

## **PATIENT INFORMATION LEAFLET**

AEROGAL<sup>®</sup>, 5 mg, Film-coated Tablets

desloratadine

**Read this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Always take this medicine exactly as stated in this leaflet or as your doctor or your pharmacist has told you.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or your pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- If you feel no improvement or if you feel worse after the period of 3 days, you must contact your doctor.

### **In this leaflet:**

1. What AEROGAL is and what it is used for
2. What you need to know before you take AEROGAL
3. How to take AEROGAL
4. Possible side effects
5. How to store AEROGAL
6. Contents of the pack and other information

## **1. What AEROGAL is and what it is used for**

AEROGAL contains the active ingredient called desloratadine, which is an antihistamine.

### **How AEROGAL acts**

AEROGAL is an antiallergy medicine that does not make you drowsy. It helps control your allergic reactions and their associated symptoms.

### **When AEROGAL should be used**

AEROGAL relieves the symptoms associated with allergic rhinitis (inflammation of the lining of the nose caused by an allergy, for example, hay fever or allergy to dust mites) in adults and adolescents aged 12 years or older. These symptoms include sneezing, itchy or runny nose, itchy palate, and red, itchy or watery eyes.

AEROGAL is also used to relieve the symptoms associated with urticaria (skin changes caused by an allergy). These symptoms include hives and itching of the skin.

Relief of the symptoms lasts a full day, helping you to resume your normal daily activities and sleep.

## **2. What you need to know before you take AEROGAL**

### **Do not take AEROGAL:**

If you are allergic (hypersensitive) to desloratadine or to any of the other ingredients of this medicine (see section 6) or to loratadine.

### **Warnings and precautions**

Talk to your doctor or your pharmacist before taking AEROGAL:

- if you have poor kidney function;
- if you have medical or familial history of fits (seizures).

### **Use in children and adolescents**

AEROGAL should not be prescribed to children less than 12 years of age.

### **Other medicines and AEROGAL**

Tell your doctor or pharmacist if you are taking, have recently taken or are planning to take any other medicines.

There are no known interactions of AEROGAL with other medicines.

### **Taking AEROGAL with food, drink and alcohol**

AEROGAL can be taken with or without food.

This medicine should be used with caution when drinking alcohol.

### **Pregnancy, breast-feeding and fertility**

If you are pregnant or breast-feeding, think that you are pregnant or plan to become pregnant, ask your doctor or pharmacist for advice before you start taking this medicine.

AEROGAL is not recommended if you are pregnant or breastfeeding.

There are no available data on effects of AEROGAL on male or female fertility.

### **Driving and using machines**

At the recommended dose, AEROGAL is not expected to affect the ability to drive or operate machinery. Although most people do not experience drowsiness, it is recommended not to engage in activities requiring mental alertness, such as driving a car or operating machinery until you have established your own response to the medicinal product.

## **3. How to take AEROGAL**

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. You should check with your doctor or your pharmacist if you are not sure.

## **Adults and adolescents (12 years of age and over)**

The recommended dose is one film-coated tablet once a day with water, with or without food.

This medicine is for oral use.

Swallow the tablet whole.

Your doctor will determine the type of allergic rhinitis (allergic inflammation of the lining of the nose) you are suffering from and will determine for how long you should take AEROGAL accordingly.

If your allergic rhinitis is intermittent (presence of symptoms for less than 4 days per week or for less than 4 weeks), your doctor will recommend you a treatment schedule that will depend on the evaluation of the history of your disease.

If your allergic rhinitis is persistent (presence of symptoms for 4 days or more per week or for more than 4 weeks), your doctor may recommend you a longer-term treatment.

For urticaria, the duration of treatment may be variable from patient to patient and therefore you should follow the instructions of your doctor.

If your symptoms get worse or if you feel no improvement after 3 days of treatment, you must tell your doctor or pharmacist.

Do not take the medicine for longer than 10 days, unless your doctor tells you to.

### **If you take more AEROGAL than you should**

Always take AEROGAL exactly as your doctor or your pharmacist has told you. No serious problems are expected with accidental overdose. However, if you take more AEROGAL than you should, tell your doctor or pharmacist straight away.

### **If you forget to take AEROGAL**

If you forget to take your prescribed dose of AEROGAL, take it as soon as possible, then go back to your regular dosing schedule. Do not take a double dose to make up for a forgotten dose.

If you have any questions on the use of this medicine, ask your doctor or pharmacist.

## **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

During the marketing of desloratadine, cases of severe allergic reactions (difficulty in breathing, wheezing when breathing in and out, itching, hives and swelling) have been reported very rarely. If you notice any of these serious side effects, stop taking this medicine and seek urgent medical assistance straight away.

In clinical studies in adults, side effects were about the same as those seen with a dummy tablet. However, fatigue, dry mouth and headache were reported more often than with a dummy tablet.

In adolescents, headache was the most commonly reported side effect.

In clinical studies with desloratadine, the following side effects were reported as:

Common side effects (may affect up to 1 in 10 patients taking the medicine):

- tiredness,
- dry mouth,
- headache.

### Adults

During the marketing of desloratadine, the following side effects were reported:

Very rare side effects (may affect up to 1 in 10 000 patients taking the medicine):

- severe allergic reactions,
- rash,

- palpitations (subjective feeling of pounding or irregular heartbeat),
- fast heartbeat,
- stomach ache,
- feeling sick,
- being sick,
- gastric problems,
- diarrhoea,
- dizziness,
- drowsiness,
- inability to sleep,
- pain in the muscles,
- hallucinations,
- seizures,
- restlessness with increased body movements,
- inflammation of the liver,
- abnormal liver function tests.

Not known (cannot be estimated from the available data):

- unusual weakness,
- yellowing of the skin and/or the whites of the eyes,
- increased sensitivity of the skin to the sun, even in case of hazy sun, and to UV (ultraviolet) light, e.g. to UV lights of a solarium,
- changes in the way the heart beats,
- abnormal behaviour,
- aggression,
- increased appetite and weight gain,
- depressed mood,
- dry eyes.

### Children

Not known (cannot be estimated from the available data):

- slow heartbeat
- changes in the way the heart beats
- abnormal behaviour,
- aggression.

### Reporting of side effects

If you get any side effects, you should tell your doctor or your pharmacist. This includes any possible side effects not listed in this leaflet. By reporting side effects, you can help provide more information on the safety of this medicine. You can also report suspected side effects to the Medicines and Medical Devices Agency of Serbia (ALIMS):

Medicines and Medical Devices Agency of Serbia  
 National Pharmacovigilance Centre  
 Vojvode Stepe 458, 11221 Belgrade  
 Republic of Serbia  
 website: [www.alims.gov.rs](http://www.alims.gov.rs)  
 e-mail: [nezeljene.reakcije@alims.gov.rs](mailto:nezeljene.reakcije@alims.gov.rs)

### **5. How to store AEROGAL**

Keep this medicine out of the sight and reach of children.

Do not use AEROGAL after the expiry date which is stated on the outer pack after Exp. The expiry date refers to the last day of the specified month.

Store at temperatures up to 30°C, in the original pack.

You should hand the medicines you no longer use to a pharmacy collecting the medicines which are no longer used. Do not throw away the medicines you no longer use via wastewater or household waste. These measures will help protect the environment.

## **6. Contents of the pack and other information**

### **What AEROGAL contains**

The active ingredient is desloratadine.

Each film-coated tablet contains 5 mg of desloratadine.

The other ingredients are:

*Tablet core:* cellulose, microcrystalline; calcium hydrogen phosphate, dihydrate; talc.

*Tablet (film-)coating: Opadry II green 85F21865:* polyvinyl alcohol; polyethylene glycol; talc; titanium dioxide; iron (III) oxide, yellow; aluminium lake blue; aluminium lake indigo carmine.

### **What AEROGAL looks like and contents of the pack**

Film-coated tablet.

Green, round, biconvex, film-coated tablets.

Aerogal, 5 mg, Film-coated Tablets (1x10):

The inner pack consists of an AL/PVC-PVC blister with 10 film-coated tablets.

The outer package is a foldable cardboard box containing one blister with 10 film-coated tablets (a total of 10 film-coated tablets) and a leaflet.

Aerogal, 5 mg, Film-coated Tablets (3x10):

The inner pack consists of an AL/PVC-PVC blister with 10 film-coated tablets.

The outer package is a foldable cardboard box with three blisters, each containing 10 film-coated tablets (a total of 30 film-coated tablets), and a leaflet.

### **Marketing Authorisation Holder and manufacturer**

GALENKA AD BEOGRAD, Batajnički drum b.b., Belgrade, Republic of Serbia

### **This leaflet was last approved**

August 2023

### **Legal category:**

Over-the-counter (OTC) medicine.

### **Number and date of Marketing Authorisation:**

Aerogal, 5 mg, Film-coated Tablets (1 x 10): 515-01-02383-22-001 of 6 July 2023

Aerogal, 5 mg, Film-coated Tablets (3 x 10): 515-01-04259-22-001 of 3 August 2023