PATIENT INFORMATION LEAFLET

ALERFIN 2 mg/5 ml oral solution For oral use.

- ***Active substance:*** Each spoon (5 ml) of solution contains 2 mg chlorpheniramine maleate.
- **Excipients:** Sorbitol (70%) (E420), sodium saccharin, methyl paraben sodium (E219), citric acid monohydrate, orange flavor, sunset yellow FCF (FD & C yellow no: 6) (E110) and deionized water

Read all of this PATIENT INFORMATION LEAFLET carefully before you start using this medicine because it contains important information for you.

- *Keep this **PATIENT INFORMATION LEAFLET.** You may need to read it again.*
- *If you have any additional questions, please contact your physician or pharmacist.*
- *This medicine has been prescribed personally for you. Do not pass it on to others.*
- *When you go to doctor or hospital while using this medicine, tell your doctor that you are using this medicine.*
- *Please completely follow the instructions in this information leaflet. Do not use higher or lower doses other than what is recommended to you.*

What is in this leaflet:

1. What is ALERFIN and what is it used for

- ALERFIN is a solution containing 2 mg of chlorpheniramine per 5 ml, available in amber colored glass bottle closed with a high density polyethylene stoppered pilfer proof polypropylene cap with a 5 ml spoon.

- ALERFIN is used for the relief of symptoms associated with seasonal allergic rhinitis known as hay fever, treatment of hives (urticaria) and allergic reactions.

2. Before you use ALERFIN

DO NOT use ALERFIN in the following conditions:

If,

- You are hypersensitive to chlorpheniramine maleate or any of the ingredients of ALERFIN
- ☐In children younger than 2 years
- you are using medicines called monoamine oxidase inhibitors used to treat depression or 2 weeks have not yet passed since you stopped taking these medicines

TAKE SPECIAL CARE with ALERFIN in the following conditions

- Heart rhythm disorder
- Epilepsy
- High blood pressure or cardiovascular diseases
- Enlarged prostate
- Liver failure
- Eye pressure (glaucoma)
- Bronchitis, bronchiectasis, asthma
- Over active thyroid dysfunction

Please consult your doctor even if these warnings apply to you at any time in the past.

Using ALERFIN with food and drink
Avoid drinking alcohol as it increases the effect of ALERFIN

Pregnancy
Before using this medicine consult your doctor or pharmacist.

Do not use during pregnancy unless your doctor thinks it is absolutely necessary.

If you notice that you have been pregnant during treatment, consult immediately your doctor or pharmacist.

Breastfeeding
Before using this medicine consult your doctor or pharmacist.

It is largely excreted in breast milk; although it is not known whether this medicine is harmful for the baby at this level, do not use during breastfeeding.

Driving and using machinery
Avoid driving and using machinery as this medicine may make feel sleepy.

Important information on some excipients present in ALERFIN
Due to 1.75 g/5 ml sorbitol (E420) contained in this medicine, if you have been told that you have in tolerance to some sugars, contact your doctor before taking ALERFIN.

Methyl paraben sodium (E219) may cause allergic reactions (possibly delayed).

Each 5 ml of this solution contains 0.72 mg of sodium. This should be taken into consideration by patients on a controlled sodium diet.

Sunset yellow FCF (FD&C yellow No.6) (E110) may cause allergic reactions.

Taking with other medicines

Concomitant use with classical antihistamines for allergy (sedative, calming), the sedative effect increases. Sedative interactions are more limited with allergy medications (antihistamines) without sedative effects.

Locally administered allergy medicines (including those by inhalation) do not show this type of interaction.

Caution is required with phenytoin containing epilepsy drugs, drugs to treat anxiety or sleep regulating drugs.

If you are taking or have recently taken any other medicines, including medicines without a prescription, tell your doctor or pharmacist..

3. How to use ALERFIN

- **Instructions for proper use and dosage/administration frequency:**

Children aged 2 to 6 years: 2.5 ml (1/2 measuring spoon) every 4 to 6 hours.

Children aged 6 to 12 years: 5 ml (1 measuring spoon) every 4 to 6 hours.

Adults and adolescents (12 years and older) 10 ml (2 measuring spoons) every 4 to 6 hours.

Your doctor will tell you how long you will need to use ALERFIN.

- **Route and method of administration:**

ALERFIN is for oral use only.

- **Different age groups:**

  Use in children:
  Do not use this medicine in children under 2 years of age.

  In elderly:
  Patients aged 65 years and older should be under the supervision of the doctor. The maximum daily dose should not exceed 12 mg.

- **Special populations:**

  Kidney / Liver Failure:
  Caution is required in patients with serious liver failure.

If you have the impression that the effect of ALERFIN is too strong or weak, talk with your doctor or pharmacist.

If you use more ALERFIN than you should:
If you used more ALERFIN than was prescribed, tell your doctor or pharmacist.

Oral use of 3-5 times the daily dose causes poisening. If you take more ALERFIN than you should; life support should be provided if required.

If you forget to use ALERFIN:
Do not use a double dose to make up for a forgotten dose.

Skip the missed dose and take the next dose as required.

Possible effects may occur when you stop taking ALERFIN: None.

4. Possible side effects
Like all medicines, ALERFIN may cause side effects in patients sensitive to its ingredients.

If any of the following reactions happen, stop taking ALERFIN and tell your doctor immediately or contact the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips, or swelling of the mouth or throat causing difficulties in breathing or swallowing
- Severe skin rash
- Fainting

These are all very serious side effects.

If you experience one of these side effects, it means that you are severely allergic to ALERFIN. You may need urgent medical attention or to be hospitalized.

These very serious side effects are all rare.

Side effects are classified as follows according to their frequency:
Very common: may be seen in at least 1 in 10 patients;
Common: may be seen less than 1 in 10 patients but more than 1 in 100 patients
Uncommon: may be seen less than 1 in 100 patients but more than 1 in 1,000 patients
Rare: may be seen less than 1 in 1,000 patients but more than 1 in 10,000 patients
Very rare: may be seen in less than one in 10,000 patients; Not known: Cannot be estimated from the available data.

Very common:

- Feeling heavy-eyed or sleepy (sedation)
- Somnolence

Common:

- Attention deficit
- Coordination disorder
- Dizziness
- Headache
- Nausea

- Dry mouth
- Fatigue

Rare:
- Difficulty to urinate (urinary retention)

Very rare:
- Fits

Not known:
- Hemolytic anemia (a type of anemia)
- Lowering in white blood cells count (blood dyscrasia) □Allergic reaction
- Swelling on the skin or respiratory tract (angioedema)
- Severe allergic reaction (anaphylactic reactions)
- Loss of appetite
- Insomnia
- Increased irritability
- Anxiety
- Confusion
- Irritability
- Nightmares
- Depression
- Tremor
- Blurred vision
- Palpitation
- Low blood pressure (Hypotension)
- Changes in heart rate (sinus tachycardia)
- Irregular heart rate (arrhythmia)
- Thickened respiratory secretion (bronchial secretion)
- Stomach ache (epigastric pain)
- Constipation
- Vomiting
- Diarrhea
- Liver infection (hepatitis)
- Jaundice
- Skin inflammation (exfoliative dermatitis)
- Redness
- Hives (urticaria)
- Sensitivity to light (photosensitivity)
- Muscle twitches
- Muscle weakness
- Chest tightness

Tell your doctor or pharmacist if you notice any other effects not listed in this leaflet.

Reporting side effects
Please inform your doctor, pharmacist or nurse if you get any side effect whether or not included in this leaflet. In addition, please report the side effect that you are experiencing to Turkish Pharmacovigilance Center (TÜFAM) by clicking to the icon "Reporting Drug Side Effects" at www.tick.gov.tr or call the reporting hotline dialing 0 800 314 00 08. By reporting the side effects, you can help provide more information on the safety of this medicine.

5. How to store ALERFIN
Store ALERFIN in its original packaging and keep out of the reach and sight of children.

Store at room temperature below 25°C.

Use in compliance with the expiry date.
Use ALERFIN before the date of expiry on the label or packaging.

Do not use ALERFIN if you notice defects on the product and/or its packaging.

Do not throw away drugs that have expired or are not used! Deliver to the collection system determined by the Ministry of Environment and Urbanism.

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