

PATIENT INFORMATION LEAFLET

POLIFLEKS RINGER SOLUTION FOR IV INFUSION

Intravenous administration

Sterile

- **Active substances:** 1000 ml solution contains 8,6 g sodium chloride, 300 mg potassium chloride and 330 mg calcium chloride dihydrate.
- **Excipients:** Sterile water for injection.

Before using this medicine, read all of this PATIENT INFORMATION LEAFLET carefully. Because, this leaflet includes important information for you.

- *Keep this PATIENT INFORMATION LEAFLET. You may need to read it again.*
- *If you have any further questions, ask your doctor or pharmacist.*
- *This medicine has been prescribed for you. Do not pass it on to others.*
- *During the use of this medicine, tell that you are using this medicine when you go to a doctor or hospital.*
- *Follow the written instructions exactly. Do not use **higher or lower** dose than the recommended dose.*

The following subjects are covered herein:

- 1. What POLIFLEKS RINGER is and what it is used for?***
- 2. Before you are given POLIFLEKS RINGER***
- 3. How you will be given POLIFLEKS RINGER?***
- 4. Possible side effects***
- 5. How to store POLIFLEKS RINGER?***

1. What is POLIFLEKS RINGER and what is it used for?

POLIFLEKS RINGER is an intravenous solution containing electrolytes which are the building blocks of the body.

Solution presented in 500 or 1000 ml PVC or PP bags.

POLIFLEKS RINGER is used to treat dehydration of the body and to prevent this condition from occurring. It works to replace fluid lost and particles called electrolytes such as electrically charged sodium, potassium, calcium and chloride from the body.

2. Before you are given POLIFLEKS RINGER

POLIFLEKS RINGER is a safe drug for many patients. However, your doctor may decide not to use this medicine if you have cardiac, renal, hepatic or lung problems.

DO NOT USE POLIFLEKS RINGER under the following circumstances:

- If there is too much fluid in the spaces around the cells of the body (extracellular hyperhydration)
- If there is larger volume of blood in your blood vessels than normal (hypervolaemia)
- If you have severe renal impairment (when your kidneys do not work well and you require dialysis)
- If you have Addison disease (impaired adrenal glands)
- If you have uncompensated heart failure. This is heart failure that is not adequately treated and causes symptoms such as shortness of breath and swelling of the ankles
- If there is too much fluid in your body caused by too many salt in the blood (hypertonic dehydration)
- If you already have higher levels of the substances contained in the medicine (higher levels of potassium, higher levels of sodium, higher levels of calcium, higher levels of chloride)
- If your blood pressure is higher than normal (hypertension)
- If there is fluid under your whole skin, affecting all parts of the body (general oedema)
- If you have any liver disease that causes fluid to build up within the abdomen (ascitic cirrhosis)
- If you are taking digitalis to treat heart failure
- If electrocautery is required as an irrigation solution
- If you have sensitivity to any ingredient of the solution.

Take SPECIAL CARE with POLIFLEKS RINGER in following conditions:

Tell your doctor if you have or had in the past any of the following conditions.

- Heart failure
- Respiratory failure (lung disease) (special monitoring may be required in above conditions)
- Any type of heart disease or impaired heart function
- Impaired kidney function
- Severe kidney disease
- High blood pressure (hypertension)
- Fluid under the skin, particularly around the ankles (peripheral oedema)
- Fluid in the lungs (pulmonary edema)
- High blood pressure during pregnancy (preeclampsia)
- A disease that causes high levels of a hormone called aldosterone (aldosteronism)
- Any other condition associated with sodium retention (when the body retains too much sodium), such as treatment with steroids (see also below “Other medicines and Ringer’s Solution for Infusion”)
- Adrenocortical insufficiency (this disease of the adrenal gland affects hormones that control the concentration of chemicals in the body)
- A loss of water from the body (acute dehydration) from vomiting or diarrhea
- Extensive tissue damage (as can occur in severe burns)

- Diseases associated with high levels of vitamin D (e.g. sarcoidosis, a disease affecting the skin and internal organs)
- Blood potassium level above normal
- A clinical picture with sodium induced oedema
- If you use digitalis

When you are given this infusion, your doctor will take blood and urine samples and monitor:

- The amount of fluid in your body
- Your vital signs
- The amount of chemicals such as sodium, potassium, calcium and chlorides in your blood (your electrolytes)

Although POLIFLEKS RINGER contains potassium and calcium, these amounts may not be sufficient in following conditions:

- Maintain levels of these chemicals in your blood
- Treat very low blood plasma levels of potassium (severe potassium deficiency) or calcium (severe calcium deficiency).

Once your dehydration has been treated using POLIFLEKS RINGER, your doctor will give you a different infusion to provide you enough potassium and calcium. Your doctor will take it into account if you are receiving parenteral nutrition (nutrition given by infusion into a vein).

If you are given POLIFLEKS RINGER for a long time, you will be given other drugs or solutions as an extra source of nutrients.

Calcium chloride can be harmful if injected into the body tissues. Therefore, POLIFLEKS RINGER must not be given by injecting it into a muscle (intramuscular injection). Also, your doctor will make every effort to avoid the escape of the solution into the tissues surrounding the vein.

POLIFLEKS RINGER must not be given through the same needle with a blood transfusion. This can damage the red blood cells or cause them to clump together.

Please consult your doctor even if these warnings apply to you at any time in the past.

Use of POLIFLEKS RINGER with food and drink

POLIFLEKS RINGER is administered intravenously; there is no interaction with food and drinks in terms of its route of administration.

Pregnancy

Before using this medicine consult your doctor or pharmacist.

Caution is required when this medicine is used in pregnancy.

Tell your doctor if you are pregnant, or if you think you may be pregnant. POLIFLEKS RINGER is not recommended for use in pregnant women because it is not known whether it is harmful to the fetus.

If you notice that you have been pregnant during treatment, tell your doctor immediately.

Breastfeeding

Before using this medicine consult your doctor or pharmacist.

It is not known whether POLIFLEKS RINGER is excreted in human milk. You should consult your doctor before you breastfeed your baby.

Ability to drive and use machines

It is not possible for you to drive or use machinery while you are given POLIFLEKS RINGER.

You can continue with your daily activities, drive and use machinery after treatment.

Vital information regarding some of the excipients contained in POLIFLEKS RINGER

Each ml of solution also contains 14.7 mmol of sodium. The sodium content should be taken into account in patients who is under a controlled sodium diet.

Use in combination with other drugs

Please tell your doctor if you are planning to take or have recently taken any other medicines, including over-the-counter medicines, vaccines and herbal medicines.

It is particularly important that you inform your doctor if you are taking:

- Heart medications (cardiotonics) such as digitalis or digoxin, used to treat heart failure. These drugs should not be used with POLIFLEKS RINGER (See "Do not use POLIFLEKS RINGER if you have the following"). The effects of these drugs can be increased by calcium. This can lead to life threatening changes to the heart rhythm
- Corticosteroids (anti-inflammatory medicines)
- Carbenoxolone (a medicine used to treat stomach ulcers)

These medicines can cause the body to accumulate sodium and water, leading to tissue swelling due to fluid under the skin (oedema) and high blood pressure (hypertension).

The following medicines can increase the concentration of potassium in the blood. This effect can be life-threatening. A rise in the blood potassium levels is more likely to occur if you have kidney disease.

- Potassium-sparing diuretics (e.g. amiloride, spironolactone, triamterene) (Note that these medicines may be included in other medicinal products)
- Angiotensin converting enzyme (ACE) inhibitors (used to treat high blood pressure)
- Angiotensin II receptor antagonists (used to treat high blood pressure)
- Tacrolimus (used to prevent rejection of a transplant and to treat some skin diseases)
- Cyclosporin (used to prevent rejection of a transplant)

Other medicines that can affect or be affected by POLIFLEKS RINGER include:

- Thiazide diuretics such as hydrochlorothiazide or chlortalidone
- Vitamin D

If you are taking or have recently taken any other medicines, with or without a prescription, tell your doctor or pharmacist.

3. How you will be given POLIFLEKS RINGER?

Your doctor will decide how much POLIFLEKS RINGER you need.

Instructions for proper use and dosage/frequency of administration:

The amount of POLIFLEKS RINGER will depend on the individual and the condition. Your doctor will decide how much POLIFLEKS RINGER you need based on your age, weight and medical condition.

Your doctor will inform you on the duration of your treatment with POLIFLEKS RINGER.

Do not stop your treatment early because you cannot get the desired result.

Route and method of administration:

POLIFLEKS RINGER is given through a plastic set in a vein (intravenous infusion).

Different age groups:

Use in children:

In children, the dose and the size of the application set is decided by the treating physician.

Elderly:

Same as in adults.

Special conditions of use:

Renal/Hepatic failure:

Adjustment may be required in the dose and duration of the infusion of the medicine in patients with impaired kidney and liver functions.

If you have the impression that the effect of POLIFLEKS RINGER is too strong or weak, talk with your doctor or pharmacist.

If you have taken more POLIFLEKS RINGER than you should have:

Tell your doctor or pharmacist if you use more POLIFLEKS RINGER than you should.

If you are given too much POLIFLEKS RINGER or you are given your infusion too quickly, this may lead to the following symptoms:

- Water and/or sodium (salt) overload with buildup of liquid in the tissues (oedema) causing swelling
- Pins and needles in the arms and legs (paresthesia)
- Muscle weakness
- An inability to move (paralysis)
- An irregular heartbeat (cardiac arrhythmias)
- Heart block (a very slow heartbeat)
- Cardiac arrest (the heart stops beating; a lifethreatening situation)
- Confusion
- A decreased appetite (anorexia)

- Nausea
- Vomiting
- Constipation
- Abdominal pain
- Mental disturbances such as irritability or depression
- Drinking lots of water (polydipsia)
- Producing more urine than normal (polyuria)
- Kidney disease due to buildup of calcium in the kidneys (nephrocalcinosis)
- Kidney stones
- Coma (unconsciousness)
- Chalky taste
- Redness in the face and neck
- Dilatation of the blood vessels in the skin
- Acidification of the blood (acidosis) leading to tiredness, confusion, lethargy and increased breathing rate

If you develop any of these symptoms you must inform your doctor immediately. Your infusion will be stopped and you will be given treatment depending on the symptoms.

If a medicine has been added to your POLIFLEKS RINGER before over-infusion occurs, that medicine may also cause symptoms. You should read the Package Leaflet of the added medicine for a list of possible symptoms.

If you forget to take POLIFLEKS RINGER:

Do not take double dose to make up the dose you have missed.

Possible effects once POLIFLEKS RINGER treatment is concluded

Not applicable.

4. Possible side effects

Like all medicines, POLIFLEKS RINGER may cause side effects in patients sensitive to its ingredients.

Side effects are listed as shown in the following categories:

Very common: It can be seen in at least one of 10 patients.

Common: Less than one in 10 patients, but more than one in 100 patients.

Uncommon: Less than one in 100 patients, but more than one in 1,000 patients.

Rare: Less than one in 1,000 patients, but more than one in 10,000 patients.

Very rare: Less than one in 10,000 patients can be seen.

Unknown: It cannot be estimated from the available data.

Very common (occurring in more than 1 of every 10 patients)

- Changes in the concentrations of the chemicals in the blood (electrolyte disturbances)

If you suffer from heart disease or fluid in the lungs (pulmonary oedema):

- Too much fluid in the body

- Heart failure

Other side effects

Reactions due to the administration technique:

- Fever
- Inflammation at the site of infusion
- Local pain or reaction (redness or swelling at the site of infusion)
- Irritation and inflammation of the vein into which the solution is infused (phlebitis). This can cause redness, pain or burning and swelling along the path of the vein into which the solution is infused.
- The formation of a blood clot (venous thrombosis) at the site of infusion, which causes pain, swelling or redness in the area of the clot
- Escape of the infusion solution into the tissues around the vein (extravasation). This can damage the tissues and cause scarring.

If a medicine has been added to the solution for infusion, the added medicine may also cause side effects. These side effects will depend on the medicine that has been added. You should read the Package Leaflet of the added medicine for a list of possible symptoms.

Tell your doctor or pharmacist if you notice any other effects not listed in this leaflet.

5. How to store POLİFLEKS RINGER?

Store POLİFLEKS RINGER in original packaging and keep out of the reach and sight of children.

Store POLİFLEKS RINGER at room temperature below 25°C.

Use in compliance with the expiry date.

Do not use POLİFLEKS RINGER after the expiry date which is stated on the packaging.

Do not throw away drugs that have expired or are not used! Deliver to the collection system determined by the Ministry of Environment and Urbanism.

Do not use POLİFLEKS RINGER if you notice defects on the product and/or its packaging.

Marketing Authorisation Holder and Manufacturer:

POLİFARMA İLAÇ SAN. VE TİC. A.Ş.
Vakıflar OSB Mah. Sanayi Caddesi No:22/1
Ergene/TEKİRDAĞ/TURKEY
Tel: +90 282 675 14 04
Fax: +90 282 675 14 05

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