PATIENT INFORMATION LEAFLET

POLİFLEKS 50% DEXTROSE SOLUTION FOR IV INFUSION

Active ingredient: Each liter contains 500 g dextrose anhydrous.

Excipients: Sterile water for injection

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

- *Keep this 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 50% DEXTROSE and what is it used for?

POLİFLEKS 50% DEXTROSE **administered intravenously** for the replacement of the carbohydrates lost from the body or cannot be taken in adequate amounts orally, and to meet the energy requirements of the body partially.

POLİFLEKS 50% DEXTROSE is offered within PVC and PP bags with volumes 100, 150, 250, 500 and 1000 ml in two forms, with and without sets.

It is used in pre- and postoperative conditions or in conditions that oral food and fluid intake is restricted including severe liver, kidney, cardiac and gastrointestinal system diseases, and together with a suitable protein in conditions where absorption of proteins in the gastrointestinal system or in conditions including burns where the protein need of the body increases excessively.

POLİFLEKS 50% DEXTROSE that can be used in some conditions that blood glucose levels fall to low levels, can also be used in the treatment of some other conditions that the body becomes dehydrated (restricted water intake and some excessive volume loss in conditions including diarrhea, vomiting or excessive urination) since it provides water together with calories.

POLİFLEKS 50% DEXTROSE is also used for the dilution of some drugs suitable for intravenous administration found in concentrated forms.

This drug is only used intravenously through a plastic pipe (set) intended for this use.

2. Before you are given POLİFLEKS 50% DEXTROSE

POLİFLEKS 50% DEXTROSE is a safe drug for many patients. However, if you have problems with your heart, kidneys, liver or lungs or if you are diabetic, your doctor may decide not to apply this drug to you.

DO NOT USE POLİFLEKS 50% DEXTROSE under the following conditions
If you have responded to any drug including dextrose, which is the active ingredient, or to inactive ingredients with hypersensitivity, that is, if you have experienced sudden stopping of breathing, skin rashes, itching or swelling in your body, DO NOT USE THIS DRUG.

In addition, if you are allergic against products with corn origin, DO NOT USE THIS DRUG.
If you are not sure if you are allergic, please consult your doctor.

This drug must not be used under the following conditions:

- Intracranial bleeding,
- Severe dehydration of the body,
- Inability of urination (conditions of anuria)
- Hepatic coma

USE POLİFLEKS 50% DEXTROSE under the following conditions
If,
• You have latent or overt diabetes or you are intolerant against carbohydrates with any reason,

• If the amount of salt in your body is low,
• If you have cardiac insufficiency (you might have excessive accumulation of fluid in your body),
• If you have renal failure (you can be less tolerant against sugar),
This drug will be administered to you with care.

Furthermore, this drug will be administered to the newborns also with care (it can cause density increase in the fluid part of the body and consequent increase in the risk of intracranial bleeding).

The doctor managing your treatment can re-examine you when you are using the drug, or particularly if the intravenous therapy is extended, and several blood tests can be carried out.

It is recommended that the hoses (sets) used to administer this drug to you will be changed every 24 hours.

Moreover, the solution must be used only if the bag is intact and not leaking, and if the solution is clear.

Use of POLİFLEKS 50% DEXTROSE with foods or drinks
POLİFLEKS 50% DEXTROSE is a drug administered intravenously, and does not interact with foods or drinks anyway as regards the mode of administration.

Pregnancy
Please consult your doctor or pharmacist before using this drug.

Do not use POLİFLEKS 50% DEXTROSE during pregnancy unless otherwise is recommended by your doctor.

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

Lactation
Please consult your doctor or pharmacist before using this drug.

If you are breast-feeding your baby, please inform your doctor about this matter. Do not take POLİFLEKS 50% DEXTROSE during pregnancy unless otherwise is recommended by your doctor.

Driving and using machines
POLİFLEKS 50% DEXTROSE does not have any affects on using vehicles or machines.

Some important information about the inactive ingredients of POLİFLEKS 50% DEXTROSE
If you are no sensitive against the ingredients of POLİFLEKS 50% DEXTROSE no adverse effects are expected in relation with these substances.

Taking other medicines
If you intend to use, using or have recently used any drugs including OTC drugs, vaccines or herbal drugs, please inform your doctor.

POLİFLEKS 50% DEXTROSE is incompliant with some drugs. Such drugs known to be incompliant must not be added to this solution, and other solutions must be preferred for infusion. In order to minimize the risk or incompliance with any drug, the final mixture must be checked if there is any turbidity or precipitation by a healthcare personnel right after mixing, before administration and with certain intervals during the administration.

POLİFLEKS 50% DEXTROSE must be used with care in patients using steroid drugs.

If you are currently using, or have used recently any prescribed drug or and OTC please inform your doctor or pharmacist about it.

3. How POLİFLEKS 50% DEXTROSE will be given?

Instructions related to proper use and dosage/application frequency:
Your doctor will decide when you need this drug and it will be administered to you. S/he will decide this based on your age, body weight and the reason for administration. Follow the instructions of your doctor until s/he gives other instructions.

Do not forget to take your drug in time.

Your doctor will inform you about the period of treatment with POLİFLEKS50% DEXTROSE. Do not stop treatment early as you will not be able to get the intended benefit this way.

Route and method of administration:
Applied to your veins by using an appropriate plastic pipe (set)

Different age groups:
Use in children:
For children, the doctor who suggests the application will decide on the dosage and size of the application set.

Geriatric use:
Dosage to be applied and administration speed will be adjusted by the physician depending upon the weight, clinical and biological condition of the patient and the treatment provided simultaneously as for adults.

Special Uses:
There are no special uses.

*If you consider that the effect of **POLİFLEKS 50% DEXTROSE** is too strong or weak, please consult your doctor or pharmacist.*

If you have exceeded the amount of POLİFLEKS 50% DEXTROSE you should have taken:
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The typical signs of overdose include increase in the fluid amount o0f the body, increase in blood sugar level, decrease in blood values (hemoglobin and hematocrit), decrease in salt amount in blood and increase in the density of blood.

In patients with normal kidney functions, urinary output will increase in overdose, and loss of salts from the body will accompany this. Dehydration in various levels will occur in the body in relation with the increase in the urinary output.

If the amount of urine is not increased, signs related to over-loading of the blood circulation can be seen (fluid accumulation in the body and decrease in the intracellular potassium levels).

If you forget to take POLİFLEKS50% DEXTROSE:
Do not take double dose to compensate the dosages forgotten.

Effects that can occur when therapy with POLİFLEKS 50% DEXTROSE is stopped:
None

4. Possible side effects
Like all drugs, adverse effects can be seen in individuals who are sensitive against the substances included in the contents of POLİFLEKS50% DEXTROSE.

Adverse effects are sequenced in the categories given below.
Common: Can be seen less than 1 patient out of 10, but can be seen in more than 1 patient out of 100.

Uncommon: Can be seen less than 1 patient out of 100 but can be seen in more than 1 patient out of 1000.
Rare: Can be seen in less than 1 patient out of 1000 but can be seen in more than 1 patient out of 10.000.

In case of any of the following, stop taking POLİFLEKS 50% DEXTROSE and immediately inform your doctor or apply to the emergency room of the nearest hospital:

- Itchy redness/swelling or burning sensation in the administration site,
- Difficulty in breathing, wheezing, or chest pain,
- Hot or cold feelings in the body
- Swelling of hands, feet, lips, face or whole body,
- Vertigo or sense of fainting
- Palpitation

These are all very serious side effects.

If you have any of these, it means you are seriously allergic to POLİFLEKS50% DEXTROSE. Urgent medical attention or hospitalization may be required.

All of these very serious side effects occur quite rarely.

If you notice any of the followings, immediately inform your doctor or apply to the emergency room of the nearest hospital:

Common side effects:
- Impairment of the salt (electrolyte) levels in the body
- Increase in blood sugar level (hyperglycemia)

Uncommon side effects:
- Dilution of blood (hemodilution)
- Accumulation of fluid (edema) in your arms or legs related to fluid amount in the body (hypervolemia), rapid respiration, difficulties in breathing, difficulty of breathing when lying down or climbing stairs (signs of congestive heart failure)
- Reactions including fever or chills,
- Inflammation in the administration site
- Glucose excretion with urine
- Sweating

Rare adverse effects
- Allergic reactions (related to the drug within the solution)

- Hardness, redness or swelling extending throughout your veins starting from the administration site (thrombophlebitis)

These are all very serious side effects. Urgent medical attention may be required.

Please inform your doctor or pharmacist in case you experience any adverse effect not included in this PATIENT INFORMATION LEAFLET.

5. How to store POLİFLEKS 50% DEXTROSE

Keep POLİFLEKS 50% DEXTROSE outside the sight and reach of children.

Keep at room temperature under 25°C.

For single use. The partially used bags must not be kept, and must be discarded according to the medical waste procedures of the healthcare facility.

The expiry date is indicated on the label of each bag. This drug shall not be administered to you if this date is expired.

Please use according to the expiry date.

Do not use POLİFLEKS 50% DEXTROSE beyond the expiry date shown on the packaging.

Marketing Authorisation Holder and Manufacturer:
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These PATIENT INFORMATION LEAFLET have been approved on 19/03/2014.

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

This medical product has been prepared for only intravenous use in sterile devices and sets. It must be used only with aseptic technique through intravenous infusion.
It is intended for single use. The partially used bags must not be kept, and must be discarded according to the medical waste procedures of the healthcare facility.

Parenteral drugs must be checked visually before use; only the products those are clear, containing no particles and intact packaging must be used.
Do not remove the outer protection until immediately before administration. Start administration right after to remove the protection. The protective outer sheath protects the product from decrease in fluid level because of vaporization of the product. The inner bag ensures the maintenance of sterility.

Attention: To avoid air embolism that might occur due to the residual air in the bag, no serial connection should be made with other infusion liquids.

To open:

- Remove the external cover immediately before use. The cover is opened by tearing and the bag is exposed. Start the administration immediately after removing the cover.
- A little opacification may occur in the bag depending upon the sterilization operation. This is normal and does not affect the quality and reliability of the solution. Opacity will lose within time.
- Check the strength of the bag by squeezing it after taking it out from the packaging. If there is any leak, the product should not be used as its sterility might have been impaired.

Preparations for administration

1- Hang the bag

2-Remove the protective cap on the administration tip

3-Tightly dip the spike of the administration set to the administration tip and attach the administration set to the bag.

4-For the administration of the solution to the patient, PATIENT INFORMATION LEAFLET of the set should be respected.

Inclusion of additional drug:

Attention: As in all parenteral solutions, all substances to be included in the product should be compatible with the product. If any other substances are to be added to the product, the compatibility in the last mixture should be checked before being administered to the patient.

Inclusion of drug before administration

1-Drug administration tip of the bag is disinfected.

2-Drug to be included is added into the bag by an injector that has a needle of 19-22 gauge thickness.

3-Solution and the drug included are stirred thoroughly. In case of high-density drugs such as potassium chloride, gently tap on the administration outlet of the bag in the upper position to ensure the drug is fully mixed with the solution.

Attention: The bags in which additional drugs were added should not be kept.

Inclusion of drug during administration

1-Clamp of the set is closed.

2- Drug administration tip is disinfected.

3- Drug to be included is added into the bag by an injector that has a needle of 19-22 gauge thickness.

4-Solution is removed from the hook and reversed.

5- In this position, gently tap on the administration outlet of the bag and injection inlet to ensure that the additional drug and solution is fully mixed.

6-Restore the bag to its original condition, open the clamp and resume the administration.

COMPLIANCE WITH OTHER INTRAVENOUS DRUGS

Do not mix this product with other drugs until its compliance is proven.

AFTER THE ADMINISTRATION

Dispose of unused product or wastes according to the instructions