PATIENT INFORMATION LEAFLET

FENİRAMİN-PF 45.5 mg / 2 ml solution for I.M./I.V. injection
Administered to the muscle and into vein.
Sterile

- ***Active ingredients:*** Each 2 ml vial contains 45,5 mg pheniramine maleate (22.75 mg/ml)
- ***Excipients:*** Water for injection

Before using this medicine, read all of this PATIENT INFORMATION LEAFLET carefully. Because, this leaflet includes important information for you.

- *Keep this PATIENT INFORMATION 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. Do not pass it on to others.*
- *During the use of this medicine, tell that you are using this medicine when you go to a doctor or hospital.*

*Follow these instructions exactly as written. Do not use **higher or lower** dose other*

The following subjects are covered herein:

1. What FENİRAMİN-PF is and what it is used for?

FENİRAMİN-PF is an intramuscular / intravenous administered drug in amber glass vial containing 2 ml colorless solution and is effective against allergic diseases.

Each vial contains 45.5 mg of pheniramine maleate in 2 ml. For use it is presented in 5 ampoule packages.

FENİRAMİN-PF is used in inflammation of the mucous membrane of the discharge and to reduce the leakage of fluid in irrigated eczema, the treatment of swelling at face and throat caused by as a results of hives, sudden hypersensitivity reactions and allergies.

2. Before you are given FENİRAMİN-PF

DO NOT USE FENİRAMİN - PF under the following circumstances

If;

- If you are hypersensitive to pheniramine,
- If you are pregnant or breastfeeding,
- If the patient is less than 1 year old,
- If you have lower respiratory tract diseases, including asthma,
- If you are being treated with drugs called monoamine oxidase (MAO) inhibitor

USE FENİRAMİN-PF with CAUTION if

If;

- If you have diseases such as growth in the prostate gland, which causes some residual urine left in your urethra, narrow angle eye tension (glaucoma), gastric ulcer with occluded stenosis (stenotic peptic ulcer), obstruction of the pyloroduodenal part of the stomach, obstruction in the neck of the bladder, high level of thyroid hormone
- If you are 60 years old or over,
- If you have cardiovascular diseases or high blood pressure,
- In case of this drug being used, it is possible to have visual impairment and to increase intraocular pressure in narrow-angle eye pressure; such cases should be checked by an ophthalmologist

If these warnings apply or applied to you, please consult your physician.

Using FENİRAMİN-PF with food and beverages
No warning is required due to the way of use.

Pregnancy

Please consult your physician or pharmacist before taking the drug.

Do not use FENİRAMİN-PF if you are pregnant.

If you realize that you are pregnant during your treatment, immediately consult your physician or pharmacist.

Lactation

Consult your doctor or pharmacist before using the medication.

Do not use FENİRAMİN-PF if you are breast-feeding.

Ability to drive and use machines
Since FENİRAMİN-PF reduces the ability to react, patient should not actively involve in city traffic and drive/use machine. The time and dose of taking the drug should be appropriate to your working time and style.

Vital information regarding some of the excipients contained in FENİRAMİN-PF
This medicinal product contains less than 1 mmol (23 mg) sodium in every 2 mL ampoule, so it is actually "sodium free"

Use in combination with other drugs

- Drugs acting on the central nervous system, e.g. strong sedatives (tranquilizers), somniferous (hypnotics), sedatives, anxiety relieving drugs (anxiolytic drugs), opium-like pain killers (opioid analgesics)
- Drugs used in the treatment of mental disorders (neuroleptics)
- It should not be used together because it increases the effect of alcohol and drugs called monoamine oxidase (MAO) inhibitor.

If you are currently taking or recently took any prescribed or over-the-counter drugs, please inform your physician or pharmacist.

3. How you will be given FENİRAMİN-PF ?
Instructions regarding correct use and dosage/administration frequency:
1/2 to 1 vial is used 1-2 times per day depending on the condition of your disease.
The duration of action of a single dose is 4-8 hours. Treatment should be continued until sudden symptoms have passed.

Method of administration:
FENİRAMİN-PF is slowly (1 ml per minute) administered into the vein or into the muscle. It is possible to combine it with calcium-containing drugs on the market, but the tolerability of the person should always be investigated.

Depending on your disease, your doctor will determine the dose of your medicine and apply it to you.

Various age groups:

- **Use in children:**

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

- **Use in the elderly:**

Patients over 60 years of age may experience dizziness and low blood pressure (hypotension).

Special usage cases:

- **Renal /hepatic failure:**

There is no specific information about the use of FENİRAMİN-PF in patients with renal failure. If you have severe liver disease, your doctor may adjust the dose of your medicine.

If you are under the impression that the effect FENİRAMİN-PF is too strong or weak, consult your physician or pharmacist.

If you have taken more FENİRAMİN-PF than you should:
If you have used FENİRAMİN-PF more than you should have or more than prescribed, consult a

physician or a pharmacist.

If you forget to take FENİRAMİN-PF
If you believe that the administration of a dose may be missed, inform your doctor.

Do not double-dose to make up for forgotten doses.

Possible effects once FENİRAMİN-PF treatment is concluded

When FENİRAMİN-PF treatment is terminated, no negative effects are expected.

4. Possible side effects

Like all medicines, FENİRAMİN-PF may have side effects in people who are sensitive to the substances contained in its ingredient.

If you notice one of the followings, stop using FENİRAMİN-PF and inform your doctor IMMEDIATELY or contact the emergency department of the hospital nearest you:

- Allergic (anaphylactic) shock; swelling of the face, lips, mouth and throat which causes difficulty in swallowing or breathing
- Decreased blood pressure
- Increased heart rate
- Abnormal heart contraction (extra systole); irregular heart beats, chest tightness

All these are very serious side effects. If you have one of these, you have a serious allergy to FENİRAMİN-PF. you may need immediate medical intervention or hospitalization.

All of these very serious side effects are very rare.

If you notice any of the following, inform to your doctor immediately or contact the emergency department of the hospital nearest you:

- Palpitations
- Series sudden contractions
- Increased density of bronchial secretions
- Nerve inflammation (neuritis)
- Frequent urination, dysuria, urine accumulation in bladder

All these are serious side effects. Emergency medical intervention may be required.

Severe side effects are rare.

If you notice any of the following, tell to your doctor:

- Itching
- Dryness in the mouth and throat
- Excessive sweating
- Headache, dizziness
- Drowsiness
- Calming, state of sleepiness
- Coordination disorder
- Fatigue, dizziness
- Sensitivity to light, discomfort, irritability
- Shivering
- Insomnia
- Excessive mobility (euphoria)
- Tingling
- Blurred vision, double vision
- Tinnitus
- Nasal congestion

These are the slight side effects of FENİRAMİN-PF.

If you encounter any side effects not mentioned in these instructions, please inform your doctor or pharmacist.

5. How to store FENİRAMİN-PF

Keep the FENİRAMİN–PF out of the sight and reach of children and in its original packaging.

Store at room temperature below 25ºC.

Use in accordance with expiration dates.

Do not use FENİRAMİN–PF after the expiration date printed on its packaging.

If you notice any irregularities in the product and/or its packaging, do not use FENİRAMİN–PF.

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: POLİFARMA İLAÇ SAN. VE TİC. A.Ş

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