



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	405693	Fungal Pancreatin 1X
ARTG entry for	Medicine Listed (Export Only)	
Sponsor	Connell Bros Company Australasia Pty Ltd	
Postal Address	26 Research Drive, Croydon South, VIC, 3136 Australia	
ARTG Start Date	3/03/2023	
Product Category	Medicine	
Status	Active	
Approval Area	Export only Medicines	

Conditions

Except where the sponsor has been contracted by an overseas party to manufacturer the goods and that party will be responsible for placing the goods on the market in countries other than Australia, the sponsor must have and shall retain, while the goods remain listed, evidence necessary to substantiate and support the accuracy of the indications in relation to the listed goods, and upon the request of the Head, Office of Prescription Medicines Authorisation Branch, Therapeutic Goods Administration, shall produce such evidence to this officer.

The sponsor shall hold stability data to support the claimed shelf life of the listed medicine according to the labelled storage conditions except where: (i) each overseas importer accepts responsibility for holding stability data for this product; (ii) the sponsor has a written agreement to this effect from each overseas importer; and (iii) the sponsor retains copies of all such agreements while the medicine remains listed on the ARTG.

This product must not be supplied for sale in Australia, including supply via duty free outlets.

Products

1 . Fungal Pancreatin 1X

Product Type	Single Medicine Product	Effective Date	3/03/2023
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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

No Specific Indications included on Record

Warnings

No Warnings included on Record

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Jar/Can	HDPE	2 Years	Store below 25 degrees Celsius	Child resistant closure	Protect from Heat Protect from Moisture Protect from direct sunlight

Pack Size/Poison information

Pack Size	Poison Schedule
Pail 10kg	(S1) This Schedule is intentionally blank

Components

1 .

Dosage Form	Powder
Route of Administration	Oral
Visual Identification	Off-white to light brown powder

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Active Ingredients

Amylase	520 DU/g
lipase	440 LipU/g
protease	3845 HUT/g

Other Ingredients (Excipients)

maltodextrin

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