PATIENT INFORMATION LEAFLET

POLİFLEKS İZOLEN-M 5% DEXTROSE SOLUTION FOR IV INFUSION
Used intravenously

Active ingredients: Each 100 ml of solution contains 5 g glucose (dextrose anhydrous), 0.28 g sodium acetate, 0.15 g sodium chloride, 0.13 g dibasic potassium phosphate and 0.091 g sodium chloride

Excipients: Sodium bisulfate and 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 İZOLEN-M and what is it used for*?**
POLİFLEKS İZOLEN-M is a solution used **intravenously** to treat or prevent the condition of water and salt deficiency (dehydration) in the body. It is helpful in the replacement of water and some substances called electrolytes and also provide some calories.

POLİFLEKS İZOLEN-M is available in PVC and PP bags with volumes 250, 500 and 1000-ml PVC and PP bags with or without sets.

POLİFLEKS İZOLEN-M is a solution that contains electrolytes that are building blocks of the body and it is administered intravenously. It glucose (sugar) content provides some calories.

It is a solution used intravenously.

POLİFLEKS İZOLEN-M is used in the treatment of fluid losses accompanied by decreased fluid intake, in over sweating, diarrhea and vomiting to replace the fluid and elements required.

Furthermore, this is a solution preferred in patients recovering after burns, patients with inflammatory bowel disease (ulcerative colitis), narrowed gastric outlet (chronic pylor obstruction), and for the replacement of potassium losses related to these disorders. Furthermore, it is also used in cases where blood had slightly shifted to the acidic side as a result of the anabolic/katabolic procedures carried out in the body (mild metabolic acidosis) and to dilute some drugs suitable for intravenous administration before administering.

2. *Before you are given* POLİFLEKS İZOLEN-M
POLİFLEKS İZOLEN-M is a safe drug in many patients. However, if you have problems in your heart, kidneys, liver or lungs, if you are diabetic or if you have swelling (edema) in your body related to excessive salt accumulation in your body, your doctor can decide not to administer this drug to you.

DO NOT USE POLİFLEKS İZOLEN-M under following conditions:
In case you have had allergic reaction when you took drugs containing the same active substances or inactive ingredients with POLİFLEKS İZOLEN-M, that is, if you have experienced sudden stopping of breath, wheezing, skin rashes, itching or swelling in your body, DO NOT USE this drug. Consult your doctor if you are not sure you are allergic.

The solution must not be used under the following conditions:

- Patients urinating too little amounts or none at all (anuria, severe oliguria); renal failure.

- A group of symptoms seen with the crushing of the muscle mass in the body in wars, accidents, slides in mines, industrial and traffic accidents (Crush syndrome).
- Destruction of red blood cells in circulation (severe hemolysis).
- Adrenal grand failure.
- Conditions that the parathormone levels are low in blood (hypoparathyroidism).
- Some cardiac diseases (cardiac block).
- Shift of normal pH of blood to the basic side (alkalosis).
- Hypersensitivity against sulfites and products with corn origin.

Use POLİFLEKS İZOLEN-M CAREFULLY under following conditions:
If you have any of the following diseases:

- Cardiac diseases (particularly if accompanied by a renal disease);
- If the circulating blood volume has increased (hypervolemia);
- If there is the possibility of cardiac failure, or if you have overt cardiac failure (particularly if you are in postoperative period or elderly);
- If your blood pressure is high;
- Accumulation of fluid in your body, extremities or lungs (edema);
- If your kidney functions are impaired, or if you have urinary obstruction because of stones or similar reasons in your kidneys or urinary tract;
- Conditions that increase predisposition for over-accumulation of potassium including acute dehydration with sudden onset, some renal diseases and serious burns;
- If you have diabetes, if you have covert diabetes or intolerance against carbohydrates with any reason;
- If pH of your blood has shifted to the basic side in relation with the anabolic/katabolic events or respiratory diseases (metabolic or respiratory alkalosis);
- If you have liver failure; in such cases, your doctor will pay extra attention when administering POLİFLEKS İZOLEN-M to you.

If you are currently under treatment with cardiac drugs in the digitalis group, your treatment will be continued with frequent electrocardiograms.

In addition, if you have excessive electrolyte loss with some reasons, your doctor will wish to administer electrolytes to you in addition to this drug; s/he can also wish to add other minerals and vitamins to your treatment.

This solution will be administered to you rather slowly. Furthermore, if blood transfusion will be administered to you simultaneously, administration of POLİFLEKS İZOLEN-M through the same set with blood is not recommended.

If this drug will be administered to you through an electronic pump, it must be ensured that the operation of the pump stops before complete emptying of the bag.

Administration of this drug requires changing of the pipes (sets) every 24 hours.
Furthermore, this drug must be used only if the bag is intact and the contained solution is clear.

Use of POLİFLEKS İZOLEN-M together with foods and drinks
POLİFLEKS İZOLEN-M is a drug administered intravenously; and it does not interact with foods and drinks in relation with the route of its administration.

Pregnancy
Consult your doctor or pharmacist before using this drug.

Do not use POLİFLEKS İZOLEN-M during pregnancy unless specifically recommended 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 your baby, inform your doctor about this. Do not use POLİFLEKS İZOLEN-M during lactation unless specifically recommended by your doctor.

Driving and use of machines
POLİFLEKS İZOLEN-M has no effects on driving or using machines.

Important information about some ingredients of POLİFLEKS İZOLEN-M
No adverse effects are expected related to the inactive ingredients included in the contents of POLİFLEKS İZOLEN-M unless you are hypersensitive against such substances.

Since POLİFLEKS İZOLEN-M contains 0.021 g sodium bisulfate in each 100 ml as preservative, it can rarely cause severe hypersensitivity reactions or bronchospasm.

Taking other medicines
If you plan to take, currently taking or have taken recently any other drugs also including OTCs, vaccines or herbal drugs please inform your doctor.

POLİFLEKS İZOLEN-M is incompatible with some drugs. The drugs known to be incompatible must not be added to the solution, and other solutions must be preferred to dilute such drugs.

With the purpose of minimizing the potential incompatibility risk with any other drugs that might be added to the solution, the healthcare personnel will check if there is any turbidity or

sedimentation right after mixing, just before administration and with certain intervals during administration.

Effects of the following drugs must be taken into consideration if to be used together with POLİFLEKS İZOLEN-M.

- Corticoids/steroid and carbenoxolone (related to the risk of retention of sodium and water).
- Diuretics including amiloride, spironolactone or triamterene singly or in combination (because of the risk of sodium accumulation in the body).
- Anti-hypertensive drugs including angiotensin converting enzyme inhibitors and possible anjiyotensin II receptor antagonists (because of the risk of sodium accumulation in the body).
- Immunosuppressants including tacrolimus and cyclosporine (because of the risk of sodium accumulation in the body).

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

3. How POLİFLEKS İZOLEN-M will be given?

Instructions for proper use and dosage/application intervals:
Your doctor will decide the amount of this drug that you need and the time of application. S/he will consider your age, body weight and the reason for the administration of this drug will also be considered. Follow these instructions unless otherwise is recommended by your doctor.

Do not forget to take your drug in a timely manner.

Your doctor will inform you about the period of your treatment with POLİFLEKS İZOLEN-M. Do not stop the treatment earlier, because if you do, you will not obtain the expected results.

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

Pediatric use:
It is not recommended for children (İZOLEN-P must be preferred).

Use in the elderly:
Since decrease of the liver, renal and cardiac functions are more frequent in the elderly and the frequency of co-morbidities or using other drugs concomitantly is also higher, dose

selection generally requires more attention by choosing the possible lowest limit of the dose range.

Since this drug is largely eliminated through the kidneys, the risk of advers effects of the drug will increase where the renal functions are impaired. Since the decrease in renal functions is greater in the elderly, care must be given in the selection of dosage and renal functions must be monitored during treatment.

• **Conditions of special use:**
Renal/hepatic impairment
Since this drug is largely excreted through the kidneys, the risk of appearance of the harmful effects of the drug will increase in cases where renal functions are impaired.

In case you have the impression that the effect of POLİFLEKS İZOLEN-M is too strong or too weak, consult your doctor or pharmacist.

In case you had used POLİFLEKS İZOLEN-M in an amount more than you should:
Consult a doctor or a pharmacist if you had used POLİFLEKS İZOLEN-M in an amount more than you should.

In case you forget to take POLİFLEKS İZOLEN-M:
Do not take double dosage to balance the skipped dosage.

Possible effects related to the termination of the treatment with POLİFLEKS İZOLEN-M:
None

4. Possible side effects
Like all drugs, POLİFLEKS İZOLEN-M can cause adverse effects in individuals sensitive to the contents.

In case you encounter any of the following, stop using POLİFLEKS İZOLEN-M, and inform your doctor immediately or apply to the emergency room of the nearest hospital:

- Itchy redness/pustules or burning sensation at the administration site;
- Respiratory distress, wheezing, chest pain
- Feeling too hot or too cold;
- Swelling in hands, feet, lips, face or in whole body;
- Vertigo, feeling of fainting;
- Palpitation.

These are very serious adverse effects.

If any of the above is present in you, this will mean that you are seriously allergic against POLİFLEKS İZOLEN-M. Emergent medical intervention or hospitalization can be required.

In addition, it signs including fever or chills appear during the administration (febrile reaction), IMMEDIATELY inform your doctor; s/he can stop the treatment in this case and make emergent intervention.

All these very serious adverse effects are seen rather rarely.

Frequency of the following adverse effects are not known (they are seen in too small numbers of patients that the available data do not allow determination).

In case you encounter any of the following, stop using POLİFLEKS İZOLEN-M, and inform your doctor immediately or apply to the emergency room of the nearest hospital:

- Inflammation at the administration site, hardness, redness or swelling starting from the administration site and spreading along the vein.
- Fluid accumulation in your body or extremities (edema), difficulty of breathing, shortness of breath when lying down or climbing the stairs (congestive cardiac failure symptoms)
- Too slow or too rapid heartbeats, feeling of compression iğn the chest, chest pain
- Numbness in your limbs, loss of reflexes, muscular or respiratory paralysis, somnolence, fatigue, hypotension, arrhythmia, electrocardiographic abnormalities (signs and symptoms of potassium intoxication).
- Frequent breathing, cyanosis

All these are very serious adverse effects that might require emergent medical intervention.

Inform your doctor in case you become aware of the following:

- Nausea, vomiting
- Abdominal pain
- Diarrhea

These are mild side effects of POLİFLEKS İZOLEN-M.

In case you experience any adverse effect not mentioned in these PATIENT INFORMATION LEAFLET, immediately inform your doctor or pharmacist.

5. How to store POLİFLEKS İZOLEN-M

Keep POLİFLEKS İZOLEN-M in places out of the sight and reach of children and within its packaging.

Keep at temperatures under 25°C.

It is for single use. 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 shown on the label of each bag. This drug will not be administered to you if this date had expired.

Comply with the expiry date when using.

Do not use POLİFLEKS İZOLEN-M after the expiry date shown on the packaging.

Do not use POLİFLEKS İZOLEN-M if you notice any impairment of the product and/or packaging.

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This patient information leaflet has been approved on 18/03/2014.

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

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The solution must be checked before administration.
Administration must be made intravenously using sterile/non-pyrogen sets.

Use only clear products not containing particles within intact packaging.

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

The outer bag must not be removed until right before the use.

To prevent any air embolism related to the residual air in the bag, no serial connection must be established with other infusion fluids.

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

Additional drugs can be mixed from the injection end with the help of a needle under aseptic conditions before or during the infusion.

Isotonicity of the end product must be determined before the parenteral administration.

The added drug must be completely mixed before being administered to the patient. Solutions containing additional drugs must be used immediately after mixing, and must not be maintained to be used later.

Adding drugs to the solution or wrong application technique can cause fever reaction related to contamination of the drug with pyrogens. Infusion must be stopped immediately in case of any adverse effects.

It is for single use. Any portion left must be discarded. Partially used drugs must not be connected to systems applied to patients again.

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.
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 PATIENT INFORMATION LEAFLET of the set must be followed when administrating solution to the patients.

Mixing additional drugs:

Caution: Like 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 solution, compatibility in the final mixture must be checked before administration to the final mixture.

Addition of 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.

Adding 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. Restore the bag, open the clamp and resume the administration.