PATIENT INFORMATION LEAFLET

POLİFLEKS 10% DEXTROSE SOLUTION FOR IV INFUSION
Used intravenously
Sterile

Active ingredients: Each one liter of solution contains 100 grams of dextrose anhydrous
Excipient: Sterile water for injection

Please read this PATIENT INFORMATION LEAFLET carefully before starting to use the drug; because important information is included here.

- *Keep these PATIENT INFORMATION LEAFLET. You may need to re-read it later.*
- *In case you have additional questions, please consult your doctor or pharmacist.*
- *This drug is prescribed personally for you, do not give to others.*
- *During the use of this drug, please tell your doctor that you are using this drug when you visit your doctor or a hospital.*
- *Please follow these instructions strictly. Do not use dosages* ***higher or lower*** *than the dosage recommended to you.*

The following topics are included in this PATIENT INFORMATION LEAFLET:

1. What is POLİFLEKS 10% DEXTROSE and what is it used for?

POLİFLEKS 10% DEXTROSE is a solution used **intravenously** to replace carbohydrates lost from the body or can't be received orally adequately and to supplement part of body's energy need.

POLİFLEKS 10% DEXTROSE is available in PVC and PP bags with 100, 150, 250, 500 and 1000 ml volumes. There are two forms, with or without set.

It is used together with an appropriate protein source in pre- or post-op periods or in conditions where oral food and liquid intake is limited such as severe liver, kidney, hearth and gastro-intestinal diseases, in situations where absorption of protein through gastro-intestinal system is impaired or conditions like burns where protein need of body is extremely increased.

POLİFLEKS 10% DEXTROSE, which can be used in some conditions where blood glucose has dropped due to its glucose (sugar) content, supplies water along with calories to the body and thus is used in treatment of some conditions where the body is dehydrated (extreme dehydration cases due to limited water intake, diarrhea, vomiting or excessive urinating).

POLİFLEKS 10% DEXTROSE is also used to dilute concentrated drugs fit for intravenous application before application.
The drug is used only inside veins and through a plastic pipe (set) fit for that purpose.

2. *Before you are given* POLİFLEKS 10% DEXTROSE

POLİFLEKS 10% DEXTROSE is a safe drug in many patients. However, if you have problems in your heart, kidneys, liver or lungs or if you are diabetic your doctor can decide not to administer this drug to you.

DO NOT USE POLİFLEKS 10% DEXTROSE under following conditions:

If you have experienced an allergic reaction when you used drugs containing POLİFLEKS 10% DEXTROSE's active ingredients dextrose or inactive ingredients, meaning you experienced sudden asphyxiation, wheezy aspiration , skin rash, itching or swelling in your body, DO NOT USE this drug.

Also, if you are allergic to corn-based products DO NOT USE this drug.

If you are not sure about whether you're allergic or not, consult your physician.

This drug should not be used in conditions below:

- Intracranial hemorrhage.
- Situations where the body is severely dehydrated.

- Situations where you can't urinate (anuria).
- Coma relating to liver disease

Use POLİFLEKS 10% DEXTROSE carefully under the following conditions:
If you have,

- Latent diabetes or explicit diabetes or carbohydrate intolerance due to any reason;
- Reduced salt in your body;
- Heart failure (there may be excessive fluid collection in your circulatory system);
- Kidney failure (in this case, you may be intolerant to sugar), this drug shall be administered to you with care

Also this drug shall be administered with care to newborn babies with very low birth weights (it may cause increase in density of liquid part of blood and thus increase in intracranial bleeding risk).

You may be re-examined by your physician treating you and various blood analyses may be performed on you while using the drug especially in case the intravenous treatment is prolonged.

It is recommended to replace pipes (sets) used to administrate this drug to you every 24 hours.
Also it shall be used only if the bag is intact and not leaking and the solution is clear.

If these warnings, even in any period in the past, is applicable to you please consult your physician.

Use of POLİFLEKS 10% DEXTROSE with foods and drinks
POLİFLEKS 10% DEXTROSE is a drug administered intravenously; it has no known interaction with foods or drinks.

Pregnancy
Consult your doctor or pharmacist before using this drug.

POLİFLEKS 10% DEXTROSE must not be used during pregnancy unless it is found appropriate by your doctor.

In case you become aware that you are pregnant during treatment, immediately consult your doctor or pharmacist.

Lactation
Consult your doctor or pharmacist before using this drug.

If you are breastfeeding, inform your physician. Do not use POLİFLEKS 10% DEXTROSE in breast feeding period unless found convenient by your physician.

Driving and use of machines
POLİFLEKS 10% DEXTROSE has no effects on driving or operating machines.

Important information about some ingredients of POLİFLEKS 10% DEXTROSE
If you are not sensitive to inactive ingredients contained in POLİFLEKS 10% DEXTROSE, no negative effects caused by these ingredients are expected.

Taking other medicines
If you are planning to use, currently using or recently used any other drugs including nonprescription drugs, vaccinations or herbal drugs, please inform your physician.

POLİFLEKS 10% DEXTROSE is incompatible with some drugs. These drugs, known to be incompatible, should not be added to solution; other solutions should be preferred to dilute these drugs. To minimize the risk of incompatibility with any other drug to be added to solution, a health officer shall check whether there is any blurring or sedimentation right after mixing, in last mix to be administered periodically before and during application.

POLİFLEKS 10% DEXTROSE shall be administered carefully in patients using drugs of steroid type.

If you are currently taking or have taken recently any other prescribed drugs or OTCs, please inform your doctor or pharmacist regarding such drugs.

3. How POLİFLEKS 10% DEXTROSE will be given?

Instructions for proper use and dosage/application intervals:
Your physician shall decide on your quantity need for this drug and when shall it be administered to you. This shall be decided based on your age, body weight and reason for administering this drug. Unless your physician gives a different advice, follow these instructions.

Do not forget to take the drug on time.

Your physician will inform you on how long your treatment with POLİFLEKS 10% DEXTROSE will take. Do not quit the treatment early because you will not get the wished result.

Route and method of administration:
This drug is administered to your vein through a proper plastic pipe (set).

Different age groups
Pediatric use:
The dosage and the size of the administration for children will be decided by the doctor that recommends the administration.

Use in the elderly:
Application dose and application rate is adjusted by the physician according to severity of patient, clinical and biological condition and combined treatment applied as in adults.

Conditions of special use:
No special conditions of use.

If you have an impression that effect of POLİFLEKS 10% DEXTROSE is too strong or too weak, consult your physician or pharmacist.

In case you have used POLİFLEKS 10% DEXTROSE in an amount more than you should:
Consult a doctor or a pharmacist if you have used POLİFLEKS 10% DEXTROSE in an amount more than you should.

Among typical starting signs of overdose, increase of water level in body, increase in blood glucose, decrease in blood values (hemoglobin and hematocrit), decrease in salt density in blood and increase in blood density are included.

In case of overdose in patients with normal kidney functions, urine outtake is increased and consequently body salt is lost. Depending on increase of urine outtake, (dehydration) with various degrees occurs in body.

Signs relating to over loading of blood circulation, in cases where urine outtake is not increased, may be observed (water collection in body and decrease in intracellular potassium levels)

Talk to a doctor or pharmacist if you have used more than you should use from POLİFLEKS *10% DEXTROSE.*

In case you forget to take POLİFLEKS 10% DEXTROSE:
Do not take double dose to balance the skipped dosage.

Possible effects related to the termination of the treatment with POLİFLEKS 10% DEXTROSE:
None

4. Possible side effects

Like all drugs, POLİFLEKS 10% DEXTROSE can cause adverse effects in individuals who are sensitive to the contents.

Side effects are listed as shown in the below mentioned categories:

- Common: It may be seen less than 1 of 10 patients, but more than 1 of 100 patients.
- Uncommon: It may be seen less than 1 of 100 patients, but more than 1 of 1000 patients
- Rarely seen: It may be seen less than 1 of 1000 patients, but more than 1 of 10.000 patients

Stop using POLİFLEKS 10% DEXTROSE and inform your doctor IMMEDIATELY or apply to the emergency room of the nearest hospital in case you encounter one of the following:

- Itchy rashes/bulging, burning sensation on area where the medication administered;
- Breathing problems, breathe noisy, pain in chest;
- Extreme heat or cold sense;
- Distention on hands, feet, lips, face or all over the body;
- Dizziness, lightheadedness;
- Heart-throb.

These are all very serious adverse effects.

Having any of the above means that you are seriously allergic against POLİFLEKS 10% DEXTROSE. Emergent medical intervention or hospitalization can be necessary.

All of these very serious adverse effects are seen rather rarely.

Inform your doctor in case you encounter any of the following:

- Common side effects:
- Defects in salt (electrolyte) levels in body.
- Increase in blood glucose (hyperglycemia)

Uncommon side effects:

- Blood dilution (hemodilution)
- Blisters on your body or on your arm or legs (edema), depends on increasing amount of liquid in the body (hypervolemia), breathe excessively, difficulty in breathing, difficulty in breathing when sleeping or ascending a ladder (congestive heart failure symptoms).
- Reactions as fever, trembling, etc.
- Inflammation on applied area.
- Sugar in urine

- Sweating.

Rarely seen side effects:
- Allergic reactions (based on the drug added into solution).
- Stiffness, blushes or panicula through your venous blood vessel starting from applied area (thrombophlebitis).

All of the above are serious adverse effects.

In case you encounter any adverse effects not mentioned in these PATIENT INFORMATION LEAFLET, please inform your doctor or pharmacists.

5. How to store POLİFLEKS 10% DEXTROSE

Keep POLİFLEKS 10% DEXTROSE in places out of sight and reach of children and within the original packaging.

Keep at temperatures under 25°C.

Single use only. Partially used bags should not be stored; must be disposed according to the medical waste procedures of the healthcare organization where application takes place.

The expiry date is written on the label of each bag. This drug will not be administered to you is this data has expired.

Use the drug according to the expiry date.

Do not use POLİFLEKS 10% DEXTROSE after the expiry date shown on the packaging.

Do not dispose of expired or unused drugs! Give to the collection system determined by the Ministry of Environment and Urbanization.

Marketing Authorisation Holder and Manufacturer:

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These PATIENT INFORMATION LEAFLET have been approved on 25.09.2019.

THE FOLLOWING INFORMATION IS FOR THE HEALTHCARE PERSONNEL WHO WILL ADMINISTER THIS DRUG

Solution should be administered through performing aseptic technique by means of sterile application set. Before administration, liquid should be passed on the application set in order to prevent air admission.

Additional medications may be administered before or during the infusion by means of a needle from its injection point in aseptic conditions. Isotonicity of the final product should be determined before parenteral application.

Additional medication and the solution must be fully mixed before administering it to the patient. Solutions including additional medication must be used immediately after administering medication; should not be stored to use later.

Administering additional medication to the solution or misapplication technique may cause fever reaction based on pyrogen contamination to the product. In case of an adverse reaction, infusion should be stopped immediately.

Single use only.

Partially used solutions should not be stored.
Partially used bags should not be connected to the systems applied to patient.

To open:
1. Check over the stability of outer package and unexpected leakages; if the package is damaged, do not use it.
2. Tear protective outer package open.
3. Check over the stability of bag within the protective package by squeezing it. Check the clearness of the solution and whether there is foreign matter.

Application preparations:
1. Hang up the bag.

2. Remove the protective cap on the application point.
3. Press the spike of application set into the application point.
4. Personnel should follow the instruction manual in order to administer solution to a patient.

Administering additional medication:

Warning: All matters that will be administered to product must be compatible with the product, as in all the parenteral solutions. If any administration will be performed, its compatibility with final mixture should be controlled before giving it to the patient.

Administering medication before application

1. Medication application point is disinfected.
2. Additional medication is administered into a bag by means of an injector that has a needle with 19-22 gauge thickness.
3. Solution and additional medicine is mixed well. While mixing condensed medication as Potassium Chloride, you should tap at application outflow of the bag on its upright position in order to blend it well.

Warning: Bags contain additional medicine should not be stored.

Administering additional during application

1. Clamp of the set is closed.
2. Medicine administration point is disinfected.
3. Additional medication is administered into a bag by means of an injector that has a needle with 19-22 gauge thickness.
4. Solution is removed from its sling and turned upside down.
5. On this position, application outflow and injection intake is tapped in order to mix additional medicine well.
6. Clamp is opened and bag is returned to its previous condition, and application continues.