

AUSTRALIAN MEDICINES TERMINOLOGY (AMT) DESCRIPTIONS for PHARMACEUTICAL BENEFITS SCHEME LISTINGS

The AMT is a standards-based national approach to the unique identification (code) and naming of medicines. It has been primarily developed to be used in clinical software applications and to facilitate interoperability between systems. For more information on the AMT and other Australian Digital Health Agency (the Agency) clinical terminology products and services, please visit the Agency website at <https://www.digitalhealth.gov.au/get-started-with-digital-health/what-is-digital-health/clinical-terminology>

SPONSOR TO COMPLETE

STEP 1 - Sponsor to provide the AMT team at the Agency the requested information for description creation.

Sponsor: Teva Pharma Australia Pty Ltd

Medicine (ingredient/s): Tiotropium

Brand: Braltus

Product Information (More than one formulation/strength/pack size can be entered for the same drug)	
Trade name	
Ingredients and strengths	
Dose form	Powder for inhalation, hard capsules
PBS pack size	30 capsules
Registered pack sizes	30 capsules
Container type	
ARTG ID	

Sponsor contact details (for AMT enquiries)

Name of representative: [REDACTED]

Email: [REDACTED]@tevapharm.com

Phone: [REDACTED]

Due date for receipt of AMT response (please allow at least 3 to 5 working days): Required ASAP (4 January 2019 at latest)

STEP 2 - Sponsor to attach ARTG registration details, Product Label, Product Information and Consumer Medicines Information documents (where available) to ensure descriptions are aligned, accurate and unambiguous. These documents will not be distributed outside of the AMT team.

a) Please indicate below the type of information provided.

- ☒ Product Label
- ☒ Product Information (PI)
- ☒ Consumer Medicines Information (CMI)
- ☒ ARTG registration details

b) Email to: help@digitalhealth.gov.au



AMT TEAM TO COMPLETE

PBAC SECRETARIAT

STEP 3 - AMT team to complete this concept description table and send the completed form back to the sponsor (please copy and create more than one table for input if multiple concepts are involved).

Concept SCT-ID*	Concept Class	Preferred Term Description
	Substance (Basis of Strength Substance –BoSS)**	tiotropium
21484011000036102	Medicinal Product (MP)	tiotropium
N/A	Medicinal Product Unit of Use (MPUU)	tiotropium 13 microgram powder for inhalation, 1 capsule
N/A	Medicinal Product Pack (MPP)	tiotropium 13 microgram powder for inhalation, 30 capsules
N/A	Trade Product (TP)	Braltus
N/A	Trade Product Unit of Use (TPUU)	Braltus 13 microgram powder for inhalation, 1 capsule
N/A	Trade Product Pack (TPP)	Braltus 13 microgram powder for inhalation, 30 capsules
N/A	Containerized Trade Product Pack (CTPP)	Braltus 13 microgram powder for inhalation, 30 capsules, bottle

Note:

* Concept SCT-ID may not be provided in all circumstances

** The BoSS is the name of the ingredient that the strength of the product is based on and has no associated SCT-ID.



[AMT contact details for any sponsor enquiries](#)

Digital Health Help Centre ticket number: 46178

Name of AMT representative: Eugene Viacrucis

Email: help@digitalhealth.gov.au

Phone: 1300 901 001

Date of reply to sponsor: 21/12/2018

Additional comments to sponsor (optional):

SPONSOR TO COMPLETE

[STEP 4](#) - Sponsor to provide completed form to PBAC Secretariat with submission.