ALLERTINE® and ALLERTINE® MELTLETS

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?

ALLERTINE and ALLERTINE MELTLETS (hereafter referred to as ALLERTINE unless otherwise stated) contain the active ingredient bilastine. ALLERTINE is used to relieve the symptoms of hayfever and other forms of allergic rhinitis. It may also be used to treat itchy skin rashes.

For more information, see Section 1. Why am I taking ALLERTINE? in the full CMI.

2. What should I know before I take ALLERTINE?

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

Talk to your pharmacist or doctor if you have kidney problems or are taking any other regular medicines listed in Section 3. What if I am taking other medicines?

Talk to your pharmacist or doctor if you are pregnant, likely to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I take ALLERTINE? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ALLERTINE 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?

ALLERTINE

- **Adults and adolescents 12 years & over:** Take one tablet daily, as required to manage your symptoms.
- Swallow the tablet with a glass of water, on an empty stomach (at least 1 hour before or 2 hours after meals or fruit juices).
- **ALLERTINE MELTLETS**
- **Adults and adolescents 12 years & over:** Take one meltlet daily, as required to manage your symptoms, at least 1 hour before or 2 hours after food or fruit juice (particularly grapefruit juice).
- Place the meltlet in your mouth. It will disperse rapidly in saliva and can then be easily swallowed. May be followed by a glass of water if desired.

More instructions can be found in Section 4. How do I take ALLERTINE? in the full CMI.

5. What should I know while taking ALLERTINE?

Things you should do	• Discuss any side effects that concern you with your pharmacist or doctor. • If you are started on a new medicine, remind your doctor or pharmacist that you are taking ALLERTINE. • If symptoms persist or appear to worsen, check with your pharmacist or doctor for advice.
Driving or using machines	• ALLERTINE has been shown not to affect adult driving performance. However, as medicine responses for each person can vary, check how this medicine affects you before driving or operating machinery.
Looking after your medicine	• Keep your medicine in a cool dry place where the temperature stays below 30°C. • Keep your medicine in the original pack until it is time to take.

For more information, see Section 5. What should I know while taking ALLERTINE? in the full CMI.

6. Are there any side effects?

The most common side effects of ALLERTINE are headache, sleepiness 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 you have 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® and ALLERTINE® MELTLETS

Active ingredient: *bilastine*

Consumer Medicine Information (CMI)

This leaflet provides important information about taking ALLERTINE and ALLERTINE MELTLETS (hereafter referred to as ALLERTINE unless otherwise stated). **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.**

Where to find information in this leaflet:

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

1. Why am I taking ALLERTINE?

ALLERTINE and ALLERTINE MELTLETS contain the active ingredient bilastine. ALLERTINE is one of a group of medicines called non-drowsy antihistamines.

ALLERTINE and ALLERTINE MELTLETS are 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).

2. What should I know before I take ALLERTINE?

Warnings

Do not use ALLERTINE if:

- you are 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 you:

- have kidney problems and are also taking other regular medicines listed in Section 3. What if I am taking other medicines?

During treatment, you 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

Check with your pharmacist or doctor if you are pregnant or likely to become pregnant.

Talk to your pharmacist or doctor if you are breastfeeding or intend to breastfeed.

Do not take ALLERTINE if you are pregnant or breastfeeding unless your doctor has advised you to.

Use in Children

Do not give ALLERTINE to a child under the age of 12 years.

The safety of ALLERTINE and how well it works has not been studied in children younger than 12 years of age.

3. What if I am taking other medicines?

Tell your pharmacist or doctor if you are 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 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 you are taking and if these affect ALLERTINE.

4. How do I take ALLERTINE?

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

How much to take

Adults and adolescents 12 years & over: Take one tablet or one meltlet (20 mg bilastine) daily, as required to manage your symptoms.

ALLERTINE

- Swallow the tablet with a glass of water.
- If you have difficulty swallowing, the tablet may be halved along the score line.
- ALLERTINE MELTLETS

Place the meltlet in your mouth. It will dissolve rapidly in saliva and can then be easily swallowed. May be followed by a glass of water if desired.

When to take ALLERTINE

Take ALLERTINE 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 by the body.

How long to take ALLERTINE

ALLERTINE helps control your condition, but it does not cure it. You can stop taking ALLERTINE when you know you are no longer exposed to your hayfever/ allergy triggers, or you know you have obtained sufficient relief from your symptoms. ALLERTINE can be restarted if your symptoms recur or are expected to recur.

If you take too much ALLERTINE

If you think that you have taken too much ALLERTINE, you 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?

Things you should do

- Discuss any side effects that concern you with your pharmacist or doctor.
- If you are started on a new medicine, remind your doctor or pharmacist that you are taking ALLERTINE.
- If your symptoms persist or appear to worsen, do not take extra tablets. Check with your pharmacist or doctor for advice.
- Tell your pharmacist or doctor immediately if you become pregnant while you are 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 you, before driving or operating 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 to take.

Follow the instructions on the carton 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.

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 you do 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. You 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: **General body-related:** • headache • sleepiness, drowsiness or tiredness • dizziness **LESS COMMON:** **Stomach and bowel-related:** • mild stomach upsets such as stomach or belly pain, nausea or diarrhoea **Heart-related:** • fast or irregular heartbeat **Other:** • tinnitus (ringing in the ears) • vertigo (a strong feeling of dizziness or spinning)	**Speak to your pharmacist or doctor if you have 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	**Call your doctor straight away, or go straight to the Emergency**

Serious side effects	What to do
• 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	**Department at your nearest hospital if you notice any of these serious side effects.**

Tell your pharmacist or doctor if you notice anything else that may be making you 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 you experience, 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 contains

Active ingredient (main ingredient)	Each tablet or meltlet contains 20 mg of bilastine
Other ingredients (inactive ingredients)	ALLERTINE • microcrystalline cellulose • sodium starch glycollate type A • colloidal anhydrous silica • magnesium stearate ALLERTINE MELTLETS • mannitol • croscarmellose sodium • sodium stearylfumarate • sucralose • red grape flavour (146208) Potential allergens: • sucralose

Do not take this medicine if you are allergic to any of these ingredients.

ALLERTINE MELTLETS contain sucralose.

ALLERTINE/ALLERTINE MELTLETS do not contain tartrazine or any other azo dyes.

What ALLERTINE looks like

ALLERTINE is a white, oval, biconvex and scored tablet (AUST R 387574).

ALLERTINE MELTLETS are a white, round and flat orally disintegrating tablet engraved with "20" on one side (AUST R 480827).

Available in blister packs of 2, 4, 10, 20, 30, 40, 50, 60, 70, 80, 90 or 100 tablets.

Not all pack sizes may be supplied.

Who distributes ALLERTINE

A. Menarini Australia Pty. Ltd.,

Sydney, Australia

Medical Information: 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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