PATIENT INFORMATION LEAFLET

POLİFLEKS 5 % MANNITOL SOLUTION FOR UROLOGIC IRRIGATION
Used for washing.
Sterile

Active ingredients: Each 1lt solution contains 5 grams mannitol.
Excipients: ***W***ater 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 5 % MANNITOL SOLUTION and what is it used for?

POLİFLEKS 5 % MANNITOL is a microbe-free solution used for washing and cleaning the bladder and urinary tracts.

It is available in plastic bags of three liters.

It is preferred as a washing solution instead of water to prevent harmful effects of the plenty of liquid used in the operations performed for a gland called as prostate in men by entering from the urinary tracts (transurethral resection of prostate; TUR). In addition, it may also be used to dilute some drugs applied to the bladder from the urinary tracts in a concentrated form.

It is used through a catheter applied to the urinary tracts; **it is never applied in an intravascular way**.

2. Before you are given POLİFLEKS 5 % MANNITOL

DO NOT USE POLİFLEKS 5 % MANNITOL under following conditions:

If you had an allergic reaction when you took the drugs containing the active matters or auxiliary agents contained in the POLİFLEKS 5 % MANNITOL previously, namely if you had symptoms of sudden stop of breath, stertorous respiration, skin eruptions, itch or distention on the body etc., DO NOT USE this drug.

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

In addition, if you:

- have symptoms of respiration stoppage due to dropsy in your lungs (pulmonary edema) etc.;

or after starting to apply this drug if you:

- have a progressive damage or functional disorder in your kidneys,
- have progressive heart failure,
- have dropsy started in your lungs, DO NOT USE this drug.

USE POLİFLEKS 5 % MANNITOL carefully under the following conditions:
If:

- the bag of this drug is not sound;
- the solution in it is not clear;
- this drug shall be used in an operation by entering from your urinary tracts, use it carefully (as the liquid used may penetrate into your blood stream).

Use of POLİFLEKS 5 % MANNITOL with foods and drinks
In terms of its method of administration, it has no known interaction with foods or drinks.

Pregnancy
Consult your doctor or pharmacist before using this drug.

This drug will be administrated to you only when absolutely required during pregnancy.

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.

POLİFLEKS 5 % MANNITOL can be used during lactation.

Driving and use of machines
The POLİFLEKS 5 % MANNITOL has no effect on use of vehicle or machine.

Important information about some ingredients of POLİFLEKS 5 % MANNITOL
If you have no sensitivity to the auxiliary agents in the POLİFLEKS 5 % MANNITOL, no adverse effect is expected in connection with these agents.

Taking other medicines
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.

The POLİFLEKS 5 % MANNITOL may be impermeable in some drugs applied to your bladder from your urinary tracts through dilution. The doctor or healthcare officer to make the application would not add these drugs known to be impermeable in the solution and would prefer other solutions for diluting these drugs.

In addition, if sodium and potassium salts are added, mannitol in the solution may settle.

For minimizing an impermeability risk with any other drug to be added in the solution, the healthcare officer shall control immediately after the mixing process if there is blurriness or settlement in the last mixture to be applied before the application and in certain intervals during the application.

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 POLİFLEKS 5 % MANNITOL will be given?
Instructions for proper use and dosage/application intervals:
Your doctor shall decide the quantities of this drug that you need, time to administer it to you and period of your treatment.

Route and method of administration:

It may be used through an administration set connected to a pipe (catheter) special to the section required to be cleaned or washed. In this case, user instruction of the used set must be followed.

Be careful: The product is not used in an intravascular way.

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:
In general, attention must be paid to dose selection considering more frequency of the reduction of liver, kidney or heart functions and use of other drugs together in the elderly.

Conditions of special use:
There are no conditions for special use.

If you have the impression that the effects of POLİFLEKS 5 % MANNITOL are too powerful or too weak, *consult your doctor or pharmacist.*

In case you had used POLİFLEKS 5 % MANNITOL in an amount more than you should:
Consult a doctor or a pharmacist if you had used POLİFLEKS 5 % MANNITOL SOLUTION FOR UROLOGIC IRRIGATION in an amount more than you should.

In case you forget to take POLİFLEKS 5 % MANNITOL:
Do not take double dose to balance the skipped dosage.

Possible effects related to the termination of the treatment with POLİFLEKS 5 % MANNITOL:
None

4. Possible side effects
Like all drugs, POLİFLEKS 5 % MANNITOL SOLUTION can cause adverse effects in individuals who are sensitive to the contents.

Frequently undesired effects were reported due to administration of the mannitol in the POLİFLEKS 5 % MANNITOL in an intravascular way but their prevalence is not known clearly. These side effects are listed below:

- decrease in quantity of the ions contained in the body liquids in a melted form
- increase in the acidity degree of the body liquids

- increase or difficulty in widdling
- dropsy in the body, arms or legs (edema)
- frequent breathing, difficulty in breathing, difficulty in breathing when lying on the bed or climbing up stairs (symptoms of heart or lung failure)
- Dryness in the mouth, thirst and dehydration
- heart throb
- breast ache
- drop in the blood pressure
- bladder, urinary tracts inflammation and inflammations in other organs
- formation of intravascular inflammatory grume
- sight blurriness, convulsions, nausea, vomiting, runny rose, shaking, dizziness, backache, hives and similar general disorders.

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

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

5. How to store POLİFLEKS 5 % MANNITOL

Keep POLİFLEKS 5 % MANNITOL SOLUTION in places out of sight and reach of children and within the original packaging.

Store at room temperature below 25°C. Do not freeze.

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 5 % 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.

Marketing Authorisation Holder and Manufacturer:

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These PATIENT INFORMATION LEAFLET have been approved on 02/10/2019.