

PATIENT INFORMATION LEAFLET

PF IZOLEN BALANCED ELECTROLYTE SOLUTION FOR I.V. INFUSION

Intravenous use

Sterile

- **Active ingredients:** Each one liter of solution contains 6.4 gram sodium acetate trihydrate, 5 gram sodium chloride, 0.75 gram potassium chloride, 0.75 gram sodium citrate dihydrate, 0.35 gram calcium chloride dihydrate and 0.31 gram magnesium chloride hexahydrate.
- **Excipients:** Glacial acetic acid, 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 PF IZOLEN BALANCED ELECTROLYTE and what is it used for?***
- 2. Before you are given PF IZOLEN BALANCED ELECTROLYTE***
- 3. How you will be given PF IZOLEN BALANCED ELECTROLYTE?***
- 4. Possible side effects***
- 5. How to store the PF IZOLEN BALANCED ELECTROLYTE***

1. What is PF IZOLEN BALANCED ELECTROLYTE and what is it used for?

PF IZOLEN BALANCED ELECTROLYTE is a solution that is used **intravenously** to treat the water and salt deficiency (dehydration) in the body. It is helpful in the replacement of water and salt lost from the body.

PF IZOLEN BALANCED ELECTROLYTE is available in glass bottles with volumes of 500 and 1000 ml with or without sets.

PF IZOLEN BALANCED ELECTROLYTE is a solution that contains the elements required for the body (building blocks).

It is a solution used intravenously.

PF IZOLEN BALANCED ELECTROLYTE is preferred particularly for dehydration of the body seen patients in postoperative period, children with diarrhea with acute onset and some diabetic patients.

PF IZOLEN BALANCED ELECTROLYTE is also used to dilute before intravenous administration some concentrated drugs suitable for intravenous administration.

2. Before you are given consideration before using PF IZOLEN BALANCED ELECTROLYTE

PF IZOLEN BALANCED ELECTROLYTE 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 PF IZOLEN BALANCED ELECTROLYTE under following conditions:

In case you have had allergic reaction when you took drugs containing the same active substances or excipients with PF IZOLEN BALANCED ELECTROLYTE that is, if you have experienced sudden stopping of breath, wheezing, skin rashes, itching or swelling in your body, **DO NOT USE** this drug. If you are not sure that you are allergic, please consult your doctor.

This solution must not be used under the following conditions:

- Patients excreting no urine at all or those urinating in very small amounts (anuria, severe oliguria).
- Renal failure.

- A group of signs and symptoms seen in wars, accidents, wreckage in mines, industrial or traffic accidents involving the crush of the muscular mass in the body (crush syndrome).
- Destruction of the red blood cells within the circulation (severe hemolysis).
- Adrenal insufficiency
- Some cardiac diseases (cardiac block).
- Shift of the normal blood pH to the basic side (alkalosis).

USE PF IZOLEN BALANCED ELECTROLYTE CAREFULLY UNDER THE FOLLOWING CONDITIONS

In case you have any of the following:

- Cardiac diseases, cardiac insufficiency, hypertension;
- Accumulation of fluid in your body, extremities or lungs (edema);
- Impairment of kidney functions,
- Pregnancy hypertension;
- Cases called aldosteronism that lead to over accumulation of sodium in body or other cases followed by sodium accumulation
- Vitamin D levels being higher than normal (with reasons like sarcoidosis, etc.);
- Renal stones,
- Acute dehydration with sudden onset, some renal diseases and serious burns that create tendency for increases in potassium levels in the body.

In such cases, your doctor will pay extra attention when administering PF IZOLEN BALANCED ELECTROLYTE to you.

Furthermore, in case blood transfusion will be administered simultaneously, use of PF IZOLEN BALANCED ELECTROLYTE through the same transfusion system with the same infusion system 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 bottle.

Administration of this drug requires changing of the pipes (sets) every 24 hours.

Furthermore, this drug must be used only if the bottle is intact and the contained solution is clear.

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

Use of PF IZOLEN BALANCED ELECTROLYTE together with foods and drinks

PF IZOLEN BALANCED ELECTROLYTE 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 PF IZOLEN BALANCED ELECTROLYTE 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 PF IZOLEN BALANCED ELECTROLYTE during pregnancy unless specifically recommended by your doctor.

Driving and use of machines

PF IZOLEN BALANCED ELECTROLYTE has no effects on driving or using machines.

Important information about some ingredients of PF IZOLEN BALANCED ELECTROLYTE

If you are not sensitive to the excipients in PF IZOLEN BALANCED ELECTROLYTE content, a negative effect due to these substances is not expected.

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.

PF IZOLEN BALANCED ELECTROLYTE 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.

Furthermore, the effects of the following drugs must be taken into consideration when using concomitantly with PF IZOLEN BALANCED ELECTROLYTE:

- Drugs generally used in allergic diseases including corticoids/steroid and carbenoxolone (the risk of retention of sodium and water will increase in case of concomitant use).
- Diuretics including amiloride, spironolactone or triamterene singly or in combination (the risk of potassium accumulation in the body will increase in case of concomitant use).

- Angiotensin converting enzyme inhibitors and possible angiotensin II receptor antagonists (the risk of potassium accumulation in the body will increase in case of concomitant use).
- Drugs that suppress the immune system including tacrolimus and cyclosporine (of the risk of potassium accumulation in the body will increase in case of concomitant use).
- Digitalis group glycosides (when taken together, the effects of these drugs increase and serious heart rhythm disorder may occur)
- Thiazide group diuretics or vitamin D (the risk of calcium in the body will increase in case of concomitant use).
- Bisphosphonates used for osteoporosis, fluoride normally found in the body and used externally in some conditions including pregnancy, some fluoroquinolone and tetracycline antibiotics (their absorptions are reduced when administered concomitantly)
- Acidic drugs including salicylates (a group of drugs used as antipyretics), barbiturates (used for convulsions) and lithium (a drug used in psychiatric disorders) (renal excretion of these drugs will increase and they can fail in making the expected effect because PF IZOLEN BALANCED ELECTROLYTE alkalizes the urine).
- Alkaline drugs including sympathomimetic drugs (e.g. ephedrine, pseudoephedrine) and drugs used as appetite suppressants or stimulants (dexamphetamine sulfate, fenfluramine hydrochloride) (renal excretion of such drugs will be decreased and their effects can exceed the expected level because PF IZOLEN BALANCED ELECTROLYTE alkalizes the urine).

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 PF IZOLEN BALANCED ELECTROLYTE 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 PF IZOLEN BALANCED ELECTROLYTE. 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 you vein through a proper plastic pipe (set).

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:

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 adverse 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 harmful effects will increase in cases where renal functions are impaired.

If you have any impression that the effects of PF IZOLEN BALANCED ELECTROLYTE are too strong or too weak, consult with your doctor or pharmacist.

In case you have used PF IZOLEN BALANCED ELECTROLYTE in an amount more than you should:

In case you have used PF IZOLEN BALANCED ELECTROLYTE in an amount more than you should, consult a doctor or a pharmacist.

In case you forget to take PF IZOLEN BALANCED ELECTROLYTE:

Do not take double dosage to balance the skipped dosage.

Possible effects related to the termination of the treatment with PF IZOLEN BALANCED ELECTROLYTE:

None.

4. Possible side effects

Like all drugs, PF IZOLEN BALANCED ELECTROLYTE can cause adverse effects in individuals who are sensitive to the contents.

Stop taking PF IZOLEN BALANCED ELECTROLYTE and inform your doctor IMMEDIATELY in case you encounter any of the following:

- Itchy redness/blistering or burning sensation in the administration site
- Difficulty in breathing, wheezing, chest pain
- Too cold or too hot feeling in the body
- Swelling in the hands, feet, lips, face or whole body
- Vertigo, feeling of fainting
- Palpitation

These are all very serious adverse effects.

If any of these are present in you, this means that you are seriously allergic against PF IZOLEN BALANCED ELECTROLYTE that might require emergent medical intervention.

Furthermore, in case signs are seen including fever or chills during the administration (febrile reaction), and inform your doctor IMMEDIATELY; your doctor may stop administration carry out emergent medical intervention.

These very serious adverse effects are seen rather rarely.

Side effects are classified as following frequencies:

Very common (seen more than 1 in 10 patients)

Common (seen 1 to 10 in 100 patients)

Uncommon (seen 1 to 10 in 1000 patients)

Rare (seen 1 to 10 in 10.000 patients)

Unknown (cannot be estimated from the available data)

Frequency of the adverse effects below are not known (that are seen in very small numbers of patients that will not allow estimation).

Unknown:

- Inflammation at the administration site, hardness, redness or swelling starting from the administration site and spreading through your vein.
- Fluid accumulation in your body or extremities (edema), difficulty of breathing, difficulties at lying down or climbing the stairs (congestive heart failure symptoms)
- Your heartbeats being slower or faster than normal, feeling of compression of chest, chest pain.
- Numbness in your extremities, loss of reflexes, muscular or respiratory paralysis, confusion, fatigue, hypotension, arrhythmia, electrocardiographic abnormalities (Signs and symptoms of potassium intoxication).
- Hot flushing, sweating, hypotension, reducing of the functions of heart and respiratory and nervous systems (Signs and symptoms of magnesium intoxication).

- Frequent breathing, cyanosis.
- Nausea, vomiting
- Abdominal pain
- Diarrhea

These are mild side effects of PF IZOLEN BALANCED ELECTROLYTE.

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

5. How to store PF IZOLEN BALANCED ELECTROLYTE SOLUTION

Keep PF IZOLEN BALANCED ELECTROLYTE 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. Partly used bottles must not be kept, and must be destroyed according to the medical waste procedures of the healthcare facility that the administration had taken place.

The expiry date of each bottle is indicated on the label. This drug will not be administered to you if this date had expired.

Use according to the expiry date

Do not use PF IZOLEN BALANCED ELECTROLYTE after expiry date on the packaging.

Do not use PF IZOLEN BALANCED ELECTROLYTE in case you become aware that the product and/or packaging are damaged.

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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This patient information leaflet has been approved on 30/09/2019.

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

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.

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.

Partly used solutions must not be kept.

Partly used bottles must not be re-connected to the systems applied to the patient.

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 bottle using an injector with a 19-22 gauge tip.
3. The solution with the added drug will be mixed thoroughly.

Caution: Bottles with added drugs must not be stored.

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 bottle using an 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 bottle.
6. The bottle will be brought to the previous position and administration will be continued.