

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

This medicine can be sold under doctor's prescription only

AERIUS[®] SYRUP 0.5 mg/ml

Each 1 ml contains:
Desloratadine 0.5 mg.

For a list of inactive ingredients see section 6.1 "**What AERIUS SYRUP contains?**" See also section 2.7 "**Important information about some of the ingredients of AERIUS SYRUP**".

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

- This leaflet contains concise information about **AERIUS SYRUP**. 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 medical condition seems similar to yours.
- **AERIUS SYRUP** does not make you drowsy. This medicine is not intended for children below one year of age.

1. WHAT AERIUS SYRUP IS AND WHAT IT IS USED FOR?

This medicine is indicated for the relief of symptoms associated with allergic rhinitis (inflammation of the nasal passages caused by an allergy, for example, hay fever or allergy to dust mites) and the symptoms associated with chronic idiopathic urticaria (a skin condition caused by an allergy) in adults, adolescents and children 1 year of age and older.

The symptoms associated with allergic rhinitis include sneezing, runny or itchy nose, itchy palate, and itchy, red or watery eyes.

The symptoms associated with chronic idiopathic urticaria 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 SYRUP

2.1 Do not use AERIUS SYRUP if you:

- re allergic (hypersensitive) to desloratadine or to any of the other ingredients of **AERIUS SYRUP** or to loratadine (for a list of inactive ingredients, see section 6.1).

2.2 Special warnings concerning use of AERIUS SYRUP

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

- you have poor kidney function.

2.3 Taking other medicines

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

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

2.4 Taking AERIUS SYRUP with food, drink and alcohol

AERIUS SYRUP may be taken with or without a meal.

Use caution when taking **AERIUS SYRUP** with alcohol.

2.5 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 SYRUP** is not recommended if you are pregnant or nursing a baby.

Fertility

There is no data available on male/female fertility.

2.6 Driving and using machines

At the recommended dose, **AERIUS SYRUP** 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.

2.7 Important information about some of the ingredients of AERIUS SYRUP

AERIUS SYRUP contains sucrose and sorbitol. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

2.8 Use in children and adolescents

this medicine is not intended for children less than 1 year of age.

3. HOW TO USE AERIUS SYRUP?

Always use **AERIUS SYRUP** as instructed by the doctor. You should check with your doctor or pharmacist if you are not sure.

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

The recommended dose for children is usually:

Children 1 through 5 years of age: 2.5 ml ($\frac{1}{2}$ of the 5ml measuring teaspoonful) once a day.

Children 6 through 11 years of age: 5 ml (one 5ml measuring teaspoonful) once a day.

The recommended dose for adults and adolescents (12 years of age and over) is usually:

10 ml (two 5ml measuring teaspoonfuls) once a day.

This medicine is for oral use.

Swallow the medicine and then drink some water. The medicine may be taken with or without food.

Do not exceed the recommended dose.

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

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 and 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 the doctor.

If you take more AERIUS SYRUP than you should

Take **AERIUS SYRUP** only as it is prescribed for you. No serious problems are expected with accidental overdose. However, if you take more **AERIUS SYRUP** 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, proceed immediately to a hospital emergency room and bring the package of the medicine with you.

If you forget to take AERIUS SYRUP

If you forgot to take your dose 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 health, do not discontinue use of this medicine before consulting the doctor.

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 further questions on the use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

Like all medicines, the use of **AERIUS SYRUP** 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**, 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 most children and adults, side effects with **AERIUS SYRUP** were about the same as with a dummy syrup or tablet. However, common side effects in children less than 2 years of age were diarrhoea, fever and insomnia while in adults, fatigue, dry mouth and headache were reported more often than with a dummy tablet.

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

Children

Common in children less than 2 years of age: the following may affect up to 1 in 10 children

- diarrhoea
- fever
- insomnia

Adults

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

- fatigue
- dry mouth
- headache

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

Adults

Very rare: the following 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
- change in the way the heart beats

Children

Not known: frequency cannot be estimated from the available data

- slow heartbeat
- change in the way the heart beats

Side effects can be reported to the Ministry of Health by using the link "Adverse Drug Reactions Report" at the home page of the Ministry of Health's web site (www.health.gov.il) which refers to the online form for reporting side effects, or by using the link:

<https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il>

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 the doctor.

5. HOW TO STORE AERIUS SYRUP?

- 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!
- Do not use **AERIUS SYRUP** after the expiry date (exp. date) which is stated on the pack. The expiry date refers to the last day of the indicated month.
- Store below 25°C. Do not use beyond 3 months from first opening.
- Do not use this medicine if you notice any change in the appearance of the syrup.
- 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 to protect the environment.

6. FURTHER INFORMATION

6.1 What AERIUS SYRUP contains?

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

Sucrose, sorbitol, propylene glycol, sodium citrate dihydrate, sodium benzoate, purified water, natural and artificial flavour for bubble gum, citric acid anhydrous, disodium edetate, dye FD&C Yellow No.6 (Color E110).

AERIUS SYRUP contains 150 mg/ml of sorbitol and 490 mg/ml sucrose. See also section 2.7 “**Important information about some of the ingredients of AERIUS SYRUP**”.

AERIUS SYRUP also contains sodium and sodium benzoate as a preservative.

6.2 What AERIUS SYRUP looks like and contents of the pack

AERIUS SYRUP is a clear, orange solution.

AERIUS SYRUP is available in a bottle of 120ml, with a childproof cap.

A measuring spoon is provided, marked for doses of 2.5 ml and 5 ml.

Marketing authorization holder:

Merck Sharp & Dohme (Israel-1996) Company Ltd., P.O.Box 7121, Petah-Tikva 49170.

Manufacturer: Schering-Plough Labo N.V., Heist-Op-Den-Berg, Belgium.

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

129.34.30778

This Leaflet was checked and approved by the Ministry of Health on October 2016