

AERIUS[®] TABLET 5MG

Desloratadine 5 mg

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What *AERIUS TABLET* is used for

AERIUS TABLET 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 TABLET 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 TABLET* works

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

Before you use *AERIUS TABLET*

- When you must not use it

- Do not use *AERIUS* if you are allergic (hypersensitive) to desloratadine, to any of the other ingredients of *AERIUS TABLET* or to loratadine.

- Before you start to use it

Talk to your doctor or pharmacist before taking *AERIUS TABLET* if you have medical or familial history of seizures.

Efficacy and safety of *AERIUS TABLET* in children under 12 years of age have not been established.

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 TABLET* is not recommended.

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

AERIUS TABLET contain lactose. 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 TABLET* with other medicines.

Tell your doctor or pharmacist if you are taking, have recently

taken or might take any other medicines.

Taking *AERIUS TABLET* with food and drink

AERIUS TABLET may be taken with or without a meal.

How to use *AERIUS TABLET*

- How much to use

Adults and adolescents (12 years of age and older): take one tablet once a day.

- When to use it

Swallow the tablet whole with water, with or without food.

- How long to use 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 TABLET*.

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 use 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 use too much (overdose)

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

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using *AERIUS TABLET*

- 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 the medicine unless advised by your doctor.
- Do not take any new medicines without consulting your doctor.
- Do not give *AERIUS TABLET* 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 TABLET* 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 TABLET* can cause side effects, although not everybody gets them. 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.

During the marketing of *AERIUS TABLET*, cases of severe allergic reactions (difficulty in breathing, wheezing, itching, hives and swelling) and rash have been reported very rarely. Cases of palpitations (irregular rapid pumping of the heart), rapid heartbeat, 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 npa.moh.gov.my

(Public → Reporting Medicinal Problems / Side Effects / AEFI)

Storage and Disposal of *AERIUS TABLET*

- Storage

- Keep out of the reach and sight of children.
- Store below 30 °C. Store in the original package. Protect *AERIUS TABLET* from excessive moisture.
- Do not take *AERIUS TABLET* after the expiry date which is stated on the carton and blister.
- The expiry date refers to the last day of that month.
- Tell your pharmacist if you notice any change in the appearance of the tablets.

- 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 TABLET 5 mg film-coated tablet is a light blue round tablet, embossed with elongated letters 'S' and 'P' on one side and plain on the other.

- Ingredients

- Active ingredient:
Desloratadine

- Inactive ingredients:
Dibasic calcium phosphate dihydrate, microcrystalline cellulose, corn starch, talc, , carnauba wax, white wax,

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purified water, Dye Opadry II
Blue and Dye Opadry Clear.

- MAL number

MAL10053655AZ

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
The Ascent, Paradigm No.1
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Date of Revision

15/08/2017 (version042017)

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