# SUMMARY OF PRODUCT CHARACTERISTICS

## 1. NAME OF THE MEDICINAL PRODUCT
ALERFIN 2 mg/5 ml oral solution, 100 ml

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each 5 ml solution contains;

**Active substance(s):**
Chlorpheniramine maleate 2 mg

**Excipient(s):**
Sorbitol (%70) 2500 mg
Sodium saccharin 0.5 mg
Methyl paraben sodium 5.0 mg

For the full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM
Oral solution
Clear solution of yellow-orange color with an aromatic odor.

## 4. CLINICAL PARTICULARS
### 4.1. Therapeutic indications
Chlorpheniramine is used for the relief of symptoms associated with seasonal allergic rhinitis and for the treatment of urticaria and allergic reactions.

### 4.2. Posology and method of administration
**Posology/frequency of administration and duration of the treatment:**
Unless recommended otherwise by the doctor, it is used as follows;

| Age | Daily dose | Maximum daily dose |
|---|---|---|
| 2-6 years | 1 x 2.5 ml (1/2 spoon), every 4-6 hours | 6 x 2.5 ml (1/2 spoon), 24 hours |
| 6-12 years | 1 x 5 ml (1 spoon), every 4-6 hours | 6 x 5 ml (1 spoon), 24 hours |
| Over 12 years | 2 x 5 ml (1 spoon), every 4-6 hours | 12 x 5 ml (1 spoon), 24 hours |
| Adults | 2 x 5 ml (1 spoon), every 4-6 hours | 12 x 5 ml (1 spoon), 24 hours |

**Additional information for special populations**
**Hepatic failure:**
It causes unwanted sedation in severe liver disease. It should not be used in patients with hepatic failure.

**Pediatric population**
It is not used in children under 2 years old.

**Geriatric population**

It should be used under the supervision of a doctor in individuals aged 65 and over. These individuals are more susceptible to neurological anticholinergic effects. The maximum daily dose should not exceed 12 mg.

**4.3. Contraindications**
It is contraindicated in people with known hypersensitivity to chlorpheniramine maleate or any of the ingredients in ALERFIN.
It is contraindicated for use under 2 years of age.
ALERFIN should not be used if you have used a monoamine oxidase inhibitor (MAOI) in the past 14 days.

**4.4. Special warnings and precautions for use**
Its use should be avoided in the following situations:

- Arrhythmias
- Epilepsy
- Severe hypertension or cardiovascular disease
- Prostate hypertrophy
- Liver failure
- Glaucoma
- Bronchitis, bronchiectasis, asthma
- Overactive thyroid dysfunctions.

Children and the elderly are more sensitive to neurological anticholinergic side effects and paradoxical excitation (increased energy, restlessness, irritability). Use under 2 years of age is contraindicated.

Since it contains 1.75g/5ml sorbitol, patients with rare hereditary fructose intolerance, glucose-galactose malabsorption or sucrose-isomaltase insufficiency should not use this medicine.

It contains methyl paraben sodium which may cause a delayed allergic reaction.

This medicinal product contains 0.72 mg sodium per 5 ml. This should be considered for patients on a controlled sodium diet.

**4.5. Interaction with other medicinal products and other forms of interaction**
The sedative effect is increased when chlorpheniramine is used in combination with alcohol, some central nervous system depressants such as anxiolytics or hypnotics, and classical antihistamines (sedating). Sedative interactions are more limited with non-sedating antihistamines. Topically applied antihistamines (including those applied by inhalation) do not show such interactions.
Chlorpheniramine inhibits phenytoin metabolism, leading to phenytoin toxicity.
Atropine, tricyclic antidepressants and MAO inhibitors (see section 4.3) may increase the anticholinergic property of chlorpheniramine.

**4.6. Fertility, pregnancy and lactation**
**General advise**
Pregnancy category: B

**Women of childbearing potential/Birth control (contraception):**
For ALERFIN, clinical data on exposure during pregnancy are not available.

Animal studies are insufficient with respect to pregnancy / and-or / embryonal / fetal growth / and-or /natal / and-or / postnatal development. The potential risk to humans is not known.

Caution should be exercised when administered to pregnant women.

**Pregnancy**
There are insufficient data on the use of chlorpheniramine in pregnant women. The potential risks in humans are unknown and use in the 3rd trimester may cause reactions in term or premature neonates. It should not be used in pregnancy unless absolutely necessary by a physician.

**Breast-feeding**
It passes into breast milk at a significant rate. Although it is not known that this amount of drug has a harmful effect on the baby, it is recommended not to use it. Chlorpheniramine maleate and other antihistamines may inhibit lactation.

**Reproductive ability /Fertility**
It should be used by the physician after evaluating the benefit/risk ratio. Chlorpheniramine did not affect fertility in rats and rabbits when used 20-25 times the maximum dose recommended for humans on a mg/m2 basis.

**4.7. Effects on ability to drive and use machines**
Since it may cause drowsiness as a side effect, driving and machine use should be avoided.

**4.8. Undesirable effects**
The indicated undesirable effects are categorised according to the following rule:
Very common (≥1/10); common (≥1/100 to <1/10); not common (≥1/1.000 to <1/100); rare (≥1/10.000 to <1/1.000); very rare (<1/10.000), not known (can not be estimated based on available data).

**Blood and lymphatic system disorders:**
Not known: Haemolytic anaemia, blood dyscrasias

**Immune system disorders:**
Not known: Allergic reaction, angioedema, anaphylactic reactions

**Metabolic and nutritional disorders:**
Not known: Loss of appetite

**Psychiatric disorders:**
Not known: Insomnia, increased excitability*, anxiety, confusion*, irritability*, nightmares*, depression
*Children and the elderly are more susceptible to neurological anticholinergic side effects and paradoxical excitation (increased energy, restlessness, irritability)

**Nervous system disorders**
Very common: Sedation, somnolence
Common: Distraction, incoordination, dizziness, headache
Very rare: Seizure
Not known: Tremor

**Eye disorders:**
Not known: blurred vision

**Ear disorders:**
Not known: Tinnitus

**Cardiac disorders:**
Not known: Palpitation, sinus tachycardia, arrhythmia

**Vascular diseases:**
Not known: hypotension

**Respiratory disorders:**
Not known: darkening of bronchial secretions

**Gastrointestinal disorders:**
Common: Nausea, dry mouth
Not known: Epigastric pain, constipation, vomiting, diarrhea

**Hepatobiliary system disorders:**
Not known: hepatitis, jaundice

**Skin and subcutaneous tissue disorders:**
Not known: exfoliative dermatitis, rash, urticaria, photosensitivity

**Musculoskeletal and connective tissue disorders:**
Not known: muscle twitches, muscle weakness

**Kidney and urinary disorders:**
Rare: urinary retention

**General disorders and administration site conditions:**
Common: Fatigue
Not known: chest tightness

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via Turkish Pharmacovigilance Center (TÜFAM). (www.titck.gov.tr; e-mail: tufam@titck.gov.tr; tel.: 0 800 314 00 08; fax: 0 312 218 35 99).

**4.9. Overdose and treatment**
If 3-5 times the daily dose is taken orally, it causes poisoning. Children are more sensitive to the anticholinergic toxic effect of antihistamines than adults. Signs and symptoms include sedation, paradoxical excitation of the CNS, toxic psychosis, convulsions, apnoea, anticholinergic effects, dystonic reactions, arrhythmia and cardiovascular collapse. The lethal dose is between 25-50 mg/kg.

If the drug has been taken within the last hour and there is no contraindication, activated charcoal should be administered. If necessary, basic and advanced life support should be given. If there is pulseless ventricular fibrillation, defibrillation is applied. Since signs and symptoms of intoxication may be delayed due to anticholinergic effect, patients with no symptoms should be monitored for at least 6-8 hours. Hypotension and arrhythmias should be treated aggressively. During the monitoring period, be aware of coma, convulsions, hyperthermia and ventricular tachycardia that may occur. Convulsions can be treated with IV diazepam.

## 5. PHARMACOLOGICAL PROPERTIES

### 5.1. Pharmacodynamic properties

**Pharmacotherapeutic group:** Antihistamines for systemic use
**ATC Code:** R06AB04

### 5.1. Pharmacodynamic properties

Chlorpheniramine maleate is a potent antihistamine derivative of alkylamine. It also has anticholinergic activity. Due to its H1 receptor antagonist property, it temporarily eliminates allergic symptoms of upper respiratory tract allergic diseases such as runny nose, watery eyes, sneezing. It is an antihistamine with good therapeutic effect. Antihistamines provide symptomatic relief, which lasts as long as the medication is taken.

### 5.2. Pharmacokinetic properties

**General characteristics**

Chlorpheniramine is administered orally (PO), subcutaneously (SC) or intramuscularly (IM). Although the absorption of H1-blockers from the gastrointestinal tract is good, the difference in solubility of different derivatives is a factor that affects the onset time of their effects. The effects of H1-blockers with low solubility start more slowly and are less likely to cause toxicity.

Absorption

Chlorpheniramine maleate is well absorbed orally, the effect begins in 15-60 minutes and reaches a maximum in 3-6 hours.

Distribution

Chlorpheniramine maleate binds approximately 70% to plasma proteins. It has a wide distribution throughout the body, including the central nervous system. It crosses the placenta and passes into breast milk.

Biotransformation

Chlorpheniramine is metabolised rapidly and extensively. It is first metabolised in the gastrointestinal mucosa and then undergoes first-pass metabolism in the liver. Different metabolites are formed by N-dealkylation.

Elimination

Chlorpheniramine maleate is renally excreted as metabolites within 24 hours. The rate of renal excretion is dependent on urine pH and urinary flow; elimination rate decreases when urine pH increases and urinary flow decreases.

Linearity/non-linearity

The kinetics of chlorpheniramine is linear.

**5.3. Preclinical safety data**
Not available.

## 6. PHARMACEUTICAL PARTICULARS

**6.1. List of excipients**
Sorbitol (70%)
Sodium saccharin
Citric acid
Methyl paraben sodium
Orange aroma
FD&C yellow no:6 (E110)
Deionised water

**6.2. Incompatibilities**
Not available.

**6.3. Shelf life**
36 months

**6.4. Special precautions for storage**
Store at room temperature below 25ºC

**6.5. Nature and contents of container**
ALERFIN is marketed in an amber coloured glass bottle (Type III) sealed with a pilfer-proof polypropylene cap with low density polyethylene seal in a box.
Each cardboard box contains one vial and one 5 ml spoon.

**6.6. Special precautions for disposal and other handling**
Any unused product or waste material should be disposed of in accordance with "Directive on Control of Medical Waste" and "Directive on the Control of Packaging and Packaging Waste".

## 7. MARKETING AUTHORISATION HOLDER

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## 8. MARKETING AUTHORISATION NUMBER(S)
255/67

## 9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
Date of first authorisation: 26.12.2013
Date of latest renewal: 11.02.2019

## 10. DATE OF REVISION OF THE TEXT