



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	160733	ALLERSOOTHE 10 promethazine hydrochloride 10mg tablet blister pack
ARTG entry for	Medicine Registered	
Sponsor	AFT Pharmaceuticals Pty Ltd	
Postal Address	PO Box 748, North Ryde, Sydney, NSW, 1670 Australia	
ARTG Start Date	1/04/2009	
Product Category	Medicine	
Status	Active	
Approval Area	Non-Prescription Medicines	

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 . ALLERSOOTHE 10 promethazine hydrochloride 10mg tablet blister pack

Product Type	Single Medicine Product	Effective Date	7/09/2021
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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
Allergies: Treatment of allergic conditions including some allergic reactions to drugs, urticaria and allergic contact dermatitis, and allergic reactions to insect bites and stings. Upper respiratory tract: Relief of excessive secretion in the upper respiratory tract as a result of hayfever and allergic rhinitis. Nausea and vomiting: Antiemetic for vomiting from various causes, including post-operative vomiting, irradiation sickness, drug induced nausea and motion sickness. Sedation: For short term use in adults under the advice of a doctor or pharmacist.

Warnings
No Warnings included on Record

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Blister Pack	Not recorded	3 Years	Store below 30 degrees Celsius	Not recorded	Protect from Light

Pack Size/Poison information

Pack Size	Poison Schedule
50	(S3) Pharmacist Only Medicine

Components

1 .

Dosage Form	Tablet, film coated
Route of Administration	Oral
Visual Identification	Light blue coloured, circular biconvex film coated tablets, plain on both the sides

Active Ingredients

promethazine hydrochloride	10 mg
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Other Ingredients (Excipients)

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brilliant blue FCF aluminium lake
hypromellose
lactose monohydrate
macrogol 6000
magnesium stearate
methylcellulose
purified talc
purified water
titanium dioxide

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