SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT FOR HUMAN USE

PF ISOTONIC SODIUM CHLORIDE IRRIGATION SOLUTION FOR SURGICAL USE

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Ingredient:

Each 100 ml of solution contains 0.9 g of sodium chloride.

Excipients:

For the full list of excipients, see section 6.1.

The osmolarity of the solution is 308 mOsmol/l.

The ion concentrations of the solution:

- Sodium: 154 mEq/l
- Chloride: 154 mEq/l

3. PHARMACEUTICAL FORM

Sterile, clear, colorless, particle-free, odorless solution for irrigation.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

PF ISOTONIC SODIUM CHLORIDE is used topically for cleaning and irrigation of body surface and cavities including eyes.

4.2. Posology and method of administration

Posology/ Administration frequency and duration

The dose to be administered and the administration frequency must be determined for each patient by their physician based on the size of the area to be irrigated and on the intervention to be carried out.

The rules of aseptic technique must be observed during irrigation. In order to avoid the risk of bacterial contamination, the solution must be used as soon as possible after opening the bottle, and the remaining unused portion must be disposed of.

Method of administration:

Used by topically pouring on the area to be irrigated.

See also section 6.6 for details of administration.

Additional information on special populations:

Renal / Hepatic insufficiency:

Since no studies were conducted specifically for this population, there are no specific dosage recommendation for this patient group.

Pediatric population:

Safe and effective use in this population has not been shown.

Geriatric population:

Since no studies were conducted specifically for this population, there are no specific dosage recommendation for this patient group.

4.3. Contraindications

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

4.4. Special warnings and precautions for use

Do not use if the product is not clear and particle-free and the package is damaged.

Do not use as parenteral injection.

Some fluids used for joint irrigation may be absorbed. Irrigation fluids containing sodium ion should be used with great caution in clinical conditions in which edema associated with congestive cardiac failure, severe renal failure and sodium retention is present. Caution should be exercised on the volume of such fluids especially in patients treated with corticosteroids or corticotropin. This medicinal product contains 154 mmol sodium per liter. This should be considered for patients on a controlled sodium diet.

4.5. Interaction with other medicinal products and other forms of interaction

Corticosteroids or corticotropin: Caution should be exercised on the volume of irrigation fluids containing sodium in patients treated with corticosteroids or corticotropin.

4.6. Pregnancy and lactation

General advice

Pregnancy category: C

Women of childbearing potential/Contraception

There is no data available.

Pregnancy

There are insufficient data regarding use of isotonic sodium chloride irrigation solutions in pregnant women.

Animal studies are insufficient with respect to effects on pregnancy / and-or / embryonic / fetal development / and-or / delivery / and-or / postnatal development (see Section 5.3). Potential risk on humans is unknown.

PF ISOTONIC SODIUM CHLORIDE should not be used during pregnancy unless clearly necessary.

Lactation

It is unknown whether this medicinal product is excreted in human milk. Since it is known that many medicinal products are excreted in human milk, PF ISOTONIC SODIUM CHLORIDE should be used with caution in breastfeeding mothers.

Reproductive Ability/Fertility

No animal reproduction studies were conducted with irrigation solutions containing sodium chloride.

Additionally, it is unknown whether PF ISOTONIC SODIUM CHLORIDE will harm the fetus or impair fertility. PF ISOTONIC SODIUM CHLORIDE should be used in pregnant women only if clearly necessary.

4.7. Effects on ability to drive and use machines

This medicinal product has no known influence on the ability to drive and use machines.

4.8. Undesirable effects

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), unknown (cannot be estimated based on the data available).

Metabolism and nutritional disorders

Unknown: Water retention and edema; Worsening of congestive cardiac failure (due to hypernatremia); Acidosis (due to hyperchloremia);

Nervous system disorders

Unknown: Headache, dizziness, anxiety, irritation, convulsions, coma and death (due to hypernatremia)

Cardiac disorders

Unknown: Tachycardia (due to hypernatremia)

Vascular disorders

Unknown: Hypertension (due to hypernatremia)

Respiratory, thoracic and mediastinal disorders

Unknown: Pulmonary edema, respiratory depression and respiratory arrest (hipernatremiye bağlı)

Gastrointestinal disorders

Unknown: Nausea, vomiting, diarrhea, abdominal cramps, thirst, hyposalivation (due to hypernatremia)

Skin and subcutaneous tissue disorders

Unknown: Decreased sweating (due to hypernatremia)

Musculoskeletal, connective tissue and bone disorders

Unknown: Muscular fasciculation and rigidity (due to hypernatremia)

Renal and urinary disorders

Unknown: Renal failure (due to hypernatremia), urinary bladder distention (due to use of excessive amounts of irrigation solution during urinary bladder irrigation)

General disorders and administration site conditions

Unknown: Fever, malaise (due to hypernatremia)

It is possible to avoid side effects due to irrigation of body cavities and tissues by adhering to the administration rules. If side effects and signs of fluid or electrolyte overload during administration of the irrigation solution, irrigation should be stopped, the patient should be closely monitored and if necessary, appropriate treatment should be initiated.

Surgical and medical procedures

Unknown: Infection occurring on the administration site or spreading from the administration site (due to failure to adhere to aseptic technique)

Additionally, the following adverse effects may occur in cases of high systemic absorption.

(These adverse effects are those seen in cases of overdose of systemically administered 0.9% sodium chloride solutions)

4.9. Overdose and treatment

Hypernatremia, fluid retention and edema may occur in cases of high systemic absorption. In such cases diuretics such as furosemide may be used to establish diuresis.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: Irrigation solutions

ATC code: B05CB01

PF ISOTONIC SODIUM CHLORIDE is an isotonic solution.

It provides mechanical cleaning in sterile irrigation of body cavities, tissues and wounds.

It is used for surgical dressing, and washing, rinsing or moistening instruments and laboratory samples. It may also be used to dilute the other medicinal products that are used for irrigation.

5.2. Pharmacokinetic properties

Absorption:

PF ISOTONIC SODIUM CHLORIDE is not absorbed into the body since it is used for irrigation. Its pharmacokinetic properties due to absorption of sodium and chloride it contains in cases of overdose are as follows.

Distribution:

The distribution of sodium varies depending on tissues: it is fast in muscles, liver, kidney, cartilage and skin, slow in erythrocytes and neurons, and very slow in bone.

Chloride is predominantly distributed in extracellular fluids.

Biotransformation:

The half-life following injection of radiolabeled sodium (^{24}Na) is 11-13 days for 99% of the injected sodium and one year for the remaining 1%.

Chloride closely follows the metabolism of sodium, and changes in the acid-base balance of the body are reflected by changes in the concentrations of chloride.

Elimination:

Sodium is primarily excreted via renal route but is also reabsorbed via the same route. Small amounts of sodium are excreted via feces and perspiration.

Chloride is primarily excreted via renal route and, in small amounts, via feces and perspiration, since it metabolically follows sodium.

5.3. Preclinical safety data

Since the ingredients of the solution are physiological components of human and animal plasma and no toxic effects are expected in clinical practice, no studies have been conducted with PF ISOTONIC SODIUM CHLORIDE to evaluate its carcinogenic and mutagenic potential and effects on fertility.

Safety of other medicinal products for irrigation that are diluted with the solution should be considered separately.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Water for injection

6.2. Incompatibilities

There is no known incompatibility.

6.3. Shelf life

24 months

6.4. Special precautions for storage

This medicinal product does not require any special storage conditions. Store at room temperature below 25°C.

6.5. Nature and contents of container

PF ISOTONIC SODIUM CHLORIDE is packaged in 500- and 1000- ml polypropylene bottles.

6.6. Special precautions for disposal and other handling

If applicable, any unused materials or waste materials should be disposed of in accordance with "Regulation on control of Medical Waste" and "Regulation on Control of Packaging and Packaging Waste".

The solution should be checked before use.

Use only if the product is clear and particle-free and the package is undamaged.

Warning: The product is not intended for intravenous use.

7. MARKETING AUTHORIZATION HOLDER

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8. MARKETING AUTHORIZATION NUMBER(S)

235/8

9. DATE OF FIRST AUTHORIZATION/RENEWAL OF THE AUTHORIZATION

Date of first authorization:: 23.09.2011

Date of renewal: 14.07.2017

10. DATE OF REVISION OF THE TEXT