

## PATIENT INFORMATION LEAFLET

### PF ISOTONIC SODIUM CHLORIDE IRRIGATION SOLUTION FOR SURGICAL USE

**Administered by pouring.**

Sterile

**Active ingredients:** Each liter of solution contains 9 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 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 only. Do not pass it on to others.*
- *When you visit a doctor or hospital during the use of this drug, inform them that you use this drug.*
- *Please exactly follow the instructions in this leaflet. Do not use **high or low** dosage other than the dose recommended to you for the drug.*

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#### **1. What PF ISOTONIC SODIUM CHLORIDE is and what it is used for**

PF ISOTONIC SODIUM CHLORIDE is a sterile (germ-free) solution that contains sodium and chloride ions that are among the building blocks of the body.

PF ISOTONIC SODIUM CHLORIDE is supplied in 500- and 1000- ml polypropylene bottle.

PF ISOTONIC SODIUM CHLORIDE is used for cleaning and irrigation of body surface and cavities including eyes. It is also used to dilute some concentrated irrigation and cleaning medicines before use.

## **2. Before you take PF ISOTONIC SODIUM CHLORIDE**

**DO NOT TAKE PF ISOTONIC SODIUM CHLORIDE under the following conditions.**

DO NOT USE PF ISOTONIC SODIUM CHLORIDE if you had an allergic reaction to any of the ingredients of this medicine, in other words you had sudden breathlessness, wheezing, skin rash, itching or swelling.

The solution must not be used during electrocauterization since it contains electrolytes.

If you're not sure whether you are allergic or not, please talk to your doctor.

**USE PF ISOTONIC SODIUM CHLORIDE in the following cases WITH CAUTION.**

If,

- the bottle of this medicine is not intact,
- the solution in it is not clear,
- you have congestive heart failure, severe kidney failure or a disease associated with fluid retention (edema) as well as salt retention.

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

### **Use of PF ISOTONIC SODIUM CHLORIDE with food and drink**

This medicine does not interact with food and drink due to its method of administration.

### **Pregnancy**

*Ask your doctor or pharmacist for your advice before taking the medicine.*

Do not take PF ISOTONIC SODIUM CHLORIDE during pregnancy unless specifically advised by your doctor.

*If you notice you are pregnant during the treatment, consult your doctor or pharmacist immediately.*

### **Breastfeeding**

*Ask your doctor or pharmacist for your advice before taking the medicine.*

If you are breastfeeding, please tell your doctor. Do not take PF ISOTONIC SODIUM CHLORIDE during breastfeeding unless specifically advised by your doctor.

### **Driving and using machines**

PF ISOTONIC SODIUM CHLORIDE has no effects on your ability to drive or use machines.

### **Important information about some excipients of PF ISOTONIC SODIUM CHLORIDE**

If you are not sensitive to any of the excipients of PF ISOTONIC SODIUM CHLORIDE, no adverse effects related to such excipients are expected.

### **Using with other medicines**

Tell your doctor if you are planning to take, taking or have recently taken any other medicines including prescription medicines, vaccines and herbal medicines.

If you are being treated with corticosteroids or corticotropin, your doctor will exercise caution regarding the amount of PF ISOTONIC SODIUM CHLORIDE to be used in you.

PF ISOTONIC SODIUM CHLORIDE is incompatible with some medicines used for irrigation after dilution.

The healthcare professional who will administer the medicine will not add such medicines known to be incompatible to the solution, and will choose to use other solutions to dilute such medicines.

To minimize the risk of incompatibility with any other medicine that may be added to the solution, the healthcare professional will check whether there are any turbidity or precipitation in the final mixture immediately after the mixing process, before the administration and at certain intervals during the administration.

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

### **3. How to take PF ISOTONIC SODIUM CHLORIDE**

- **Instructions for appropriate usage and dose/application frequency:**

Your doctor will decide the amount of this medicine required for you and when it will be administered to you.

- **Route and method of administration:**

This medicine is used by pouring on the area that is required to be cleaned or irrigated.

**Warning:** This product should not be used via intravenous route.

- **Different age groups**

#### **Use in children:**

Safe and effective use in children has not been established.

**Use in the elderly:**

Since this medicine is predominantly excreted via kidneys when overdosed and absorbed into the body, the risk of occurrence of the harmful effects of it is increased in cases of impaired kidney functions. Because impaired kidney functions is more common in the elderly, doses should be chosen with caution and the kidney functions should be monitored during treatment.

- **Special conditions for use:**

None.

*If you notice that the effect of PF ISOTONIC SODIUM CHLORIDE is too strong or weak, consult your doctor or pharmacist.*

**If you take more PF ISOTONIC SODIUM CHLORIDE:**

*If you used PF ISOTONIC SODIUM CHLORIDE more than you should have used, please consult a doctor or pharmacist.*

**If you forget to take PF ISOTONIC SODIUM CHLORIDE:**

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

**Effects that may occur when treatment with PF ISOTONIC SODIUM CHLORIDE is stopped:**

None.

**4. Possible side effects**

Like all medicines, side effects may occur in individuals who are sensitive to the ingredients of PF ISOTONIC SODIUM CHLORIDE.

- If an overdose is used during irrigation of closed body cavities such as urinary bladder, distention may occur in the body cavity.

- Infection on the administration site or spreading from the administration site may occur due to failure to adhere to aseptic rules (which are used to avoid microbial contamination).

Additionally there is a risk of occurrence of some side effects when this medicine is overdosed and absorbed into the body. Such side effects result from inadequate or excessive amounts of sodium and chloride in the solution, and are not expected to occur under normal treatment conditions. The frequency of such side effects is unknown.

**If you notice any of the following, stop taking PF ISOTONIC SODIUM CHLORIDE and inform your doctor IMMEDIATELY, or refer to the emergency service of the nearest hospital:**

- Water retention, swelling (edema), and worsening of heart failure associated with fluid retention (congestive heart failure)
- Increased acidity of body fluids (acidosis)
- Headache
- Dizziness
- Anxiety
- Irritability
- Spasms
- Coma and death
- Tachycardia
- Increased blood pressure
- Fluid retention (edema) in lungs
- Slowed breathing
- Stopped breathing
- Nausea, vomiting, diarrhea, abdominal cramps, feeling thirsty, decreased amount of saliva
- Decreased sweating
- Muscular fasciculation and rigidity
- Kidney failure
- Fever, weakness
- Infection occurring on the administration site

All of these are very serious side effects that may require immediate medical intervention.

*If you notice any side effects and any side effects not listed in this leaflet, please tell your doctor or pharmacist.*

## **5. How to store PF ISOTONIC SODIUM CHLORIDE**

*Keep PF ISOTONIC SODIUM CHLORIDE out of the sight and reach of children.*

Store at temperatures below 25°C.

The label of each bottle indicated its expiry date. If this date has expired, you will not be given this medicine. **Please use this medicine consistent with its expiry date.**

*Do not use PF ISOTONIC SODIUM CHLORIDE after the expiry date indicated on the package.*

*Do not throw away any expired or unused medicines! Give to the collection system determined by the Ministry of Environment and Urbanization.*

***Marketing Authorization Holder***

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