

ALLERTINE® KIDS

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about taking this medicine, speak to your pharmacist or doctor.

▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

1. Why am I taking ALLERTINE KIDS?

ALLERTINE KIDS contains the active ingredient bilastine. ALLERTINE KIDS is used to relieve the symptoms of hayfever (sneezing, itching, runny or blocked-up nose and red and watery eyes) and other forms of allergic rhinitis. It may also be used to treat itchy skin rashes (hives or urticaria). ALLERTINE KIDS is indicated for children aged 6-11 years with a body weight of at least 20 kg.

For more information, see Section [1. Why am I taking ALLERTINE KIDS?](#) in the full CMI.

2. What should I know before I take ALLERTINE KIDS?

Do not use if your child has ever had an allergic reaction to bilastine or any of the ingredients listed at the end of the CMI.

Do not give this medicine to a child under the age of 6 years and/or with a body weight below 20 kg.

Talk to your pharmacist or doctor if your child has kidney problems or is taking any other regular medicines listed in Section [3. What if I am taking other medicines?](#)

Talk to your pharmacist or doctor if you have concerns of pregnancy or breastfeeding.

For more information, see Section [2. What should I know before I take ALLERTINE KIDS?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ALLERTINE KIDS and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I take ALLERTINE KIDS?

Children 6-11 years with a body weight of at least 20 kg:

- Take one 10 mg meltlet or 4 mL of the oral liquid daily, as required to manage your child's symptoms.
- Take on an empty stomach (at least 1 hour before or 2 hours after meals or fruit juices).

More instructions can be found in Section [4. How do I take ALLERTINE KIDS?](#) in the full CMI.

5. What should I know while taking ALLERTINE KIDS?

Things you should do	• Discuss any side effects that concern you with your pharmacist or doctor. • If your child has been started on a new medicine, remind your doctor or pharmacist that he/she is taking ALLERTINE KIDS. • If symptoms persist or appear to worsen, check with your pharmacist or doctor for advice.
Driving or using machines	• ALLERTINE KIDS has been shown not to affect adult driving performance. However, as medicine responses for each person can

	vary, check how this medicine affects your child before you let your child ride bicycles, drive other vehicles or operate machinery.
Looking after your medicine	• Keep this medicine in a cool dry place where the temperature stays below 30°C. • Keep this medicine in the original pack until it is time for your child to take. • The oral solution must be discarded 6 months after first opening.

For more information, see Section [5. What should I know while taking ALLERTINE KIDS?](#) in the full CMI.

6. Are there any side effects?

The most common side effects of ALLERTINE KIDS in children are headache; eye redness, itching and watery discharge (allergic conjunctivitis); nasal irritation including sneezing, itchy, runny and congested nose (rhinitis); and stomach pain. Serious side effects may include difficulty breathing, swelling of face, lips or tongue, sudden or rapidly developing rash or itching of skin or collapsing or losing consciousness. For more information, including what to do if your child has any

side effects, see Section [6. Are there any side effects?](#) in the full CMI.

- ▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

ALLERTINE® KIDS

Active ingredient: bilastine

Consumer Medicine Information (CMI)

This leaflet provides important information about taking ALLERTINE KIDS. **You should also speak to your pharmacist or doctor if you would like further information or if you have any concerns or questions about taking ALLERTINE KIDS.**

Where to find information in this leaflet:

- [1. Why am I taking ALLERTINE KIDS?](#)
- [2. What should I know before I take ALLERTINE KIDS?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I take ALLERTINE KIDS?](#)
- [5. What should I know while taking ALLERTINE KIDS?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I taking ALLERTINE KIDS?

ALLERTINE KIDS contains the active ingredient bilastine. ALLERTINE KIDS is one of a group of medicines called non-drowsy antihistamines.

ALLERTINE KIDS is used to relieve the symptoms of hayfever (sneezing, itchy, runny, blocked nose, red watery and itchy eyes) **and other forms of allergic rhinitis. It may also be used to treat itchy skin rashes** (hives or urticaria).

ALLERTINE KIDS is indicated for children aged 6-11 years with a body weight of at least 20 mg and it is available as:

- 10 mg meltlets (orally disintegrating tablets)
- 10 mg/ 4 mL oral solution.

ALLERTINE KIDS is fast acting and provides 24-hour hayfever and allergy relief.

2. What should I know before I take ALLERTINE KIDS?

Warnings

Do not use ALLERTINE KIDS if:

- your child is allergic to bilastine, or any of the ingredients listed at the end of this leaflet.

Always check the ingredients to make sure you can use this medicine.

Check with your pharmacist or doctor if your child:

- has kidney problems and is also taking other regular medicines listed in Section [3. What if I am taking other medicines?](#)

During treatment, your child may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

This medicine is for use in children from 6-11 years of age with a body weight of at least 20 kg. However, the following information should be noted regarding the safe use of this medicine. There are limited data on the use of bilastine in pregnant women and during breastfeeding, and on the effects on fertility.

In case of pregnancy or breastfeeding, it is recommended to ask your pharmacist or doctor for advice before taking this medicine.

Do not use ALLERTINE KIDS during pregnancy or whilst breastfeeding unless your doctor has advised you to.

Use in Children

Do not give ALLERTINE KIDS to a child under the age of 6 years.

The safety of ALLERTINE KIDS and how well it works has not been studied in children younger than 6 years of age.

3. What if I am taking other medicines?

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

Some medicines and ALLERTINE KIDS may interfere with each other and affect how well each works.

These include:

- Diltiazem, a medicine for the treatment of high blood pressure and angina.
- Ciclosporin, a medicine used to reduce the activity of the immune system.
- Ketoconazole, a medicine used to treat fungal infections.
- Erythromycin, a medicine used to treat a wide variety of bacterial infections.

Check with your pharmacist or doctor if you are not sure about what medicines, vitamins or supplements your child is taking and if these affect ALLERTINE KIDS.

4. How do I take ALLERTINE KIDS?

Follow the instructions provided with the medicine.
Check with your pharmacist or doctor if you are unsure.

How much to take

- Children 6 - 11 years, who weigh at least 20 kg: Take one 10 mg meltlet or 4 mL of the oral liquid daily, as required for the relief of symptoms.

ALLERTINE MELTLETS:

- Place the meltlet in the mouth of your child. It will disperse rapidly in saliva and can then be easily swallowed.
- Alternatively, you may dissolve the meltlet in a teaspoon of water before giving it to your child. Do not disperse in grapefruit juice or any other fruit juices.

ALLERTINE ORAL LIQUID:

- Press the plastic screw-cap downwards and turn anti-clockwise at the same time to open the bottle.
- Use the enclosed measuring cup to measure 4 mL correctly and give it to your child.
- Tighten the cap after use to engage child resistant closure and wash the measuring cup after use.

When to take ALLERTINE KIDS

Give ALLERTINE KIDS to your child on an **empty stomach, at least 1 hour before or 2 hours after food or fruit juice (particularly grapefruit juice).**

Food and fruit juice can interfere with the absorption of ALLERTINE KIDS by the body.

How long to take ALLERTINE KIDS for

ALLERTINE KIDS helps control your child's condition, but it does not cure it. Your child can stop taking ALLERTINE KIDS when he/she is no longer exposed to hayfever/ allergy triggers, or you know that he/she has obtained sufficient relief from their symptoms.

ALLERTINE KIDS can be restarted if symptoms recur or are expected to recur.

If you take too much ALLERTINE KIDS

If you think that your child has taken too much ALLERTINE KIDS, he/she may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26 in Australia**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while taking ALLERTINE KIDS?

Things you should do

- Discuss any side effects that concern you with your pharmacist or doctor.
- If your child has been started on a new medicine, remind your doctor or pharmacist that he/she is taking ALLERTINE KIDS.
- If your child's symptoms persist or appear to worsen, do not take extra doses. Check with your pharmacist or doctor for advice.
- Tell your pharmacist or doctor immediately if your child becomes pregnant while taking this medicine.

Driving or using machines

It has been demonstrated that bilastine does not affect adult driving performance. However, the response from each patient to the medicine may be different. Therefore, as for any new medicine, you should check how this medicine affects your child before you let your child ride bicycles, drive other vehicles or operate machinery.

Looking after your medicine

- Keep your medicine where the temperature stays below 30°C.
- Keep your medicine in the original pack until it is time for your child to take it.

Follow the instructions on the carton and/or the bottle on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

When to discard your oral solution

The oral solution must be discarded 6 months after first opening. It may be helpful to write down the date when first opening the bottle to help you remember when to discard the oral solution.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If your child does experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your pharmacist or doctor if you have any further questions.

Do not be alarmed by the following list of side effects. Your child may not experience any of them. Similar side effects were seen in patients taking 'dummy' or placebo tablets during the clinical studies.

Less serious side effects

Less serious side effects	What to do
COMMON: • headache • eye redness, itching and watery discharge (allergic conjunctivitis) • nasal irritation including sneezing, itchy, runny or congestion (rhinitis) • stomach pain	Speak to your pharmacist or doctor if your child has any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
Allergic reaction-related: • sudden or rapidly developing rash, swelling, itchiness or hives on the skin • shortness of breath, wheezing or difficulty breathing or swallowing • swelling of face, lips, tongue, throat or other parts of the body • fainting, collapsing or losing consciousness	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you or your child notices any of these serious side effects.

Tell your pharmacist or doctor if you notice anything else that may be making your child feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects your child experiences, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side

effects, you can help provide more information on the safety of this medicine.

7. Product details

This medicine is available over-the-counter without a doctor's prescription.

What ALLERTINE KIDS MELTLETS contains

Active ingredient (main ingredient)	Each meltlet contains 10 mg of bilastine
Other ingredients (inactive ingredients)	Mannitol, croscarmellose sodium, sodium stearyl fumarate, sucralose and Luctadry Red Grape 29665A (PI No. 146208)
Potential allergens	Sucralose

What ALLERTINE KIDS ORAL LIQUID contains

Active ingredient (main ingredient)	Each 4 mL contains 10 mg of bilastine
Other ingredients (inactive ingredients)	Betadex, hyetellose, methyl hydroxybenzoate, propyl hydroxybenzoate, sucralose, Soless

	Raspberry Colourless 0616 (PI No. 148236), hydrochloric acid, sodium hydroxide and purified water
Potential allergens	Methyl hydroxybenzoate, propyl hydroxybenzoate and sucralose

Do not use this medicine if your child is allergic to any of the ingredients.

ALLERTINE KIDS does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

What ALLERTINE KIDS looks like

ALLERTINE KIDS MELTLETS are round, slightly biconvex, white orally disintegrating tablets (AUST R 530321).

The meltlets are available in blister packs of 4, 10, 20, 30, 40, 50, 60, 70, 80, 90 or 100 meltlets. Not all pack sizes may be supplied.

ALLERTINE KIDS ORAL LIQUID is a clear, colourless and slightly viscous (syrupy) aqueous solution with no visible signs of particles (AUST R 530291).

It is packaged in an amber glass bottle with a white child resistant cap. Each pack contains one bottle of 120 mL oral liquid and one measuring cup for dosage with a mark of 4 mL.

Who distributes ALLERTINE KIDS

A. Menarini Australia Pty Ltd

Level 8, 67 Albert Avenue, Chatswood NSW 2067

Phone: 1800 644 542

For further information or the most up-to-date version of this leaflet visit www.allertine.com.au

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