SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT
POLİFLEKS 30% DEXTROSE SOLUTION FOR IV INFUSION

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Active ingredients:
Each 100 ml solution contains 30 g dextrose anhydrous.

Osmolarity: approximately 1665 mOsm/liter

Excipients:
See section 6.1 for inactive ingredients.

3. PHARMACEUTICAL FORM
Solution for intravenous infusion

4. CLINICAL PARTICULARS
4.1 Therapeutical indications
Intravenous administration of dextrose solution in high concentrations is provided water and calories. These solutions may induce diuresis by the patient's clinical status.

POLİFLEKS 30% DEXTROSE indicated in the following situations:

- Dehydration, which developed due to excessive fluid loss due to a lack of glycogen storage in the liver, excessive catabolic conditions, limited food and water intake, diarrhea, vomiting or excessive fluid loss due to salt diuresis situations.
- In order to provide calorie parenteral nutrition regimen. The following cases need parenteral nutrition, a suitable protein to correct the negative nitrogen balance or to prevent the loss of nitrogen (nitrogen) is used in conjunction with the source:
    - Preoperative and postoperative periods, or severe liver, kidney, heart and gastrointestinal diseases as well as in cases where restriction of oral food and water intake.
    - Situations where the absorption of proteins from gastrointestinal impaired.
    - Increased metabolic needs to proteins etc. severe burns.

Insulin dependent or non-dependent hypoglycemia (including the new-born babies and infants with acute symptomatic hypoglycemia blood glucose levels to normal upgrade).

4.2 Posology and route of administration
Posology/ Frequency and period of administration:
Rate of administration and dose will be adjusted by the doctor based on age, the clinical and biological status of the patient.

When used as a solvent for another drug infusion it is determined by the proposed use of the drug to be administered by dissolving volume to be selected.

Frequency of administration and dose will be adjusted by the doctor based on the clinical status of the patient. To prevent the development of hyperglycemia, the infusion rate should not exceed the patient's glucose oxidation capacity. Therefore, the maximum application rate of dextrose 500-800 mg / kg / hr.

Route of administration:
Administration will be made intravenously using sterile apyrogen sets.
For details see 6.6

Additional information related to 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.

Paediatric 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.

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
Hypertonic dextrose solutions are contraindicated in the following cases.

- Intracranial or inraspinal bleeding.
- Severe dehydration conditions.
- Anuria conditions.
- Hepatic coma.
- Patients known to be allergic to corn and corn products.

4.4 Special warnings and precautions for use
Clinical evaluation and periodic laboratory tests are required to monitor fluid balance, electrolyte concentrations, and changes in acid-base balance when prolonged parenteral therapy or the patient's condition requires.

One liter of POLİFLEKS 30% DEXTROSE provides 1020 kcal calories. Dextrose-containing solutions should be used with caution in patients who are known to have clear or clinically indeterminate diabetes.

In patients with sodium deficiency, administration of sodium-free dextrose solutions by intravenous infusion can lead to peripheral collapse and oliguria.

Using these solutions for long periods with intravenous infusion can lead to a thrombophlebitis condition that starts from the place of application.

The osmolarity of POLİFLEKS 30% DEXTROSE is 1665 mOsm / liter. Hypertonic dextrose solutions can lead to irritation, damage and thrombosis in the veins when administered through a peripheral vein without diluting properly. Therefore, it is recommended that excessive hypertonic solutions be administered to a large central vein, if possible, through an intravenous catheter placed in the vena cava superior. Care should be taken to avoid overloading the circulation, especially in patients with heart failure. In patients with kidney failure, glucose tolerance may be impaired.

Applying too much hypertonic dextrose solution to patients can result in significant hypokalemia. Additional potassium should be administered, if necessary, by looking at serum potassium levels.

Care should be taken to avoid overloading the circulation, especially in patients with heart failure. Administration of hypertonic dextrose solutions can result in fluid and / or solute loading at dilution of serum electrolyte concentration, resulting in excess hydration, congestive conditions, or pulmonary edema. Dilution risk is inversely proportional to electrolyte concentration. The risk of developing congestive conditions that can lead to peripheral and pulmonary edema is directly proportional to the concentration of electrolytes in the solution.

Excessive or rapid administration of dextrose injections in very low birth weight newborn babies may cause an increase in serum osmolality and possible intra-cerebral hemorrhage.

4.5 Interactions with other medical products and other modes of interaction
Electrolyte-free dextrose solutions should not be applied same infusion set with blood, due to the possibility of agglomeration or erythrocyte hemolysis.

Patients who receive corticosteroids or corticotropin need attention during the implementation of hypertonic dextrose solution. Hyperglycemic effect of the solution may change the requirement for insulin in diabetics.

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 POLİFLEKS 30% DEXTROSE in pregnant women are not available.

Pregnancy
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 30% DEXTROSE should not be used in pregnant women, except when the benefit to be obtained is above the possible risks to the fetus.

The literature contains dextrose and sodium chloride in the labor and delivery has been reported that the action of the solution used. The mother and fetus fluid balance, acid-base balance and

electrolyte concentration of dextrose and should be evaluated on a regular basis or when the situation requires the patient or fetus.

Lactation
There is no known adverse effect on breastfeeding babies implementation of an intravenous infusion of dextrose solution. In case of any doubt, the patient should not breast feed.

Fertility
Effect on reproductive ability of intravenous infusion of the dextrose solution was not investigated.

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 after administration.

4.8 Undesirable effects
POLİFLEKS 30% DEXTROSE can cause hyperglycemia, fluid balance disorders (hypervolemia) and to changes in electrolyte levels (hypokalemia, hypomagnesemia and hypophosphatemia).

Adverse effects depending on application techniques include febrile reactions, injection site infection, venous thrombosis or phlebitis at the injection site starting spreading, has extravasation and hypervolemia.

Very rapid infusion of hypertonic solutions lead to local pain and venous irritation. Application rate should be adjusted according to patient tolerance. Widest peripheral vein and possible fine needle is recommended to be selected. It was recognized early this kind of effect patients should be monitored regularly during practice for the implementation of appropriate treatment.

Dilution of additional drugs administered with the liquid in the bag must be vigilant about what led to the adverse effects. In such a case, additional information should be viewed.

The infusion should be interrupted in case of occurrence of adverse effects, patients should be evaluated, appropriate therapeutic measures should be retained for analysis and the remaining solution in the bag when it should be needed.

Adverse effects seen during the administration of POLİFLEKS 30% DEXTROSE is as follows.

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)

Immune system disorders
Rare: Allergic reactions (depend on additive drug)
Unknown: Anaphylactic reaction; hypersensitivity

Metabolic and nutritional disorders
Common: Electrolyte imbalance and hyperglycemia

Uncommon: Hemodilution and hypervolemia

Skin and subcutaneous tissue disorders
Uncommon: Sweating

General disorders and administration site conditions
Uncommon: Fever, tremor, febril reactions, infection in the injection site;
Rare: Thrombophlebitis

Investigations
Uncommon: Glucosuria

4.9. Overdose and treatment
Typical initial signs of overdosing are increase in extracellular fluid, hyperglycemia, decreased hemoglobin and hematocrit, decrease in serum electrolyte concentration, increase in extracellular potassium passage and plasma osmolarity range of cells.

Overdose in patients with normal renal function - depending on the applied hyperosmolarity solution - more or less abundant cause an osmotic diuresis; of this electrolyte, especially accompanied by a loss of potassium.

Due to the excess of water-binding capacity of infused hypertonic carbohydrate solution, low-dose or multi dehydration occurs during osmotic diuresis in case of overruns.

Dehydration is characterized by reduction of the initially increased plasma osmolarity. Therefore, falling hemoglobin and hematocrit levels after the overdose return to normal values during diuresis immediately.

If diuresis develops slowly, metabolic disorders may occur with dextrose overdoses; this is especially characterized by the production of lactic acid and reduction of pH. If diuresis does not occur, circulating edema symptoms associated with overload (including pulmonary edema) - and a heavy reduction in intracellular potassium can be seen.

Treatment of overdose, the other measures to be taken in overdose
Appropriate level of diuresis:
Implementation of a slightly hypotonic electrolyte solution by continuously monitoring fluid balance and acid-base status, serum electrolyte levels is recommended due to replace lost of fluids and specific electrolytes (especially potassium) with osmodiuresis.

Formulation of a solution can be proposed to replace lost fluids and major electrolytes are as follows: 1000 ml of each solution at about 120 mmol of sodium, 30 mmol of potassium, 150 mmol chloride. Defeats other electrolytes must be replaced as well.

What next diuresis replace lost fluids and electrolytes, if an acid-base imbalance, which in laboratory values should be continuously monitored and corrected.

Overdose treatment in case of oliguria / anuria:

Using peritoneal dialysis solutions without carbohydrates can be done as a last resort or extracorporeal hemodialysis.

5. PHARMACOLOGICAL PROPERTIES

Osmolarity of the solution is 1665 mOsm/l. Each liter of POLİFLEKS 30% DEXTROSE provides 1020 kcal.

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Parenteral nutritional solutions/ Carbohydrates
ATC code: B05BA03

Osmolarity of POLİFLEKS 30% DEXTROSE is 1665 mOsm/l. Each liter of POLİFLEKS 30% DEXTROSE provides 1020 kcal. Hypertonic dextrose solutions have value as a source of water and calories. It is capable of inducing diuresis depending on the clinical condition of the patient.

Dextrose is readily metabolized, may decrease losses of body protein and nitrogen, promotes glycogen deposition and decreases or prevents ketosis if sufficient doses are provided. Therefore high concentration dextrose solutions mainly used to provide calories in parenteral nutrition.

Used with suitable protein source to prevent nitrogen loss or correct the negative nitrogen balance (nitrogen) in such cases parenteral nutrition is indicated that the preoperative and postoperative periods, or severe liver, kidney, heart, and as in gastrointestinal disorders where the oral food and water intake restricted, proteins gastrointestinal where impaired absorption from the system and protein burns with increased severe metabolic requirements, etc.

Also in hypoglycaemia (including the new-born babies and infants blood glucose levels in acute symptomatic hypoglycemia upgrade normal) for hydration next calories they provide hypertonic dextrose solution used for dehydration because they provide the necessary water, depending on the excessive fluid loss due to a lack of glycogen storage in the liver in excessive catabolic states, limited food and water intake, diarrhea, vomiting or salt in excessive fluid loss due to diuresis status is used.

5.2 Pharmacokinetic properties

Dextrose is metabolised to carbon dioxide and water with the release of energy.

Absorption:
Active substances in the drugs administered intravenously reached maximum plasma concentration immediately after administration.

Distribution:
Dextrose can be administered without causing glucosuria with dosages up to 0.5 g/kg. Approximately 95% of the administered dextrose will remain in the body is administered with a rate of 0.8g/kg, which is the highest infusion rate.

Biotransformation:
Dextrose is easily and fully metabolized in the body through pyruvic acid or lactic acid route and provides energy while largely turning into carbon dioxide and water.

Elimination:
Carbon dioxide formed as a result of biotransformation is excreted from the lungs, and water is mainly excreted through the kidneys, and with sweat, feces and expiration air in lesser amounts.

Linearity / non-linear conditions:
POLİFLEKS 30% DEXTROSE in the composition of the body at a rate that will complement deficiency shows a linear pharmacokinetic behavior when administered at therapeutic doses.

5.3 Pre-clinic safety data
Since the components of the solution are physiological components of the human and animal plasma, and since no toxic effects are expected from clinical administrations, no safety studies have been performed on POLİFLEKS 30% DEXTROSE SOLUTION.

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
The compatibility of the drug to be added to the solution must be evaluated in advance. If compatibility data cannot be found, the solution should not be mixed with any medication.

Solubility and stability of the drug to be added to POLİFLEKS 30% DEXTROSE at the pH of the solution must be confirmed before adding drug to be the solution.

6.3. Shelf-life
24 months

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

6.5 Nature and contents of the packaging
100, 150, 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
The solution must be checked before use.

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

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

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

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

Additional drugs 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 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 by squeezing the bag. 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.
4. The instructions of use of the set must be followed when administering the solution to the patient.

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 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.

Addition of 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)

204/71

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date Of First Authorisation: 05.10.2004
Renewal Of The Authorisation: 10.05.2010

10. DATE OF REVISION OF THE TEXT

10.04.2020