.
The administration is made intravenously 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.

Addition of drugs

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 and 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

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