



Australian Government
Department of Health and Aged Care
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	387574	ALLERTINE bilastine 20 mg tablet blister pack
ARTG entry for	Medicine Registered	
Sponsor	A Menarini Australia Pty Ltd	
Postal Address	Level 8/67 Albert Avenue, CHATSWOOD, NSW, 2067 Australia	
ARTG Start Date	27/04/2022	
Product Category	Medicine	
Status	Active	
Approval Area	Non-Prescription Medicines	



Medicine under additional monitoring

Conditions

Conditions applicable to all therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995.

Conditions applicable to the relevant category and class of therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995.

Products

1 . ALLERTINE bilastine 20 mg tablet blister pack

Product Type	Single Medicine Product	Effective Date	29/04/2022
---------------------	-------------------------	-----------------------	------------

Permitted Indications

No Permitted Indications included on Record

Indication Requirements

No Indication Requirements included on Record

Standard Indications

No Standard Indications included on Record

Specific Indications

For the symptomatic treatment of allergic rhinoconjunctivitis (AR - both seasonal allergic rhinitis (SAR) and perennial allergic rhinitis (PAR)) and/or urticaria.

Warnings

No Warnings included on Record

Additional Product information

This product is included in the Black Triangle Scheme

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Blister Pack	Al/Al	5 Years	Store below 30 degrees Celsius	Neither child resistant closure nor restricted flow insert	Not recorded

Pack Size/Poison information

Pack Size	Poison Schedule
30	(S3) Pharmacist Only Medicine
10	(S3) Pharmacist Only Medicine
20	(S3) Pharmacist Only Medicine
50	(S3) Pharmacist Only Medicine
60	(S3) Pharmacist Only Medicine
4 sample pack	(S3) Pharmacist Only Medicine
40	(S3) Pharmacist Only Medicine

Components

1 .

Public Summary



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Dosage Form Tablet, uncoated
Route of Administration Oral
Visual Identification Oval, biconvex, scored white tablets

Active Ingredients

bilastine 20 mg

Other Ingredients (Excipients)

colloidal anhydrous silica
magnesium stearate
microcrystalline cellulose
sodium starch glycollate type A

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.

Public Summary