

**PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS'
REGULATIONS (PREPARATIONS) – 1986**

This medicine can be sold under doctor's prescription only

AERIUS® TABLETS

Film-coated tablets

Each film coated tablet contains:

Desloratadine 5 mg

For a list of inactive ingredients please refer to section 6 “**What AERIUS TABLETS contains?**”

See also section 2.8 “**Important information about some of the ingredients of the medicine**”.

Read all of this leaflet carefully before you start using this medicine.

- This leaflet contains concise information about **AERIUS TABLETS**. 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. It may harm them, even if their ailment seems similar to yours.
- This medicine is intended for adults and adolescents 12 years of age and older.

1. WHAT IS AERIUS TABLETS INTENDED FOR?

AERIUS TABLETS is an antiallergy medicine that does not make you drowsy. It helps control your allergic reaction and its symptoms.

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

AERIUS TABLETS is also used to relieve the symptoms associated with urticaria (a skin condition caused by an allergy). These symptoms include itching and hives.

Relief of these symptoms lasts a full day and helps you to resume your normal daily activities and sleep.

Therapeutic group: H₁ receptor antagonists - antihistamines.

2. BEFORE YOU USE AERIUS TABLETS

2.1 Do not use AERIUS TABLETS if you:

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| <ul style="list-style-type: none">• are allergic (hypersensitive) to desloratadine, or any of the other ingredients of AERIUS TABLETS (for a list of inactive ingredients, see section 6.1) or to loratadine. |
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2.2 Special warnings concerning use of AERIUS TABLETS

Before starting treatment with AERIUS TABLETS, tell the doctor if:

- you have poor kidney function.
- you have medical or familial history of seizures.

2.3 Use in children and adolescents

This medicine is not intended for children under the age of 12 years.

2.4 Drug interactions

If you are taking or have recently taken any other medicines, including non-prescription medicines and nutritional supplements, you should tell the attending doctor or pharmacist.

There are no known interactions of **AERIUS TABLETS** with other medicines.

2.5 Taking AERIUS TABLETS with food, drink and alcohol

AERIUS TABLETS may be taken with or without a meal.
Use caution when taking **AERIUS TABLETS** with alcohol.

2.6 Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Taking **AERIUS TABLETS** is not recommended if you are pregnant or nursing a baby.
There is no data available on male/female fertility.

2.7 Driving and using machines

At the recommended dose, **AERIUS TABLETS** is not expected to affect your ability to drive or use machines. 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.

2.8 Important information about some of the ingredients of the medicine

AERIUS TABLETS contain lactose (see section 6.1 “**What AERIUS TABLETS contains?**”).
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. HOW DO YOU USE AERIUS TABLETS?

Always use **AERIUS TABLETS** as instructed by the doctor. Check with your doctor or pharmacist if you are unsure regarding the dosage and treatment regimen.

The dosage and duration of treatment will be determined by the doctor only.

Adults and adolescents (12 years of age and older)

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

Do not exceed the recommended dose.

This medicine is for oral use.

Swallow the tablet whole.

No information is available with regards to crushing/splitting/chewing the tablets.

Regarding the duration of treatment, your physician will determine the type of allergic rhinitis you are suffering from and will determine for how long you should take **AERIUS TABLETS**.

If your allergic rhinitis is intermittent (presence of symptoms for less than 4 days per week or for less than 4 weeks), your physician 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 and for more than 4 weeks), your physician 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 physician.

If you take more AERIUS TABLETS than you should

Take **AERIUS TABLETS** only as it is prescribed for you. No serious problems are expected with accidental overdose. However, if you take more **AERIUS TABLETS** than you were told to, tell your doctor or pharmacist immediately.

If you have taken an overdose or if a child has accidentally swallowed the medicine, immediately refer to a doctor or to a hospital's emergency room and bring the medicine's package with you.

If you forget to take AERIUS TABLETS

If you forgot to take **AERIUS TABLETS** on time, take it as soon as possible and then go back to your regular dosing schedule. Do not take a double dose to make up for a forgotten dose. Complete the full course of treatment as instructed by the doctor. Even if there is an improvement in your condition, do not discontinue use of this medicine, without consulting your doctor or pharmacist.

Do not take medicines in the dark! Check the label and the dose each time you take your medicine. Wear glasses if you need them.

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

4. SIDE EFFECTS

Like all medicines, the use of **AERIUS TABLETS** can cause side effects in some of the users. Do not be alarmed by reading the list of side effects, you may not suffer from any of them.

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

In clinical studies in adults, side effects were about the same as 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 **AERIUS TABLETS**, the following side effects were reported as:

Common: the following side effects may affect up to 1 in 10 people

- fatigue
- dry mouth
- headache

During the marketing of **AERIUS TABLETS**, the following side effects were reported as:

Very rare: the following side effects may affect up to 1 in 10,000 people

- severe allergic reactions
- rash
- pounding or irregular heartbeat
- fast heartbeat
- stomach ache
- feeling sick (nausea)
- vomiting
- upset stomach
- diarrhoea
- dizziness
- drowsiness
- inability to sleep
- muscle pain
- hallucinations
- seizures
- restlessness with increased body movement
- liver inflammation
- abnormal liver function tests

Not known: frequency cannot be estimated from the available data

- unusual weakness
- yellowing of the skin and/or eyes
- increased sensitivity of the skin to the sun, even in case of hazy sun, and to UV light, for instance to UV lights of a solarium
- changes in the way the heart beats
- abnormal behaviour
- aggression
- weight increased, increased appetite
- depressed mood
- dry eyes

Children

Not known: frequency cannot be estimated from the available data

- slow heartbeat
- change in the way the heart beats
- abnormal behaviour
- aggression

Side effects can be reported to the Ministry of Health by using the link "Reporting side effects due to medicinal treatment" at the home page of the Ministry of Health's web site (www.health.gov.it) which refers to the online form for reporting side effects, or by using the link: <https://sideeffects.health.gov.it/>

If a side effect appears, if any of the side effects gets serious or if you notice a side effect not mentioned in this leaflet, consult your doctor.

5. HOW TO STORE AERIUS TABLETS?

- Avoid Poisoning! This medicine, as all other medicines, must be stored in a safe place out of the reach and sight of children and/or infants, in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Store below 30°C. Store in the original package.
- Do not use **AERIUS TABLETS** after the expiry date (exp. date) which is stated on the blister and outer carton. The expiry date refers to the last day of the indicated month.
- Do not use this medicine if you notice any change in the appearance of the tablets.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

6. FURTHER INFORMATION

6.1 What AERIUS TABLETS contains?

The active substance is desloratadine. Each film coated tablet contains 5 mg desloratadine.

In addition to the active ingredient, the medicine also contains inactive ingredients:

Tablet core: dibasic calcium phosphate dihydrate, microcrystalline cellulose, corn starch, blue colour film coat material, talc, clear film coat material, carnauba wax, white wax.

Tablet coating:

Blue colour film coat material contains:

lactose monohydrate (see section 2.8 "**Important information about some of the ingredients of the medicine**"), hydroxypropyl methylcellulose, titanium dioxide, polyethylene glycol, indigotin (E132).

Clear film coat material contains:

hydroxypropyl methylcellulose, polyethylene glycol.

Each tablet contains approximately 2.4 mg lactose monohydrate.

6.2 What AERIUS TABLETS looks like and content of the pack

AERIUS TABLETS are light blue, round and embossed with elongated letters “S” and “P” on one side and plain on the other.

Pack sizes:

AERIUS TABLETS are packed in blister in packs of 2, 5, 7, 10, 14, 15, 20 or 30 tablets.

Not all pack sizes may be marketed.

License holder and address:

Organon Pharma Israel Ltd., 1 Atir Yeda, Kfar Saba

Manufacturer: Organon LLC, NJ USA

Drug registration no. listed in the official registry of the Ministry of Health:

125.49.30441

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