SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

POLİFLEKS 5% DEXTROSE SOLUTION FOR IV INFUSION

Sterile

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredients:

Each 100 ml solution contains 5 g dextrose anhydrous.

Osmolarity: approximately 253 mOsm/liter

Calories: 170 kcal/liter

Excipients:

See section 6.1 for inactive ingredients.

3. PHARMACEUTICAL FORM

Sterile and apyrogen solution for intravenous infusion

4. CLINICAL PARTICULARS

4.1 Therapeutical indications

− POLİFLEKS 5% DEXTROSE SOLUTION FOR IV INFUSION is indicated for the treatment of carbohydrate and fluid deficiencies.

− POLİFLEKS 5% DEXTROSE SOLUTION FOR IV INFUSION is also used to the dilute the compatible drugs for parenteral administrations.

4.2 Posology and route of administration

Posology/ Frequency and period of administration:

The dose to be administered will be adjusted according to age and clinical and biological status of the patient and the treatments to be administered concomitantly. Serum glucose concentrations must be monitored closely during the treatment.

Doses recommended for the treatment of carbohydrate and fluid deficiencies: 500 to 3000 ml per 24 hours in adults, adolescents and elderly.

Frequency and period of administration:

Frequency of administration and dose will be adjusted by the doctor based on the clinical status of the patient.

Route of administration:

Administration will be made intravenously using sterile apyrogen sets (through peripheral or central veins).

Administration rate:

With the purpose of preventing the development of hyperglycemia, the infusion rate must not exceed the glucose oxidation capacity of the patient.

Therefore, the highest dose allowable in adults must not exceed 5mg/minute, and 10-18 mg/kg in children depending on the age and total body surface.

The infusion rate for use as diluter will be adjusted according to the recommended dosage of the diluted drug.

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.

It is generally recommended in the dosage range of 20-100 ml/kg /24 hours for this population, and this dose will be adjusted according to the body weight as follows.

- 0-10 kg : 100ml/kg/day
- 10-20 kg : 1000 ml + 50 ml/day for each kg over 10 kg
- > 20 kg : 1500 ml + 20 ml/day for each kg over 20 kg

Geriatric population:

Adult doses will be used also in the elderly.

4.3. Contraindications

The solution is contra-indicated in decompensate diabetes, under glucose intolerance conditions including metabolic stress, hyperosmolar coma and in hyperlactatemia.

Solutions containing dextrose can be contra-indicated in patients with hypersensitivity against products containing corn.

4.4 Special warnings and precautions for use

-POLİFLEKS 5% DEXTROSE SOLUTION FOR IV INFUSION is an isotonic solution. Infusions with high volumes must be administered under careful follow-up in conditions of water intoxication or severe renal failure with oliguria/anuria, and in cardiac or pulmonary failure cases.

− Administration of dextrose solutions can cause hyperglycemia. Since any possible hyperglycemia can increase the ischemic brain damage and retard healing, it is recommended not to use POLİFLEKS 5% DEXTROSE SOLUTION FOR IV INFUSION after acute ischemic strokes.

− Dextrose infusion must not be administered within the first 24 hours following head traumas and blood glucose levels must be followed closely in intracranial hypertensive periods.

− The initial period in all the intravenous infusions require careful clinic follow-up.

− Administrations must be made regularly and under careful follow-up. Clinical and biological parameters and particularly blood glucose levels must be monitored.

− Infusion rate must be adjusted in case of hyperglycemia and insulin must be administered. Parenteral potassium supplement must be added if required.

− Solutions containing dextrose must be administered to patients known to have diabetes mellitus or to sub-clinic diabetics or to patients with carbohydrate intolerance with any reason.

− Glucose tolerance can be impaired in patients with renal failure or in patients with diabetes mellitus. Blood glucose levels must be monitored carefully when POLİFLEKS 5% DEXTROSE SOLUTION FOR IV INFUSION administered to such patients, and insulin and/or potassium levels must be re-determined to adjust the treatment accordingly.

− Infusion rate must be slow to decrease the osmotic diuresis risk.

− Dextrose solutions without electrolytes must not be administered together with blood transfusion or through the same infusion set before or after the infusion, this can cause hemolysis or agglutination of erythrocytes.

− Administration of solutions not containing potassium can cause significant hypokalemia. Serum potassium levels must be maintained at normal levels, and potassium must be added to the treatment if required.

− With the purpose of minimizing the risk of incompatibility with any other 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.

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

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

− Use only if the solution is clear and if the packaging and caps are intact.

4.5 Interactions with other medical products and other modes of interaction

− Like all the other parenteral solutions, compatibility with the added drugs must be evaluated by a doctor before use. To make sure of compatibility, the drugs to be added to the solution must be evaluated based on the instructions for use. It must be made sure that there are no color changes, not dissolving particles or crystallization following the addition of drugs to the POLİFLEKS 5% DEXTROSE SOLUTION IN WATER FOR IV INFUSION.

− Some of the drugs added to the solution can be incompatible. If other substances will be added to the solution, aseptic technique must be used and shaken till the substance is mixed.

4.6 Pregnancy and lactation

General recommendations

Pregnancy category: C.

Women of childbearing potential /Contraception

There are no known adverse effects.

Pregnancy

Adequate data related to the use of dextrose solutions containing POLİFLEKS 5% DEXTROSE SOLUTION FOR IV INFUSION 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.

It must not be used during pregnancy unless considered absolutely necessary by the doctor (is treatment of the patient with another intravenous fluid is not possible).

Lactation

POLİFLEKS 5% DEXTROSE SOLUTION FOR IV INFUSION must not be used in breastfeeding mothers unless it is absolutely necessary.

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 after administration.

4.8 Undesirable effects

Adverse effects seen during the administration of POLİFLEKS 5% DEXTROSE SOLUTION FOR IV INFUSION 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)

Metabolic and nutritional disorders

Unknown: Fluid and electrolyte imbalance*; Hyperglycemia and dehydration**

Renal and urinary disorders

Unknown**:** Poliuria

Surgical and medical procedures***

Unknown: Infection in the injection site; local pain or irritation; venous irritation; venous thrombosis or phlebitis starting the injection site and spreading; extravasation and hypervolemia

* Including hypokalemia, hypomagnesemia or hypophosphatemia

** Adverse effects generally seen as a result of erroneous parenteral administration

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

Drugs administered by mixing with the solutions also can cause adverse effects. In such cases, the the adverse reactions will depend on the characteristics of the drug added.

Infusion must be stopped in case of adverse effects.

4.9. Overdose and treatment

Rapid or long-term administration of POLİFLEKS 5% DEXTROSE SOLUTION FOR IV INFUSION can cause hyperosmolarity, dehydration, hyperglycemia, hyperglucosuria and osmotic diuresis (related to hyperglycemia). Edema related to fluid overloading and water intoxication (together with hyponatremia) can develop in patients.

If overdose is related to the drugs added to the solution, then the signs and symptoms of the overdose will depend on the characteristics of 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: Parenteral nutritional solutions/ Carbohydrates

ATC code: B05BA03

P POLİFLEKS 5% DEXTROSE SOLUTION FOR IV INFUSION contains 5 grams of dextrose anhydrous ($C_6H_{12}O_6$) in each 100 ml. Molecular weight of dextrose anhydrous is 180.2.

Each liter of POLİFLEKS 5% DEXTROSE SOLUTION FOR IV INFUSION provides 170 kcal. Furthermore, dextrose infusion will ensure nonionic hydration.

Dextrose solutions are also administered as carbohydrate sources in parenteral nutrition. However, more concentrated forms are preferred for this purpose.

Pharmacodynamic properties of POLİFLEKS 5% DEXTROSE SOLUTION FOR IV INFUSION consist of the properties of dextrose, which is the active ingredient and the main energy source in the cellular metabolism.

POLİFLEKS 5% DEXTROSE SOLUTION FOR IV INFUSION is an almost isotonic solution with approximately 253 mOsm/l osmolarity.

POLİFLEKS 5% DEXTROSE SOLUTION FOR IV INFUSION is used in the clinic to provide hydration without administering electrolytes, and can stimulate diuresis depending on the clinical conditions of the patient.

The pharmacodynamic properties of the drugs added to the solution are the same with the individual properties of the drug.

5.2 Pharmacokinetic properties

Absorption:

Since POLİFLEKS 5% DEXTROSE SOLUTION FOR IV INFUSION is a product developed for intravenous administration, there is no information related to this section.

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.

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 5% DEXTROSE SOLUTION IN WATER FOR IV INFUSION. No toxic effects are expected from clinical administrations.

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

Like for all the parenteral solution, compatibility of the drug to be added to POLİFLEKS 5% DEXTROSE SOLUTION FOR IV INFUSION must be evaluated before addition.

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 POLİFLEKS 5% DEXTROSE SOLUTION FOR IV INFUSION must be made according to the instructions for use of the drug.

Solubility and stability of the drug to be added to POLİFLEKS 5% DEXTROSE SOLUTION FOR IV INFUSION at the Ph of the solution must be confirmed before adding drug to be the solution.

POLİFLEKS 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

36 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 25 ml PVC, 50, 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.

Administration is made intravenously through 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 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

POLİFARMA İLAÇ SAN. VE TİC. A.Ş.
Vakıflar OSB Mah. Sanayi Caddesi No:22
Ergene/TEKİRDAĞ

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date Of First Authorisation: 05/10/2004
Renewal Of The Authorisation: 05/04/2010

10. DATE OF REVISION OF THE TEXT

25/09/2019