

Australian Government

# Department of Health and Aged Care

Therapeutic Goods Administration

## **Public Summary**

Summary for ARTG Entry:	13591	PANADOL TABLETS paracetamol 500mg - filmcoated tablets blister pack			
ARTG entry for	Medicine Registered				
Sponsor	Haleon Australia Pty Ltd				
Postal Address	Level 48 / 8 Parramatta Square 10 Darcy Street, Parramatta, NSW, 2150 Australia				
ARTG Start Date	30/08/1991				
Product Category	Medicine				
Status	Active				
Approval Area	Non-Prescriptio	n 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

Product Type	Single Medicine Pro	duct	Effective Date	23/03/2022	
Permitted Indicati	ons				
No Permitted Indica	ations included on Record	I			
Indication Require	ements				
No Indication Requ	irements included on Rec	ord			
Standard Indicatio	ons				
No Standard Indica	tions included on Record				
Specific Indication	15				
For fast effective te tension headache a	mporary relief of pain and and sinus pain/headache. ociated with headache, m	Reduces fever. INDIC	CATIONS AS AT 22 NOVEMB	ER 2000: For fast,	urthritis, toothache, migraine, cold & flu, effective, temporary relief of the pain ache, sinus pain/headache, colds and flu
For fast effective te	mporary relief of pain and and sinus pain/headache. ociated with headache, m	Reduces fever. INDIC	CATIONS AS AT 22 NOVEMB	ER 2000: For fast,	effective, temporary relief of the pain
For fast effective te tension headache a and discomfort ass and toothache. Rec	mporary relief of pain and and sinus pain/headache. ociated with headache, m duces fever.	Reduces fever. INDIC	CATIONS AS AT 22 NOVEMB	ER 2000: For fast,	effective, temporary relief of the pain
For fast effective te tension headache a and discomfort ass and toothache. Rec Warnings	mporary relief of pain and and sinus pain/headache. ociated with headache, m duces fever. led on Record	Reduces fever. INDIC	CATIONS AS AT 22 NOVEMB	ER 2000: For fast,	effective, temporary relief of the pain
For fast effective te tension headache a and discomfort ass and toothache. Rec Warnings No Warnings includ	mporary relief of pain and and sinus pain/headache. ociated with headache, m duces fever. led on Record	Reduces fever. INDIC	CATIONS AS AT 22 NOVEMB	ER 2000: For fast,	effective, temporary relief of the pain
For fast effective te tension headache a and discomfort ass and toothache. Rec Warnings No Warnings includ	mporary relief of pain and and sinus pain/headache. ociated with headache, m duces fever. ded on Record	Reduces fever. INDIC	CATIONS AS AT 22 NOVEMB	ER 2000: For fast,	effective, temporary relief of the pain
For fast effective te tension headache a and discomfort ass and toothache. Rec Warnings No Warnings incluc Additional Produc	mporary relief of pain and and sinus pain/headache. ociated with headache, m duces fever. ded on Record	Reduces fever. INDIC	CATIONS AS AT 22 NOVEMB	ER 2000: For fast,	effective, temporary relief of the pain

### Pack Size/Poison information

Pack Size		Poison Schedule
2		Not scheduled. Not considered by committee
20		Not Scheduled after consideration by Committee
24's		Not Scheduled after consideration by Committee
50's		(S2) Pharmacy Medicine
100's		(S2) Pharmacy Medicine
12's		Not Scheduled after consideration by Committee
Components		
1.		
Dosage Form	Tablet, film coated	
Route of Administration	Oral	

degrees Celsius

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## This is not an ARTG Certificate document.

Oral

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Visual Identification	Shining white, filmcoated bevelled edge, shallow convex, double radius, 1.27cm diameter tablet, front face marked PANADOL, break bar on back face.
Active Ingredients	
paracetamol	500 mg
Other Ingredients (Excipie	ents)
Carnauba Wax	
hypromellose	
maize starch	
potassium sorbate	
povidone	
pregelatinised maize starc	h
purified talc	
stearic acid	
triacetin	

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