PATIENT INFORMATION LEAFLET

POLİFLEKS 20% MANNITOL SOLUTION FOR I.V. INFUSION
For Intravenous use
Sterile

Active ingredients: Each 1 liter solution contains 200 grams of mannitol.
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 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 20% MANNITOL and what is it used for?

POLİFLEKS 20% MANNITOL contains the active substance called diuretic effective mannitol and is **an intravenous solution.**

It increases quantity of urine decreased due to a group of diseases or causes production of urine not produced at all. It is also used to reduce the elevated intracranial pressure and intraocular pressure or to encourage discharge of agents discharged from the kidneys in case of intoxication with such agents.

POLİFLEKS 20% MANNITOL is available in PVC and PP bags of 100, 150, 250, 500 and 1000 ml. It has two form and a set and without set.

The drug is administered only in the vein and through a plastic pipe (set) appropriate for this purpose.

2. Before you are given POLİFLEKS 20% MANNITOL

DO NOT USE POLİFLEKS 20% MANNITOL under following conditions:

If you had an allergic reaction when you took the drugs containing the active matters or auxiliary agents contained in POLİFLEKS 20% MANNITOL previously, namely if you had symptoms of sudden stop of breath, stertorous respiration, skin eruptions, itch or distention on your body etc., DO NOT USE this drug.

If you are not sure if you have allergy, consult with your doctor.

The solution must not be used in the following cases:

- Where intensity of the liquid part of your blood is already higher than normal level (hyperosmolarity).
- If your body is dehydrated severely (severe dehydration).
- If you have not urine for a long time.
- If you have severe heart failure.
- In case plenty of liquid accumulation in your lungs, arms, legs or whole body (severe edema).
- If you suffer from intracranial bleeding.
- If your blood-brain barrier was disordered.

Use POLİFLEKS 20% MANNITOL in the following conditions:

If you have one of the diseases below:

- Disorder in kidney functions, kidney disease or kidney failure;
- Heart disease or heart failure;
- Lung disease;
- Shock or if you take a drug which may give damage to your kidneys, your doctor shall pay due attention in administration of POLİFLEKS 20% MANNITOL to you.

If this drug shall be administered to you through an electronic pump, it is required to make sure that operation of the pump stopped before full discharge of the bag.
This drug shall be administered to you only if its bag is sound and the solution in it is clear.

It is recommended to replace the pipes (sets) used in every 24 hours when this drug is administered to you.
If you require blood transfusion concurrently, it shall not be administered from the same set used for POLİFLEKS 20% MANNITOL.

Please consult your doctor if these warnings are valid for you, even at any time in the past.

Use of POLİFLEKS 20% MANNITOL with foods and beverages
POLİFLEKS 20% MANNITOL is a drug administered in a vascular way; it has no interaction with foods and drinks in terms of method of administration.

Pregnancy
Consult your doctor or pharmacist before using this drug.
If it is not seen appropriate by your doctor specifically, do not use POLİFLEKS 20% MANNITOL in the pregnancy period.
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 breastfeed your baby, inform your doctor. If it is not seen appropriate by your doctor specifically, do not use POLİFLEKS 20% MANNITOL in the breastfeeding period.

Ability to drive and use machines
POLİFLEKS 20% MANNITOL has no effect on use of vehicle or machine.

Vital information regarding some of the excipients contained in POLİFLEKS 20% MANNITOL SOLUTION

If you have no sensitivity to the auxiliary agents in POLİFLEKS 20% MANNITOL, no adverse effect is expected in connection with these agents.

Use in combination with other drugs
If you plan to buy, if you buy or have recently bought any other drug including drugs, vaccines and herbal drugs bought without prescription, please inform your doctor.

POLİFLEKS 20% MANNITOL is impermeable in some drugs. These drugs which are known to be impermeable must not be added in the solution; other solutions must be preferred for diluting these drugs.

Effect of this drug may increase if it is used with other diuretic s. therefore; dose setting may be required in case of collective use.

POLİFLEKS 20% MANNITOL may increase the speed of discharging some drugs discharged from the body with urine (e.g. lithium and methotrexate). Therefore, sufficient response may not be taken for these drugs in case of collective use.

Collective administration may cause increase in harmful effect of the drug being used due to possible changes in the liquid balance of POLİFLEKS 20% MANNITOL for the patients using some drugs which may be harmful for kidneys. Therefore, the patients who collectively take a drug suppressing the immune system called as cyclosporine must be closely monitored in terms of these harmful effects.

In addition, although there is limited information about incidence in human beings, effects of the following drugs must be considered during use of POLİFLEKS 20% MANNITOL with these drugs:

- Possible interactions with the aminoglycoside group:

Harmful effects of these drugs on hearing may increase when they are used with POLİFLEKS 20% MANNITOL

- Possible interactions with some myorelaxant drugs (depolarizing neuromuscular blocker drugs):

Effects of these drugs may increase when they are used with POLİFLEKS 20% MANNITOL.

- Possible interactions with the orally administered blood diluent drugs (oral anticoagulants):

Effects of these drugs may decrease when they are used with POLİFLEKS 20% MANNITOL due to increased intensity of the coagulation factors in the blood in connection with its effect to reduce water in the body.

- Interactions with the digoxin which is a heart drug:

There is an intoxication risk in connection with this drug in case of reduction in the potassium levels in the blood after treatment with POLİFLEKS 20% MANNITOL (hypokalemia).

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.

3. How you will be given POLİFLEKS 20% MANNITOL?
Instructions regarding correct use and dosage/administration frequency:

Your doctor shall decide the quantities of this drug that you need and time to administer it to you. He shall decide it depending on your age, body weight and reason for administering this drug to you. Follow up these instructions unless your doctor gives a separate recommendation to you.

Do not forget to take your drug timely.

Your doctor shall inform you about period of your treatment with the POLİFLEKS 20% MANNITOL. Do not discontinue treatment earlier because you may not get the desired result.

Method of administration:
It is used through a plastic pipe (set) appropriate for your veins.

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

Use in elderly:
As the kidney functions might have been started to be disordered, this situation is considered before deciding dose.

Special usage cases:
Hepatic impairment:
If you have a severe kidney failure, a test dose shall be administered to you firstly and administration shall be started only if you sufficiently urinate after this dose.

If you have the impression that the effects of POLİFLEKS 20% MANNITOL is too powerful or too weak, *consult your doctor or pharmacist.*

In case you had used POLİFLEKS 20% MANNITOL in an amount more than you should:
Consult a doctor or a pharmacist if you had used POLİFLEKS 20% MANNITOL in an amount more than you should.

In case you forget to take POLİFLEKS 20% MANNITOL:
Do not take double dose to balance the skipped dosage.
Possible effects related to the termination of the treatment with POLİFLEKS 20% MANNITOL:
None

4. Possible side effects

Like all drugs, POLİFLEKS 20% MANNITOL can cause adverse effects in individuals who are sensitive to the contents.

If you are aware any of the followings, please inform your doctor immediately or consult with the emergency unit of the closest hospital:

Uncommon side effects (those which may be seen in one person out of 100 to 1.000 persons):

- Disorders in the water and ion balance of your body
- Hypotension
- Hardness, redness or swelling, bruising (thrombophlebitis) starting from the section of administration along with your veins

Rare ones (those which may be seen in one person out of 1.000 to 10.000 persons):

- A kind of shock case occurred with the symptoms of swelling in hands, feet, lips, face or whole body, respiration problem, stertorous respiration, breast ache, dizziness, feel of faint, sudden drop in tension etc. (anaphylactic shock)
- Convulsion
- Increase in intracranial pressure
- Disorder in your heartbeat rhythm, your heart performing faster or slower than the normal level
- Dropsy in your lungs (pulmonary edema)
- Dropsy in your arms or legs or whole body (edema)
- Hypertension
- Dehydration
- Excessive urinating and relative kidney disease (osmoticnephrosis)
- Allergic reactions
- Bulges from place to place on your skin (hives)
- Headache
- Dizziness / drowsiness
- Sight blurriness
- Muscle cramps
- Xerostomia, thirst, nausea, vomiting
- Breast ache
- Shaking, fever, cold
- Loss of liveliness in the area where the drug is administered (skin necrosis)

Very rare ones (those which may be seen less than one person out of 10.000 persons):

- Difficulty in your breathing, difficulty in breathing when lying on the bed or climbing up stairs (symptoms of congestive heart failure)
- Accumulated urine in your body, sudden kidney failure.

All of the above are serious adverse effects and may require immediate medical attention.

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 20% MANNITOL

Keep POLİFLEKS 20% MANNITOL in places out of sight and reach of children and within the original packaging.
Store at room temperature below 25°C. Do not freeze.

This drug is intended for single use. Partially used bags should not be kept and they should be disposed in accordance with the medical waste procedures of the healthcare institution where the administration was applied.

The expiry date is written on the label of each bag. This drug will not be administered to you is this date has expired.
Use in accordance with its expiry date.

Do not use POLİFLEKS 20% MANNITOL 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.

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

The solution must be checked before administration.

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.

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.

This drug is intended for single use.
Partially used solutions must not be kept.
Do not connect partially used bags to systems applied to patients.

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 by squeezing if the bag within the protective packaging is intact. 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 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: Do not keep the bags in which additional drugs were added.

Mixing 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, clamp will be opened and administration will be continued.