

PATIENT INFORMATION LEAFLET

PF 3% HYPERTONIC SODIUM CHLORIDE SOLUTION FOR I.V. INFUSION

Used intravenously.

Sterile

- **Active ingredients:** Each 100 milliliters of solution contain 3 grams of sodium chloride (salt).
- **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 this 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.*

In this leaflet:

- 1. What is PF 3% HYPERTONIC SODIUM CHLORIDE and what is it used for?***
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- 4. Possible side effects***
- 5. How to store PF 3% HYPERTONIC SODIUM CHLORIDE***

headlines are included.

1. What is PF 3% HYPERTONIC SODIUM CHLORIDE and what is it used for?

PF 3% HYPERTONIC SODIUM CHLORIDE is a solution which can be administered intravenously.

Each milliliter of solution contains 30 milligrams of salt called as sodium chloride. The sodium chloride solution contains sodium and chloride ion which are from the primary elements of the body.

PF 3% HYPERTONIC SODIUM CHLORIDE is offered in glass bottles with the volumes of 500 and 1000 milliliters (These bottles contain respectively 15 grams and 30 grams of salt).

The drug is administered only in the vein and through an appropriate plastic pipe (set).

PF 3% HYPERTONIC SODIUM CHLORIDE is used in the following cases:

- In case of loss of liquid or electric loaded ions (agents called electrolyte) from your body, if you were treated with sodium-free solutions and sodium and chloride levels in your blood decreased (cases of hyponatremia and hypochloremia)
- Excessive dilution of water in your body due to administration of enema to you or excessive volumes of wash waters used during a closed method prostate operation (transurethral prostate resection operation) penetrated in your body.
- In case of critical loss of salt due to excessive perspiration, vomiting, diarrhea and other reasons and if this condition is desired to be treated rapidly.

2. Before you are given PF 3% HYPERTONIC SODIUM CHLORIDE

DO NOT USE PF 3% HYPERTONIC SODIUM CHLORIDE under following conditions:

If:

- You have allergy (excessive sensitivity) to sodium, chloride or the auxiliary agents contained in the product, do not use the PF 3% HYPERTONIC SODIUM CHLORIDE. These allergic reactions may be in the form of itch, redness on your skin or stertorous respiration or similar difficulty in breathing. If you are not sure about them, consult with your doctor.
- The potassium levels in your blood (an electric-loaded ion) are lower than the normal level (hypokalemia), do not use the PF 3% HYPERTONIC SODIUM CHLORIDE.
- Your blood is in an acid structure more than the normal level (acidosis), do not use the PF 3% HYPERTONIC SODIUM CHLORIDE.
- If the electrolyte (electric-loaded sodium, potassium, chloride and similar agents) levels in your blood are high, normal or slightly low, do not use the PF 3% HYPERTONIC SODIUM CHLORIDE.

Use PF 3% HYPERTONIC SODIUM CHLORIDE under following conditions CAREFULLY:

- In the event of a past inflammation related to your veins (In this case, your doctor shall administer the drug from a large vein of you to reduce the possibility of a further inflammation in your veins, shall replace your vein administered in every 24 hours and shall make the administration as slow as possible).
- If you have an untreated heart failure,
- If your tension is high,
- If there is bloating (edema) in your arms, legs and body,

- If you take the drugs called as steroid or drugs increasing secretion of this hormone on the body,
- If you have serious kidney failure,
- If you are a cirrhosis disease,
- If you use cortisone,
- If you are old or are in the post-surgery period,
- If your physical condition is weak or if your alcoholic (as administration of the hypertonic sodium chloride solution in an excessive speed or in an excessive volume may cause critical effects related to your nervous system in particular for those who have a poor physical condition or those having taken alcohol for a long period, your doctor shall make sure that the sodium level in your blood not to be higher than a certain value and shall ensure the administration to be as slow as possible).

If these warnings are applicable to you even for a part period, consult with your doctor.

Use of PF 3% HYPERTONIC SODIUM CHLORIDE together with foods and drinks

It is not practically possible to use it with foods and drinks in the course of administration. If you have taken alcohol for a long period, administration of the drug in an excessive speed or in an excessive volume may cause critical effects related to your nervous system (See Section 2: Conditions requiring CAREFUL USE)

Pregnancy

Consult your doctor or pharmacist before using this drug.

Do not use it in the pregnancy period unless it is found expressly required by the 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.

There is not any known negative effect.

Driving and use of machines

Driving and use of machine is not practically possible during the administration. It has no known effect on driving and use of machine after the administration.

Important information about some ingredients of PF 3% HYPERTONIC SODIUM CHLORIDE

Does not contain any excipients which require warning.

Taking other medicines

There is no known drug interaction. However, if you use the drug named steroid or drugs increasing secretion of this hormone on the body, the PF 3% HYPERTONIC SODIUM

CHLORIDE must be carefully used to prevent increase in your tension and dropsy on your body (See Section 2: CAREFUL USE CONDITIONS)

If you take any of the drugs above, your doctor may change dose of these drugs or give you another drug or adjust dosage of the PF 3% HYPERTONIC SODIUM CHLORIDE.

Do not use several medicines concomitantly without consulting your doctor.

Please tell your doctor or pharmacist if you are taking or have recently taken any other prescription or non-prescription medicines.

3. How PF 3% HYPERTONIC SODIUM CHLORIDE will be given?

Your doctor shall decide volume of the drug you need and period of your treatment.

Volume of the drug that you shall take depends on your age, weight, current clinical condition, other drugs being used by you and type and severity of the disease to be treated.

Instructions for appropriate use and dose/administration frequency:

Your doctor shall determine dose of the drug based on your disease and administer it to you accordingly.

In general, 100 ml of solution shall be administered to you for a period longer than one hour.

For continuing the treatment, your doctor shall measure electrolyte intensities in your blood and shall decide to continue or not to continue treatment accordingly.

Route and method of administration:

PF 3% HYPERTONIC SODIUM CHLORIDE is a solution ready for administration and administered in the vein (intravenous). It is given in the vein by a specialized healthcare officer (doctor or nurse) in a period longer than 60 minutes.

This medical product may be blended with another drug before administration in the vein or during administration (See section titled “DETAILS OF THE HEALTHCARE PERSONNEL TO ADMINISTER THE DRUG” at the end of this User manual).

- **Different age groups:**

Use in children:

PF 3% HYPERTONIC SODIUM CHLORIDE may also be used for children. Your doctor shall determine dose of your drug depending on your disease and shall administer it accordingly.

Use in the elderly:

Do not use PF 3% HYPERTONIC SODIUM CHLORIDE for elderly. Your doctor shall determine dose of your drug depending on your disease and shall administer it accordingly.

- **Conditions of special use:**

Renal/hepatic impairment:

Your doctor shall determine dose of your drug depending on your disease and shall administer it accordingly in case of kidney failure and liver failure.

In case you have the impression that the effect of PF 3% HYPERTONIC SODIUM CHLORIDE is too strong or too weak, consult your doctor or pharmacist.

In case you had used PF 3% HYPERTONIC SODIUM CHLORIDE in an amount more than you should:

If you have used PF 3% HYPERTONIC SODIUM CHLORIDE more than the required volume, your doctor shall measure performance of your kidney and intensity of electrolytes in your blood and shall decide use of a diuretic drug or requirement of dialysis accordingly.

If you used PF 3% HYPERTONIC SODIUM CHLORIDE more than you should have used, please consult a doctor or pharmacist.

In case you forget to take PF 3% HYPERTONIC SODIUM CHLORIDE:

Do not take a double dose on the same day to make up for a forgotten dose

Possible effects upon finalization of treatment with PF 3% HYPERTONIC SODIUM CHLORIDE:

No effect occurs when treatment with PF 3% HYPERTONIC SODIUM CHLORIDE is finalized.

4. Possible side effects

Like all other drugs, PF 3% HYPERTONIC SODIUM CHLORIDE may also cause side effects but all patients may not be affected.

The following side effects can be seen due to excessive use of PF 3% HYPERTONIC SODIUM CHLORIDE, and their incidence is unknown. Therefore, they are listed in the order of severity:

- Coma and death
- Conditions arising from bleeding in brain (hemorrhagic encephalopathy)
- Convulsion
- Delirium with shakes and shocks
- Functionless kidneys (kidney failure)
- Increase in blood acidity
- Difficulty in breathing or hard breathing (deteriorated congestive heart failure)
- Increase in heartbeat (tachycardia)
- Low tension (hypotension) or high tension (hypertension)
- Decrease in urine volume
- Distention in hands, arms, feet, legs or whole body (edema)
- Vomiting blood
- East excitability, twitch and stiffening in muscles
- Unrest

- Fever
- Headache
- Dizziness
- Drowsiness
- Diarrhea
- Abdominal cramps
- Vomiting
- Nausea
- Doziness
- Decrease in perspiration, decrease in salivation

In addition, the following side effects may also be seen due to intravenous administration:

- Inflammation in the places of administration and veins.
- Leakage out of vein.

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

5. How to store PF 3% HYPERTONIC SODIUM CHLORIDE

Keep PF 3% HYPERTONIC SODIUM CHLORIDE out of the sight and reach of children and store within its packaging.

This medical product has been prepared only for administration intravenously by sterilized devices. Each infusion bottle has been designed in a **disposable** form. Once it is opened, its unused portion must be disposed.

Use according to the expiry date.

Do not use PF 3% HYPERTONIC SODIUM CHLORIDE after the expiry date indicated on the package.

If you notice disorders in the product and/or its package, do not use PF 3% HYPERTONIC SODIUM CHLORIDE.

Do not throw away any expired or unused medicines! Give to the collection system determined by local regulations.

Marketing Authorisation Holder and Manufacturing Site:

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THE FOLLOWING INFORMATION IS INTENDED FOR MEDICAL OR HEALTHCARE PROFESSIONALS ONLY

Solution should be inspected visually before use.

The administration is by intravenous route with sterile, apyrogen sets.

Only products that are clear, particle-free and intact in packaging integrity should be used.

The administration should be started as soon as possible after the application set is attached to the product.

In order to prevent an air embolisation that may occur due to the residual air in the bottle, no serial connection should be made with other infusion fluids.

The solution should be applied using the aseptic technique through the sterile application set. In order to prevent air from entering the system, liquid must be passed through the application set before use.

Additional medication may be added before and during infusion with the aid of Injection a needle in aseptic conditions. The final product's isotonicity should be determined before parenteral administration.

The added drug must be completely mixed with the solution before application to the patient. Solvents containing additional drug should be used immediately after drug addition; it should not be stored for later use.

Addition of additive or wrong application technique may result in a fever reaction due to pyrogen contamination of the product. If an adverse reaction occurs, the infusion should be terminated immediately.

For single use only.

Do not store partly used solutions.

Do not reconnect partly used bottles to the administration systems.

Addition of additional drug:

Attention: As with all parenteral solutions, all substances to be added to the product must be compatible with the product. If an addition is to be made, compatibility should be checked in the final mixture before administration to the patient.

Adding medication before administration

1. Stopper of the bottle is disinfected.

2. Inject the drug to be added to the bottle by using syringe with 19 to 22 gauge needle.
3. Mix the solution and the added drug thoroughly.

Attention: Do not store the bottles which mixed with additional medication.

Adding medication during administration

1. Close the clamp.
2. Stopper of the bottle is disinfected.
3. Inject the drug to be added using syringe with 19 to 22 gauge needle.
4. Remove the solution from the hanger and invert.
5. In this position, tap gently the bottle to allow mixing of solution and medication.
6. Return the bottle to its former position and open the clamp and continue administration.