

# AERIUS® D-12 MODIFIED RELEASE TABLET

Desloratadine/Pseudoephedrine sulphate (2.5 mg/120 mg)

## What is in this leaflet

1. What AERIUS D-12 is used for
2. How AERIUS D-12 works
3. Before you take AERIUS D-12
4. How to take AERIUS D-12
5. While you are taking AERIUS D-12
6. Side effects
7. Storage and Disposal of AERIUS D-12
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of Revision

## What AERIUS D-12 is used for

AERIUS D-12 tablets **relieve symptoms** associated with seasonal allergic rhinitis (**hay fever**), such as, sneezing, runny or itchy nose, and eyes, **when accompanied by nasal congestion**.

## How AERIUS D-12 works

AERIUS D-12 tablets contain a combination of two active ingredients, desloratadine which is an antihistamine and pseudoephedrine sulphate which is a decongestant.

Antihistamines help to reduce allergic symptoms by blocking the effects of a substance called histamine, which is produced by the body. Decongestants help to clear nasal congestion.

## Before you take AERIUS D-12

### When you must not take it

Do not take AERIUS D-12 if you:

- are allergic (hypersensitive) to desloratadine, loratadine, pseudoephedrine sulphate or to any of the other ingredients of AERIUS D-12
- have severe high blood pressure, heart or blood vessel disease or a history of stroke
- have glaucoma (build-up of pressure within the eye), difficulty in urinating, urinary

tract blockage, or an overactive thyroid

- are taking monoamine oxidase (MAO) inhibitor (a class of antidepressant agents) therapy or have stopped taking these types of medicines within the last 14 days.

### Before you start to take it

Certain conditions may make you unusually sensitive to the decongestant pseudoephedrine sulphate contained in this medicine. Before taking AERIUS D-12, tell your doctor or pharmacist if you:

- are 60 years of age or older. Older adults may be more sensitive to the effects of this medicine
- have diabetes
- have high blood pressure
- have prostate enlargement
- have problems with your liver, kidney, or bladder.
- have medical or familial history of seizures

### Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. This is especially important if you are taking:

- digitalis, a medicine used to treat certain heart disorders
- medicines for blood pressure (e.g.  $\alpha$ -methyldopa, mecamylamine, reserpine, veratrum alkaloids and guanethidine)
- decongestants (oral or nasal)

## How to take AERIUS D-12

Always take AERIUS D-12 tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

### How much to take

**Adults and adolescents 12 years of age and over:**

- AERIUS D-12 should **not** be

used in children under 12 years of age.

Take one AERIUS D-12 tablet twice daily with a glass of water, with or without food. Swallow the tablet whole; do not crush, break or chew the tablet before swallowing.

### When to take it

Take as directed by your doctor or pharmacist.

### How long to take it

- Do not take more AERIUS D-12 tablets than recommended on the label.
- Do not take AERIUS D-12 tablets more often than recommended.

### If you forget to take it

If you forget 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.

### If you take too much (overdose)

If you take more AERIUS D-12 than you were told to, tell your doctor or pharmacist immediately.

## While you are taking AERIUS D-12

### 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 or pharmacist.
- Do not give AERIUS D-12 to anyone else, even if they have the same symptoms or condition as you.

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## Things to be careful of

### **Pregnancy and breast-feeding**

Ask your doctor or pharmacist for advice before taking any medicine during pregnancy or breast-feeding. Taking AERIUS D-12 is not recommended if you are pregnant. If you are breast-feeding taking AERIUS D-12 is not recommended.

There have been rare cases of reversible conditions related to brain dysfunction and narrowing of brain blood vessels (also known as Posterior Reversible Encephalopathy Syndrome (PRES) / Reversible Cerebral Vasoconstriction Syndrome (RCVS)) observed with pseudoephedrine-containing medicines such as this product.

Reported symptoms include sudden onset of severe headache, nausea, vomiting, visual disturbances, seizure and altered mental status. Most cases have resolved within days following discontinuation of the medication and appropriate treatment.

Please discontinue this product and seek medical advice immediately if signs or symptoms above develop.

### **Driving and using machines**

At the recommended dose, AERIUS D-12 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 D-12 can cause side effects, although not everybody gets them. The following side effects have been seen in studies:

- Mouth dry
- Fatigue
- Headache
- Dizziness
- Anorexia (Eating disorder)
- Insomnia (sleeping difficulty)
- Nervousness

- Sleepiness
- Hypersensitivity reactions (anaphylaxis and rash)
- Increase heart rate
- Palpitations
- (feeling of heart pounding)
- Psychomotor hyperactivity
- (restlessness)
- Seizures (fit)
- Elevated liver enzymes (including bilirubin and liver inflammation)
- Increased appetite

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 visiting the website [npa.moh.gov.my](http://npa.moh.gov.my) [Public → Reporting Side Effects to Medicines or Vaccines (AEFI)]. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

### **Storage and Disposal of AERIUS D-12**

#### Storage

- Keep out of the reach and sight of children.
- Store below 30°C. Store in original package. Protect from excessive moisture. Do not use AERIUS D-12 after the expiry date which is stated on the blister.
- The expiry date refers to the last day of that month.

#### 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 D-12 is a blue and white oval bi-layer tablet with “D12” branded on the blue layer.

## Ingredient

### Active Ingredients:

The active substances are desloratadine and pseudoephedrine (as sulphate)

Inactive ingredients: Microcrystalline cellulose, hydroxypropyl methylcellulose, povidone, magnesium stearate, silicon dioxide, corn starch, edetate sodium, citric acid, stearic acid vegetable, alcohol SDAG-1 (95%), Indigo Carmine E132, Aluminium Lake and purified water.

## MAL number

MAL11050002ACRZ

## **Manufacturer**

Patheon Inc., Ontario, Canada

## **Product Registration Holder**

Organon Malaysia Sdn. Bhd.  
3A-08-02, Level 8,  
Corporate Tower 3A,  
Pavilion Damansara Heights,  
No. 3, Jalan Damansara  
50490 Kuala Lumpur, Malaysia.

## **Date of Revision**

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