

## Medicine Shortage Notification

## Notifier

## Notifier

<b>Sponsor Name:</b>	Sun Pharma ANZ Pty Ltd
<b>Sponsor Address:</b>	Suite 2 02 Level 2 12 Waterloo Road Macquarie Park NSW 2113
<b>Australian telephone number for public contact purposes:</b>	0298872600
<b>Medical information email for public contact purposes:</b>	Regulatory.Australia@sunpharma.com
<b>Primary Contact</b>	
<b>Name:</b>	s22
<b>Phone Number:</b>	s22
<b>Email Address:</b>	s22 @sunpharma.com
<b>Secondary Contact</b>	
<b>Name:</b>	s22
<b>Phone Number:</b>	s22
<b>Email Address:</b>	s22 @sunpharma.com

## ARTG Entry

## ARTG Entry

ARTG number of the product that has a supply disruption:

ARTG ID	ARTG Name	Active Ingredient	Strength	Dosage Form
444951	ARIPENA aripirazole 400 mg powder and diluent for prolonged release suspension for injection vial kit	aripirazole monohydrate	416.07mg	Injection, powder for injection, diluent for

<b>ATC Descriptor:</b>	Nervous system
<b>Are all pack sizes for this ARTG entry affected?</b>	Yes
<b>Is this ARTG entry listed in the PBS?</b>	Yes
<b>Provide the PBS number for this listing:</b>	10219W
<b>Do you have a designated sponsor representative within your organisation who is a point of contact on PBS matters?</b>	Yes

## PBS Contact Details

<b>Name:</b>	s22
<b>Phone Number:</b>	s22
<b>Email Address:</b>	s22 @sunpharma.com

## Details

When was the shortage known to the sponsor?	15/08/2025	
Nature of the shortage:	Anticipated	
Shortage reason:	Manufacturing	
Manufacturing site problem:	s47G	
Shortage reason - further information:		
Estimated period supply will be affected at wholesaler points:	From:	18/08/2025
	To:	30/09/2025
Availability:	Available	
Indicate preference for date of publication:	Date of processing	
Is this shortage related to other medicines within the same Therapeutic class?	No	
Is this shortage specific to Australia?	Yes	
Estimated normal demand volumes for Australia:	s47	
Estimated percentage share of the Australian market:		
Estimated current stock at sponsor / manufacturing level in Australia:		
Estimated current stock at wholesaler / distributor level in Australia:		
What is meant by 1 unit in this context:	1 unit is a pack containing 1 Vial	

## Impact

Are there therapeutic alternatives on the Australian market?	Yes
What is the status of substitute options for this product in Australia?	Exact Therapeutic Alternatives
Are they available in adequate supplies to meet demand?	Yes
Provide details:	
Do any specific population groups use this product?	No
Based on your answers above and the Assessment Framework, what is the shortage impact rating?	3 - Low Impact

## Shortage Action

What communication activities have happened or are planned?	<b>Communication Action</b>	<b>Date of Communication</b>
	Letter to Wholesalers	15-Aug-2025
Letter attached in Supporting Information:	No	
Further comments on communications:		
What supply management actions have happened or are planned?	<b>Management Action</b>	<b>Date of Management Action</b>
	Working to expedite next shipment	15-Aug-2025
Further comments on management actions:		

Supporting data will be:

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Sponsor website where medicine shortage information is available:

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<b>Are all pack sizes for this ARTG entry affected?</b>	Yes
<b>Is this ARTG entry listed in the PBS?</b>	Yes
<b>Provide the PBS number for this listing:</b>	10219W
<b>Do you have a designated sponsor representative within your organisation who is a point of contact on PBS matters?</b>	Yes
<b>PBS Contact Details</b>	
<b>Name:</b>	s22
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## Details

When was the shortage known to the sponsor?	15/08/2025	
Nature of the shortage:	Current	
Shortage reason:	Manufacturing	
Manufacturing site problem:	s47G	
Shortage reason - further information:		
Estimated period supply will be affected at wholesaler points:	From:	18/08/2025
	To:	30/09/2025
Availability:	Unavailable	
TGA publication date:	18/08/2025	
Is this shortage related to other medicines within the same Therapeutic class?	No	
Is this shortage specific to Australia?	Yes	
Estimated normal demand volumes for Australia:	s47	
Estimated percentage share of the Australian market:		
Estimated current stock at sponsor / manufacturing level in Australia:		
Estimated current stock at wholesaler / distributor level in Australia:		
What is meant by 1 unit in this context:	1 unit is a pack containing 1 Vial	

### Impact

Are there therapeutic alternatives on the Australian market?	Yes
What is the status of substitute options for this product in Australia?	Exact Therapeutic Alternatives
Are they available in adequate supplies to meet demand?	Yes
Provide details:	
Do any specific population groups use this product?	No
Based on your answers above and the Assessment Framework, what is the shortage impact rating?	3 - Low Impact

### Shortage Action

What communication activities have happened or are planned?	<b>Communication Action</b>	<b>Date of Communication</b>
	Letter to Wholesalers	15-Aug-2025
Letter attached in Supporting Information:	No	
Further comments on communications:		
What supply management actions have happened or are planned?	<b>Management Action</b>	<b>Date of Management Action</b>
	Working to expedite next shipment	15-Aug-2025

**Supporting Information**

Supporting data will be:

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Sponsor website where medicine shortage information is available:

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**ATC Descriptor:** Nervous system

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**Do you have a designated sponsor representative within your organisation who is a point of contact on PBS matters?** Yes

## PBS Contact Details

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When was the shortage known to the sponsor?	15/08/2025	
Nature of the shortage:	Current	
Shortage reason:	Manufacturing	
Manufacturing site problem:	s47G	
Shortage reason - further information:		
Estimated period supply will be affected at wholesaler points:	From:	18/08/2025
	To:	31/12/2025
Availability:	Unavailable	
TGA publication date:	18/08/2025	
Is this shortage related to other medicines within the same Therapeutic class?	No	
Is this shortage specific to Australia?	Yes	
Estimated normal demand volumes for Australia:	s47	
Estimated percentage share of the Australian market:		
Estimated current stock at sponsor / manufacturing level in Australia:		
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Shortage reason:	Manufacturing	
Manufacturing site problem:	s47G	
Shortage reason - further information:		
Estimated period supply will be affected at wholesaler points:	From:	18/08/2025
	To:	20/02/2026
Availability:	Unavailable	
TGA publication date:	18/08/2025	
Is this shortage related to other medicines within the same Therapeutic class?	No	
Is this shortage specific to Australia?	Yes	
Estimated normal demand volumes for Australia:	s47	
Estimated percentage share of the Australian market:		
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Shortage reason:	Manufacturing	
Manufacturing site problem:	s47G	
Shortage reason - further information:		
Estimated period supply will be affected at wholesaler points:	From:	18/08/2025
	To:	17/04/2026
Availability:	Unavailable	
TGA publication date:	18/08/2025	
Is this shortage related to other medicines within the same Therapeutic class?	No	
Is this shortage specific to Australia?	Yes	
Estimated normal demand volumes for Australia:	s47	
Estimated percentage share of the Australian market:		
Estimated current stock at sponsor / manufacturing level in Australia:		
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Manufacturing site problem:	s47G	
Shortage reason - further information:		
Estimated period supply will be affected at wholesaler points:	From:	18/08/2025
	To:	30/04/2026
Availability:	Unavailable	
TGA publication date:	18/08/2025	
Is this shortage related to other medicines within the same Therapeutic class?	No	
Is this shortage specific to Australia?	Yes	
Estimated normal demand volumes for Australia:	s47	
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