

Consumer Medicine Information**What is in this leaflet**

This leaflet answers some common questions about AERIUS.

It does not contain all of the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor or pharmacist has weighed the risks of you taking AERIUS against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What AERIUS is used for

AERIUS belongs to a class of medicines known as antihistamines.

Antihistamines help reduce allergic symptoms by preventing the effects of a substance called histamine. Histamine is produced by the body in response to foreign substances which the body is allergic to.

With its anti-allergic effects, AERIUS relieves symptoms associated with allergic rhinitis (including hayfever), such as sneezing, runny or itchy nose, itchy palate and itchy, red or tearing eyes.

AERIUS may also be used to relieve symptoms associated with a skin condition called chronic idiopathic urticaria (also known as hives or nettle rash); these symptoms include pinkish, itchy swellings on the skin.

AERIUS can be used in adults and children.

Your doctor or pharmacist, however, may recommend AERIUS for another purpose.

Ask your doctor or pharmacist if you have any questions about why AERIUS has been recommended for you.

There is no evidence that AERIUS is addictive.

Before you take AERIUS*When you must not take it*

Do not take AERIUS if you have an allergy to AERIUS, loratadine or any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include skin rash, difficulty in breathing or faintness.

Do not take AERIUS if you are pregnant or breastfeeding unless you and your doctor or pharmacist have discussed the risks and benefits involved.

AERIUS should not be used for allergic rhinitis in children under 12 months of age and for chronic idiopathic urticaria (hives) in children under 6 months of age. Consult your doctor or pharmacist about treatment options.

Do not take AERIUS after the expiry date printed on the pack.

Do not take AERIUS if the packaging is torn or shows signs of tampering.

Before you start to take it

You must tell your doctor or pharmacist:

- if you are allergic to any other medicines or any foods, dyes or preservatives
- if you have severe kidney problem or any other medical conditions.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including medicines that you buy without a prescription from a pharmacy, supermarket or health food shop.

How to take AERIUS

AERIUS should not be used for allergic rhinitis in children under 12 months of age and for chronic idiopathic urticaria (hives) in children under 6 months of age. Consult your doctor or pharmacist about treatment options.

*How much to take***Allergic Rhinitis**

Adults and adolescents 12 years and over:

One AERIUS tablet or 10mL AERIUS syrup once daily.

Children 6 to 11 years of age:

5mL AERIUS syrup once daily

Children 1 to 5 years of age:

2.5mL AERIUS syrup once daily

Your allergic rhinitis symptoms may come and go over time (intermittent) or may occur continuously (persistent). Allergic rhinitis where symptoms appear for less than 4 days per week, or for less than 4 weeks per year is known as Intermittent Allergic Rhinitis (IAR). Allergic rhinitis where symptoms are present for more than 4 days per week and for more than 4 weeks is known as Persistent Allergic Rhinitis (PER).

For intermittent symptoms (IAR) you may take AERIUS until your symptoms are relieved and then stop taking them. Treatment may be re-started if symptoms re-occur.

For persistent symptoms (PER) you may continue treatment whilst you are exposed to your allergy triggers. These triggers may be pollens from flowers, grasses or trees, dust mites, pet fur, moulds or other substances. Talk to your doctor or pharmacist if you are not sure what is triggering your allergies.

Chronic Idiopathic Urticaria

Adults and adolescents 12 years and over:

One AERIUS tablet or 10mL AERIUS syrup once daily.

Children 6 to 11 years of age:

5mL AERIUS syrup once daily

Children 1 to 5 years of age:

2.5mL AERIUS syrup once daily

Children 6 months to 11 months of age:

2.0 mL AERIUS Syrup once daily

Be sure to take AERIUS exactly as your doctor or pharmacist has told you to.

If you do not follow their instructions, you may not get relief from your symptoms.

It does not matter if you take AERIUS before or after food.

If your symptoms persist consult your doctor or pharmacist.

How to take it

Tablets:

Take with a glass of water.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose you missed.

If you take too much (overdose)

Immediately telephone your doctor, pharmacist or Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much AERIUS. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Keep telephone numbers for these places handy.

While you are taking AERIUS*Things you must do*

Tell all doctors, dentists and pharmacists who are treating you that you are taking AERIUS.

Tell your doctor or pharmacist if you become pregnant while you are taking AERIUS.

Things you must not do

Do not give AERIUS to anyone else, even if their symptoms seem similar to yours.

Do not use it to treat any other complaints unless your doctor or pharmacist says to.

Things to be careful of

Make sure you know how you react to AERIUS before you drive a car or operate machinery.

AERIUS is unlikely to make you drowsy. If you are drowsy, do not drive a car or work with machinery.

Stop taking AERIUS 48 hours before you have any skin tests.

Antihistamines may interfere with the results of skin tests.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using AERIUS.

AERIUS helps most people with allergies, but it may have unwanted effects in a few people.

Like other medicines, AERIUS can cause some side effects. If they occur, they are most likely to be minor and temporary.

Ask your doctor or pharmacist any questions you may have.

The most commonly reported unwanted events were headache.

Other uncommonly reported unwanted events were dry mouth and fatigue.

Patients taking AERIUS or sugar pills reported the same incidence of sedation, dizziness, nose bleed and nausea.

Sleepiness dizziness, nose bleed and nausea occurred as often in patients taking sugar pills as it did in patients taking desloratadine.

Other unwanted effects may occur in some people taking AERIUS.

After taking AERIUS

Storage

Keep your tablets in the blister pack in a dry place until it is time to take them.

If you take your tablets out, they will not keep well.

Keep your syrup in the bottle until it is time to take it.

Keep your tablets and syrup in a cool dry place (below 25 degree C for tablets and syrup).

Do not leave it in the car on hot days or on window sills.

Keep it where children cannot reach it.

Disposal

If your doctor or pharmacist tells you to stop taking AERIUS or the medicine has passed the expiry date, ask your pharmacist what to do with any left over.

Product description

AERIUS tablets and syrup can be bought without a doctor's prescription.

What it looks like

There are two forms of AERIUS, tablets and syrup.

- AERIUS tablets are light blue round filmed coated tablets.
- AERIUS syrup is a clear orange coloured solution.

Ingredients

AERIUS tablets contain:

- desloratadine 5mg
- calcium hydrogen phosphate
- microcrystalline cellulose
- maize starch
- talc

Tablet coating contains:

- lactose
- hypromellose
- titanium dioxide
- macrogol
- carnauba wax
- white wax
- indigo carmine (E132)

AERIUS tablets do not contain sucrose or gluten.

AERIUS syrup contains:

- desloratadine 2.5mg/5mL
- propylene glycol
- sorbitol
- citric acid
- sodium citrate
- disodium edetate
- sucrose
- bubble gum flavour
- sunset yellow (E110)
- water
- sodium benzoate as preservative

AERIUS syrup does not contain lactose or gluten.

Sponsor

Schering-Plough Pty. Limited
Level 4, 66 Waterloo Road
North Ryde NSW 2113
AUSTRALIA

Australian Registration Numbers

Tablets, 7's and 28's - AUST R 91116
Syrup, 100mL and 200mL - AUST R 97260
(200mL syrup not currently marketed)

Date of Preparation

April 2008