SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

FENİRAMİN-PF 45.5 mg / 2 ml solution for I.M./I.V. injection
Sterile

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:

Pheniramine maleate 45.5 mg (22.75 mg/ml)

Excipients:

For excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Amber colored glass vial containing a solution for injection

Sterile, colorless, clear solution

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

FENİRAMİN - PF is used in hypersensitivity reactions and in the treatment of itching caused by various reasons. Reduces leakage of fluid in mucosa inflammation with discharge and irrigated eczema. It is used parenterally in the treatment of urticaria, anaphylactic reactions and angioedema.

4.2 Posology and method of administration

Posology/frequency and duration of administration

Unless otherwise recommended by the Doctor; Depending on the patient's condition, 1/2 to 1 - 1 vial is administered slowly in 1 or 2 times a day(1 ml per minute) into the vein or the muscle. The maximum dose is 3 mg/kg body weight and should be given in two doses per day. The duration of action of a single dose is 4-8 hours. Treatment should be continued until acute symptoms have passed. It is possible to combine it with calcium-containing drugs on the market, but the tolerability of the person should always be investigated.

Method of administration:

It is administered intramuscularly or intravenously.

Additional information on special populations:
Renal/Hepatic failure:

There is no information about the use of FENİRAMİN-PF in patients with renal failure. Dose reduction may be necessary for patients with severe hepatic impairment.

Pediatric population:

0.4-1 ml is administered to children between the ages of 1 and 3 intramuscularly 1-2 times a day, and 0.8-2 ml is administered 1-2 times a day to children from the age of 4.

Geriatric population:
It should be applied with caution since it may cause dizziness and hypotension in people aged 60 years and over.

4.3. Contraindications

Contraindicated in the following cases;

- Those with hypersensitivity to pheniramine,

- Pregnancy, nursing women, children under 1 year old,

- Lower respiratory tract diseases including asthma,

- In patients treated with monoamine oxidase (MAO) inhibitors

4.4 Special warnings and precautions for use

It should be used with caution in the treatment of prostate hypertrophy which causes residual urine, narrow-angle glaucoma, stenotic peptic ulcer, piloroduodenal obstruction, symptomatic prostatic hypertrophy, bladder neck obstructions, hyperthyroidism, cardiovascular diseases and hypertension.

It is possible to see vision disorders and increase intraocular pressure in narrow angle glaucoma in patients who uses FENİRAMİN-PF; In such cases patients should be checked by an ophthalmologist.

It should be applied with caution since it may cause dizziness and hypotension in people aged 60 years and over.

This medicinal product contains less than 1 mmol (23 mg) of sodium in 2 ml dose; so it is actually "sodium free".

4.5 Interaction with other medicinal products and other forms of interaction

FENİRAMİN-PF should not be used together with drugs that are effective on the central nervous system (eg, tranquilizers, hypnotics, sedatives, anxiolytic drugs and opioid analgesics), neuroleptics, MAO inhibitors and alcohol since it increases the effect of these drugs.

Additional information on special populations:
Pediatric population:

No interaction studies of pheniramine have been conducted in the pediatric population.

4.6 Pregnancy and lactation

General recommendation

Pregnancy Category: C

Women with childbearing potential / Contraception

There is no suggestion for the use of the drug in women with childbearing potential and in the practice of contraception.

Pregnancy
Animal studies do not show any direct or indirect adverse effects on pregnancy /and-or/ embryonal/fetal development /and-or/ birth /and-or/ postnatal development.
Data on the use of pheniramine during pregnancy are insufficient. Use during pregnancy should be avoided until reliable data is obtained.

Lactation

FENİRAMİN-PF should not be used during lactation.

Fertility
There are no clinical or non-clinical studies on reproductive ability.

4.7 Effects on ability to drive and use machines

Since FENİRAMİN-PF reduces the ability to react, patients should not actively involve in city traffic and should not drive / use machines. The administration time and dosage of the drug should be appropriate to the patient's working time and style, except in cases requiring urgent intervention.

4.8 Undesirable effects

Although antihistamines vary depending on the drug used and the individuals who uses, they generally show the following undesirable effects: Side effects are listed below according to the system organ class. Frequencies are defined as follows: 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), Not known (cannot be estimated from the available data).

Nervous system disorders

Common: Drowsiness

Rare: State of sleep (somnelence), sedation, dizziness, lack of coordination, fatigue, confusion, discomfort, nervousness, tremor, irritability, insomnia, euphoria, paresthesia, neuritis, convulsions.

Paradoxical effects are mostly observed in pediatric and geriatric patients.

Eye disorders
Rare: Blurred vision, diplopia.

Ear and internal ear disorders
Rare: Vertigo, tinnitus.

Cardiac disorders

Rare: Hypotension, headache, palpitation, tachycardia, extrasystoles.

Respiratory, chest failures and mediastinal disorders

Common: Dryness in the nasal mucosa, pharyngeal dryness, increase in the viscosity of bronchial secretion.

Rare: Nasal obstruction.

Gastrointestinal disorders

Common: Dry mouth.

Rare: Nausea, vomiting, anorexia, diarrhea, constipation.

Kidney and urinary disorders

Rare: Frequent urination, dysuria, urinary retention.

General disorders and diseases related to the application site

Rare: Urticaria, anaphylactic shock, photosensitivity, excessive sweating**.**

4.9. Overdose and therapy

The use of antihistamines in high doses is especially dangerous for children. FENİRAMİN-PF poisoning may cause: dryness, tachycardia and urinary retention, fatigue, drowsiness, delirium, sometimes hallucinations and irritability, muscle contractions, rigidity (especially in children), tonic-clonic convulsions with vomiting, elevation of body temperature, initial stimulation of the respiratory center and then paralysis of respiratory center, circulation collapse, deep coma.

First aid precautions, such as respiratory support and stabilization of heart-circulation function, should be taken immediately. In hypopension treatment, treatment is performed with vasopressors (norepinephrine, phenylephrine, dopamine). Epinephrine should not be given, may worsen hypotension. If convulsions had occurred, no central nervous system depressants including diazepam should not be given, and intravenous phenytoin should not be used. Especially in children fever should be reduced by cold baths and other similar methods. In severe cases, hemoperfusion can be performed. With the diuresis being increased, pheniramine excretion can be accelerated; however, the electrolyte and fluid balance must be checked. If necessary, blood should be changed or cleaned in infants and young children.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Systemically used antihistamines, substituted alkylamines

ATC code: R06AB05

Pheniramine is a potent antihistamine. Pheniramine antagonizes H1-receptors as histamine competitive and reversibly. Thus, histamine-induced effects, such as contraction of smooth muscles and increased permeability in capillaries, can be eliminated.

5.2 Pharmacokinetic properties

General properties

Absorption:

When administered intravenously, the drug is mixed directly into the blood from the site of administration. It is rapidly absorbed when administered intramuscularly.

Distribution:

In terms of application, the drug is dispersed directly in the blood.

Biotransformation:

The metabolites of pheniramine are N-desmethylpheniramine and N-didesmethylpheniramine. They are largely metabolised by the cytochrome P-450 system.

Elimination:

The terminal half-life after IV administration is between 8-17 hours. 68-94% of the IV dose is excreted in the urine as unchanged or metabolites of pheniramine.

Linearity / Nonlinear Condition:

No information is available.

5.3. Preclinical safety data

Pre-clinical studies have shown that phenyramine can be used safely in humans for the above-mentioned effects. For this reason, the active ingredient has long been included in the treatment.

6. PHARMACEUTICAL PROPERTIES

6.1. List of Excipients

Water for Injection

6.2. Incompatibilities

Not valid

6.3. Shelf life

24 month.

6.4. Special precautions for storage

It should be store at room temperature below 25 °C.
Do not use this product if have any defects in the product and/or its packaging

6.5. Nature and contents of container

2 ml Amber colored Type I glass vial (5 pcs)

6.6 Special precautions for disposal and other handling

Unused products or waste materials must be disposed of in accordance with the "Medical Wastes Control Regulations" and the "Packaging and Packaging Waste Control Regulations".

7. MARKETING AUTHORISATION HOLDER

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8. MARKETING AUTHORISATION NUMBER

2019/206

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 09.04.2019

Date of latest renewal:

10. DATE OF REVISION OF THE TEXT