

AERIUS[®] SYRUP

Desloratadine 0.5 mg/ml

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What *AERIUS SYRUP* is used for

AERIUS SYRUP relieves symptoms associated with allergic rhinitis (inflammation of the nasal passages caused by an allergy, for example, hay fever or allergy to dust mites). These symptoms include sneezing, runny or itchy nose, itchy palate, and itchy, red or watery eyes.

AERIUS SYRUP 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.

How *AERIUS SYRUP* works

AERIUS SYRUP is an anti-allergy medicine that does not make you drowsy. It helps control your allergic reaction and its symptoms.

Before you take *AERIUS SYRUP*

- When you must not take it

Do not take *AERIUS SYRUP*

- if you are allergic (hypersensitive) to desloratadine, loratadine, or to any of the other ingredients of *AERIUS SYRUP*.

AERIUS SYRUP is indicated for children 1 through 11 years of age, adolescents (12 years of age and older), and adults, including the elderly.

- Before you start to take it

Talk to your doctor or pharmacist before taking *AERIUS SYRUP* if you have medical or familial history of seizure

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine during pregnancy and breast-feeding.

If you are pregnant or nursing a baby, taking *AERIUS SYRUP* is not recommended.

Important information about some of the ingredients of *AERIUS SYRUP*

AERIUS SYRUP contains 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.

- Taking other medicines

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

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

Taking *AERIUS SYRUP* with food and drink

AERIUS SYRUP may be taken with or without a meal.

How to take *AERIUS SYRUP*

- How much to take

Children 1 through 5 years of age: take 2.5 ml ($\frac{1}{2}$ of a 5 ml spoonful) of syrup once a day.

Children 6 through 11 years of age: take 5 ml (one 5 ml spoonful) of syrup once a day.

Adults and adolescents (12 years of age and older): take 10 ml (two 5 ml spoonfuls) of syrup once a day.

In case an oral measuring syringe is provided with the bottle of syrup, you can alternatively use it to take the appropriate amount of syrup.

Swallow the dose of syrup, then drink some water.

- When to take it

You can take this medicine with or without food.

- How long to take it

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 SYRUP*.

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.

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- If you forget to take it

If you forget to take your dose on time, 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 take too much (overdose)

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, contact your doctor or pharmacist.

While you are taking *AERIUS SYRUP*

- Things you must do

- Take your medicine exactly as your doctor has told you.
- Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

- Do not stop taking this medicine unless advised by your doctor.
- Do not take any new medicines without consulting your doctor.
- Do not give *AERIUS SYRUP* to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines

At the recommended dose, *AERIUS SYRUP* is not expected to cause you to be drowsy or less alert. However, very rarely some people experience drowsiness, which may affect their ability to drive or use machines.

Side effects

Like all medicines, *AERIUS SYRUP* can cause side effects, although not everybody gets them. In most children and adults, side effects with *AERIUS SYRUP* were about the same as

with a dummy solution 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.

During the marketing of *AERIUS SYRUP*, cases of severe allergic reactions (difficulty in breathing, wheezing, itching, hives and swelling) and rash have been reported very rarely. Cases of palpitations, rapid heartbeat, seizures, restlessness with increased body movement, drowsiness, liver inflammation and abnormal liver function tests have also been reported very rarely.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website np.ra.moh.gov.my (Public → Reporting Medicinal Problems / Side Effects / AEFI)

Storage and Disposal of *AERIUS SYRUP*

- Storage

- Store below 30°C.
- Keep out of the reach and sight of children.
- Do not freeze. Store in the original package.
- Do not take *AERIUS SYRUP* after the expiry date which is stated on bottle.
- The expiry date refers to the last day of that month.
- Tell your pharmacist if you notice any change in the appearance of syrup.

- Disposal

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.

Product Description

- What it looks like

AERIUS SYRUP is a clear, orange solution. *AERIUS SYRUP* is available in bottles of 50, 60, 100, 120, 150, in glass bottle.

- Ingredients

- Active ingredient:

The active substance is desloratadine 0.5 mg/ml

- Inactive ingredient:

Propylene glycol, liquid sorbitol, anhydrous citric acid, sodium citrate dihydrate, sodium benzoate, disodium edetate, sucrose, FD&C Yellow Dye No. 6, natural and artificial flavour, and purified water.

- MAL number

MAL05012317AZ

Manufacturer

Schering-Plough Labo N.V., Heist-op-den-Berg, Belgium.

Product Registration Holder

Merck Sharp & Dohme (Malaysia) Sdn. Bhd.
Lot No. B-22-1 & B-22-2, Level 22
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