SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

POLİFLEKS 5 % MANNITOL SOLUTION FOR UROLOGIC IRRIGATION
Sterile

2. QUALITATIVE & QUANTITATIVE COMPOSITION

Active ingredient:
Each 100 ml of solution contains 5 g of mannitol.

Excipients:
See section 6.1 for excipients.

3. PHARMACEUTICAL FORM

Sterile solution for urological irrigation

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

The POLİFLEKS 5 % MANNITOL SOLUTION is used for urological irrigation.

It is used as an irrigation (washing) solution to reduce hemolytic effects of water in transurethral prostate resections and prevent development of hemoglobinemia as a result of general circulation of hemolyzed blood and critical renal complications.

In addition, it is used in all kinds of bladder irrigation and for diluting certain drugs used by instillation to the bladder.

4.2 Posology and method of administration

Posology / Frequency and period of administration:
Dosage to be administered and administration frequency must be determined by the doctor of each patient depending on size of the area of administration and intervention to be performed.

Aseptic technical rules must be observed during irrigation. It must be used as soon as possible after opening the bag in order to prevent the risk of bacterial contamination and the portion which is not used and remain in the bag must be disposed.

Route of administration:
In urological irrigations, it is used through an administration set connected to the urethral catheter.
Also see section 6.6 for the details about administration.

Special populations:
Renal / hepatic impairment:

As there is no study carried out specifically for this population, there is no specific dosage recommendation for this patient group.

Paediatric population:
As there is no study carried out specifically for this population, there is no specific dosage recommendation for this patient group.

Geriatric population:
As there is no study carried out specifically for this population, there is no specific dosage recommendation for this patient group. However, dosage must be carefully selected considering reduction in liver, renal or cardiac functions and concurrent use of another drug are considered to be more frequent in this population in general.

4.3. Contraindications
It must not be used in the following conditions.

- Critical lung congestion or pulmonary edema.
- Progressive renal damage or dysfunction (increased oliguria and azotemia), anuria after start of administration.
- Progressive heart insufficiency or lung congestion after start of administration.

4.4 Special warnings and precautions for use
It must not be used in the form of parenteral injection.

If the solution is not clear, contains particles or integrity of the package was damaged, it must not be used. It must be used as soon as possible after opening the bag to prevent bacteria reproduction and pyrogen formation in the solution. As the solution does not contain protective agents, the solution remained in the bag must not be used again.

It must be used carefully as it is proven that irrigation fluids used in high volumes may be in systemic circulation during transurethral prostatectomy.

Osmotic diuresis which occurs due to absorption of the fluids containing mannitol may change the heart – lung and renal dynamic of the patient. Therefore, the irrigation solutions must be carefully used in patients with critical heart – lung or renal dysfunction and cardiovascular condition must be carefully considered in cardiac patients in particular. The mannitol solution in systemic circulation through Prostatic veins may cause increase in extracellular fluid volume and congestive heart insufficiency.

4.5 Interactions with other medical products and other forms of interaction
No known interaction.

4.6 Pregnancy and lactation
General recommendation
Pregnancy category: C

Women of childbearing potential/Contraception
Not applicable.

Pregnancy
The studies on animals are insufficient regarding the effects on pregnancy / and-or / embryonal / fetal development / and-or / delivery / and-or / postnatal development (see Part 5.3). The potential risk for human beings is not known. The POLİFLEKS 5 % MANNITOL must be used in pregnant women only if it is required very much.

Lactation
As exposure of a breastfeeding woman to 5% mannitol used for irrigation is at a negligible level, no effect expected to be seen on the breastfed child. The POLİFLEKS 5 % MANNITOL may be used in the breastfeeding period.

4.7 Effects on ability to drive and use machines
It has no known effect of driving and using machines.

4.8 Undesirable effects
Adverse effects were reported due to intravenous infusion of mannitol occasionally but their frequency is not known precisely.

Very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1.000 to <1/100); rare (≥1/10.000 to <1/1.000); very rare (<1/10.000), not known (may not be estimated from the available data).

Metabolism and nutrition disorders
Not known: Fluid and electrolyte imbalances (acidosis, loss of electrolyte, evident dieresis, urinary retention, edema, xerostomia, thirst and dehydratation etc.)

Cardiac disorders
Not known: Tachycardia; ache similar to Angina; Congestive heart insufficiency (due to the increase in extracellular fluid volume when it is used as an irrigation solution in transurethral resection of prostate)

Vascular disorders
Not known: Hypotension; Thrombophlebitis

Respiratory, thoracic and mediastinal disorders
Not known: Pulmonary congestion

General disorders and administration site conditions
Not known: General disorders (such as sight blurriness, convulsions, nausea, vomiting, rhinitis, shake, vertigo, backache and hives)
Surgical and medical procedures

Not known: Infection (due to failure to comply with the aseptic rules)

In case of adverse effects during administration, administration of the irrigation solution must be stopped; condition of the patient must be evaluated; appropriate treatment precautions must be taken and the remaining fluid must be kept for examination if required.

4.9 Overdose and treatment
If side effects or fluid or electrolyte overload symptoms are seen during administration of the POLİFLEKS 5 % MANNITOL, the irrigation must be ceased and the patient must be followed closely and appropriate treatment must be started if required.

5. PHARMACOLOGICAL PARTICULARS

5.1 Pharmacodynamic properties

Pharmacotherapeutic Group: Surgical irrigation solutions
ATC code: B05CX04

Mannitol which is a sugar alcohol with six carbons is obtained through reduction of dextrose. It is an inert agent in metabolic terms in human beings; it is contained in fruits and vegetables naturally.

The POLİFLEKS 5 % MANNITOL has been developed to reduce hemolytic effects of water used in the bladder irrigations and prevent hemoglobinemia development as a result of general circulation of hemolyzed blood and critical renal complications.

It ensures mechanic cleaning in sterile irrigation inside the bladder and irrigation of wounds on the inner walls of the bladder. Furthermore, it may also be used to dilute other drugs used for instillation in the bladder.

5.2 Pharmacokinetic properties

Absorption:
The POLİFLEKS 5 % MANNITOL is not absorbed by the body when it is used for irrigation. However, it is known that the irrigation solutions may be in systemic circulation in the irrigations in high volumes during transurethral prostatectomy.

Distribution:
Mannitol does not penetrate into the tissues.

Biotransformation:
Mannitol does not undergo biotransformation in the body.
Elimination:
80% of the administered intravenous dose is eliminated from kidneys without change within three hours. It is freely slipped from glomerulus; its tubular reabsorption is less than 10% and it has no tubular secretion.

Elimination half-life is approximately 2 hours in adults. Its half-life extends in case of renal insufficiency.

5.3 Pre-clinic safety data
As the mannitol which is the constituent of the solution is an agent in pharmacopeias and has a common intra venous use, no pre-clinic study was performed with the POLİFLEKS 5 % MANNITOL to evaluate its effects on carcinogen, mutagen potential and fertility.

It is required to separately consider safety of other drugs diluted by the solution for irrigation.

6. PHARMACEUTICAL PARTICULARS
6.1. List of excipients
Water for injection

6.2. Incompatibilities
Compatibility of the drug to be included in the solution must be considered in advance. If the compatibility data is not available, the solution must not be mixed with any drug. The drugs known to be incompatible must not be included in the solution.

Addition of potassium or sodium chloride in the solution may cause deposition of mannitol.

In addition, some of the drugs known to be incompatible with the intravenous mannitol solutions are stated below:

- Sefepim
- Imipenem / Silastatin
- Silastatin
- Filgrastim

6.3. Shelf life
24 months.

6.4. Special precautions for storage
There are no special conditions for storage; it must be kept at room temperature under 25 °C. It must not be frozen.

6.5. Nature and contents of the container
Available in 3000 ml PVC (Polifleks®) bags.
The product is available in two forms with a set and without a set.
6.6 Destruction of the residual materials human medicinal product and other special precautions
The solution must be checked before use.

Only clear, particle-free products in an integral package must be used.

In urological irrigations, it is used through an administration set connected to the urethral catheter.
In use with the administration set, user manual of the set must be observed.
Be careful: The product is not used in an intravenous way.

7. MARKETING AUTHORISATION HOLDER

POLİFARMA İLAÇ SAN. VE TİC. A.Ş.
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8. MARKETING AUTHORISATION NUMBER(S)

248/35

9. DATE OF INITIAL LICENSING /LICENSE RENEWAL DATE

Date Of First Authorisation: 13.02.2013
Renewal Of The Authorisation:

10. DATE OF REVISION OF THE TEXT

02.10.2019