SUMMARY OF PRODUCT CHARACTERISTICS

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredients:
Each 100 ml solution contains:
Dextrose anhydrous: 5 g
Sodium acetate: 0.28 g
Potassium chloride: 0.15 g
Dibasic potassium phosphate: 0.13 g
Sodium chloride: 0.091 g

Excipients:
Each 100 ml solution contains:
Sodium bisulfide: 0,021g/

See section 6.1 for excipients:

Electrolyte concentrations:
Sodium : 38 mEq/L,
Potassium : 35 mEq/L,
Chloride : 36 mEq/L,
Phosphate : 15 mEq/L,
Acetate : 20 mEq/L,
Bisulfide : 2 mEq/L

3. PHARMACEUTICAL FORM
Sterile, apyrogen solution for intravenous infusion

4. CLINICAL PROPERTIES
4.1 Therapeutical indications
POLİFLEKS İZOLEN-M 5% DEXTROSE SOLUTION FOR IV INFUSION is indicated in adults as a source of electrolytes, calories, water for hydration and an alkalizing agent.

It is preferred in the following conditions:
- Maintenance of the daily fluid and electrolyte requirements.
- Sweating.
- Fluid losses accompanied by low fluid intake.
- Diarrhea, vomiting, long-term infusion of solutions not containing potassium, burns in healing process, ulcerative colitis, potassium losses related to chronic pyloric obstruction.
- Mild metabolic 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 clinical conditions and particularly on the hydration status of the

patient. Frequent laboratory and clinical evaluations must be carried out to monitor the changes in serum electrolyte concentrations and fluid-electrolyte values.

In general, 1300 ml /24 hours per square meter of the body will meet the minimum fluid and electrolyte requirements in adults. Dosage can be increased up to 3000 ml/24 hours in cases where requirements are high.

The daily dose of 40 mEq/l potassium will suffice to meet the potassium requirement in normal level of losses in adults. Infusion rate must not exceed 10 mEq/h and 120 mEq/day.

The frequency and dosage will be adjusted by the doctor individually for each patient taking the clinical conditions of the patient into consideration.

In case the added fluid includes calcium or magnesium ions, it must be taken into consideration that the solution contains phosphate ions to avoid a potential precipitation.

Administration rate:
Administration rate will be 120-240ml/h per square meter of the body.

Route of administration:
Used only through the intravenous route.

Administration will be made with sterile apyrogen sets intravenously through peripheral or central veins.
Please see section 6.6 for details of administration.

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.

See also section 6.6 for the 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:
Efficacy and safety have not been shown in this population.

Geriatric population
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.

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.

It is also contra-indicated in patients with hypersensitivity against sulfides and products of corn origin.

4.4 Special warnings and precautions for use

Administration of intravenous solutions can cause fluid and/or solute overload that can result in dilution of serum electrolyte concentrations, over hydration, congestive conditions or pulmonary edema. The risk of dilution is inversely proportional with electrolyte concentrations. The risk of congestive conditions that can result in peripheral or pulmonary edema is directly proportional with the electrolyte concentrations in the solution.

The ion concentrations of the solution are as follows:

- Sodium (Na^+): 38 mEq/liter
- Chloride (Cl^-): 36 mEq/liter
- Potassium (K^+): 35 mEq/liter
- Acetate (CH_3COO^-): 20 mEq/liter
- Phosphate ($HPO_4^{=}$): 15 mEq/liter (7.5 mmol P/liter)
- Bisulfide (HSO_3^-) 2 mEq/liter

Osmolarity of the solution is about 415.2 mOsml/liter and pH is 5.0 (4.0-6.0).
One liter of solution provides 170 kcal energy.

Careful clinical observation is required at the beginning of all the intravenous infusions. Administration must be implemented under regular and careful observation. Clinical and biologic parameters and particularly the serum electrolyte must be monitored.

Solutions containing sodium chloride must be used carefully in congestive cardiac failure, severe renal failure and conditions that sodium accumulation accompanies edema.

Solutions containing potassium must be used carefully in patients with hyperkalemia, severe renal failure and potassium accumulation.

Administration of solutions containing sodium or potassium ions can result in sodium and potassium accumulation.

With the purpose of avoiding phosphate intoxication, infusion of solutions containing, phosphate must be made as slow as possible. High concentrations of phosphate can cause hypocalcemia and tetanus. Serum phosphorus and calcium levels must be observed closely.

Solutions containing acetate must be used very carefully in patients with metabolic or respiratory alkalosis. Acetate administration must be made very carefully in patients increased acetate levels or in cases with impaired acetate destruction like in liver failure.

This solution must be administered carefully in conditions of hypervolemia, renal failure, and obstruction of urinary tracts, potential cardiac failure or overt cardiac insufficiency.

Administration of additional electrolytes can be needed in excessive nasogastric irrigation, vomiting, diarrhea or drainage from gastrointestinal fistulas.

Essential electrolytes, minerals and vitamins must also be added to the treatment where required.

Sodium- or potassium-containing solutions must be administered carefully in patients with renal or cardiovascular insufficiency accompanied or not accompanied by congestive heart failure, particularly in the postoperative period or in the elderly.

Treatment must be implemented with serial electrocardiograms when administering potassium treatment particularly if the patient is taking drugs from digitalis group.

Solutions containing potassium must be administered carefully in cardiac patients, particularly if they have renal disease also.

Solutions containing acetate must be administered carefully. Administration in excessive amounts can cause metabolic acidosis.

Solutions containing dextrose must be administered carefully in patients known to be diabetic as well as those with sub-clinic diabetes or in those with carbohydrate intolerance with any reason.

With the purpose of minimizing the risk compatibility with any drug that might be added to the solution, turbidity or sedimentation must be checked in the final solution to be infused immediately after mixing and with certain intervals during the administration.

Do not use in serial connections.
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.

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.

Since it contains 0.021 g sodium bisulfide in each 100 ml, it can cause serious hypersensitivity reactions or bronchospasm.

4.5 Interactions with other medicinal products and other modes 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.

The solution must be administered carefully to patients under treatment with corticosteroids or corticotropin and other patients with sodium accumulation.

4.6 Pregnancy and lactation

General recommendations

Pregnancy category: C.

Women of childbearing potential /Contraception

Adequate data related to the use of multiple electrolyte solutions 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. POLİFLEKS İZOLEN-M 5%DEXTROSE SOLUTION FOR IV INFUSION must not be used during pregnancy unless it is required for vitally important conditions.

POLİFLEKS İZOLEN-M 5% DEXTROSE 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 POLİFLEKS İZOLEN-M 5% DEXTROSE SOLUTION FOR IV INFUSION causes fetal damage if used in pregnant women, or if it causes impairment on ability of fertility are not known. POLİFLEKS İZOLEN-M 5% DEXTROSE 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, POLİFLEKS İZOLEN-M DEXTROSE 5% SOLUTION FOR IV INFUSION must be used carefully in breastfeeding mothers.

Fertility

It has no effects on fertility.

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 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.

The adverse effects reported in the clinical trials and after-marketing studies are listed according to the frequency order given below.

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)

Metabolic and nutritional 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 hyperpotassemia); reducing of the central nervous system functions (related to hypernatremia)

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

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

Respiratory, thoracic and mediastinal disorders
Unknown: Respiratory arrest (related to hyperpotassemia); 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 hypopotassemia).

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

Musculoskeletal and connective tissue disorders
Unknown: Paresthesia in extremities, loss of reflexes, paralysis in extremities (related to hyperpotassemia); deterioration of neuromuscular functions (related to hypopotassemia); 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 hyperpotassemia);

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 PROPERTIES
5.1 Pharmacodynamic properties
Pharmacotherapeutic group: Intravenous solutions/ Solutions that affect the electrolyte balance
ATC code: B05BB02

POLİFLEKS İZOLEN-M DEXTROSE 5% SOLUTION FOR IV INFUSION is a sterile, stable and apyrogen solution intended for intravenous use. It includes no bactreriostatic substances.

POLİFLEKS İZOLEN-M DEXTROSE 5% SOLUTION FOR IV INFUSION provides electrolyte, calories and water for hydration. It can stimulate diuresis depending on the condition of the patient.

Sodium is the main cation of the extracellular fluid. It shows its effects primarily on the control of the distribution of the fluids in the body, fluid balance and osmotic pressure of body fluids. Sodium is also related to the regulation of acid-base balance in the body together with chloride and bicarbonate.

Potassium is the main cation of the intracellular fluid. It is involved in the distribution carbohydrates and protein synthesis, and plays a critical role in muscular contraction particularly in the myocardium.

Chloride, which is the main anion of the extracellular fluid, closely follow the sodium concentration, and changes in the acid-base are reflected to the changes in the chloride concentration.

Phosphate is the most important intracellular anion, and it provides energy for the substrate metabolism and plays a role in the important metabolic and enzymatic reactions taking place in almost all the tissues and organs. It has regulating effect on calcium levels, buffers the acid-base balance and plays the primary role in the excretion of hydrogen ions from the kidneys.

Acetate is a hydrogen acceptor organic anion and helps bicarbonate to metabolize into carbon dioxide and water. It functions as an alkalizing agent if it is found in adequate amounts.

Dextrose functions as the source of calories. Dextrose metabolizes rapidly, can decrease protein and nitrogen losses in the body, promotes glycogen storage, and can reduce or prevents ketosis if administered in adequate amounts.

5.2 Pharmacokinetic properties
General properties

Pharmacokinetic properties of POLİFLEKS İZOLEN-M 5% DEXTROSE SOLUTION FOR IV INFUSION consists 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 enters the cells rapidly in relation with the insulin in the 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. The pH changes in the extracellular fluid cause changes in the plasma potassium concentrations.

Magnesium is mainly distributed in the intracellular fluid (particularly in the cells of the soft tissues).

Phosphate is mainly distributed in the intracellular fluid. The normal serum level of phosphorus, which is one of the most important components of phosphate is in the 0.3-0.45 mg/l range.

Biotransformation:
Dextrose is rapidly metabolized and turns 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 through the glomerules and more than 80% is reabsorbed through the tubules.

Acetate, after being converted into acetyl-coenzyme A, which is the final carbon source of fat synthesis, is fully oxidized and metabolized in Krebs cycle.

Acetate is infused to the organism as a sodium salt takes one hydrogen ion and gives one bicarbonate ion for each acetate ion consumed; then rapidly metabolized to carbon dioxide and water. Acetate ion is primarily metabolized in muscles and other peripheral tissues.

Sodium gluconate, which is the salt of the gluconic acid, turns into sodium and gluconic acid. Gluconic acid is particularly metabolized in liver. Its metabolism takes place as phosphorilation in the pentose-phosphate cycle. Gluconate is finally broken down into carbon dioxide and water and gives bicarbonate through the metabolism.

Elimination:
Sodium is mainly excreted through the renal route; the great majority is reabsorbed through the renal route. Small amounts of sodium are excreted with feces and sweat.

Chloride, which follows sodium in the metabolic sense, it is mainly excreted through the renal route.

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.

Phosphates are excreted through the renal route. Although the renal excretion mechanism of phosphorus, which is one of the most important components of phosphate with normal serum levels in the 0.3-0.45 mg/l range, is not clearly known, it is accepted that the phosphate in plasma is filtered through the kidneys, and then reabsorbed in the tubules by 85-90% and vitamin D increases this ratio.

Gluconate and acetate are metabolized into carbon dioxide and water. Carbon dioxide is excreted through respiration, and water is mainly excreted with the renal route, and also with feces, sweat and respiration.

Linearity/ nonlinear conditions:
Electrolytes contained in POLİFLEKS İZOLEN-M 5% DEXTROSE SOLUTION FOR IV INFUSION display linear pharmacokinetic behavior if administered within the recommended dosage range, that is, in doses sufficient to supplement the deficiencies in the body.

When any drug is added to POLİFLEKS İZOLEN-M 5% DEXTROSE 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 no toxic effects are expected from clinical administrations, no studies have been performed on POLİFLEKS İZOLEN-M 5% DEXTROSE 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 PROPERTIES

6.1 List of excipients
Sodium bisulfide
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 POLİFLEKS İZOLEN-M 5% DEXTROSE SOLUTION FOR IV INFUSION.

Before adding any drug to the solution, it must be confirmed that the drug is soluble and stable at the pH 5.0 (4.0-6.0) of POLİFLEKS İZOLEN-M 5% DEXTROSE SOLUTION FOR IV INFUSION.

POLİFLEKS POLİFLEKS İZOLEN-M 5% DEXTROSE SOLUTION FOR IV INFUSION 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.

6.5 Nature and contents of the packaging
POLİFLEKS İZOLEN-M 5% DEXTROSE SOLUTION FOR IV INFUSION is available 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

The unused or waste products must be discarded according to the "Regulation Related to the Control of Medical Wastes" and the "Regulation Related to the Control of Packaging and Packaging Wastes".

Instructions for use

Solution must be checked before administration.
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.

The outer packaging must not be removed until right before administration.

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.

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.

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 through the set.

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.
5. 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.
6. The bag will be brought to the previous position and administration will be continued.

7. MARKETING AUTHORISATION HOLDER
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8. MARKETING AUTHORISATION NUMBER(S)
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