



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	19983	Orthoplex Hydrozyme
ARTG entry for	Medicine Registered	
Sponsor	Bio Concepts Pty Ltd	
Postal Address	PO Box 190, Banyo, Brisbane, QLD, 4014 Australia	
ARTG Start Date	4/10/1991	
Product Category	Medicine	
Status	Active	
Approval Area	Registered Complementary Medicines	

Conditions

Conditions applicable to the relevant category and class of therapeutic goods as specified in the document "Conditions Applying to Therapeutic Goods Accepted for Registration or Listing as Goods Currently Supplied at the Commencement of the Therapeutic Goods Act 1989"

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 February 1992.

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 February 1992.

Products

1 . Orthoplex Hydrozyme

Product Type	Single Medicine Product	Effective Date	22/06/2006
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Permitted Indications

No Permitted Indications included on Record

Indication Requirements

No Indication Requirements included on Record

Standard Indications

This product accepted for registration/listing as 'currently supplied' at the time of commencement of the Act. Indications held in ARTG paper records. (Old code)

Specific Indications

NUTRITIONAL SUPPLEMENT; Contains pepsin, a proteolytic enzyme involved in proper digestion; Betaine hydrochloride is a source of hydrochloric acid and has a similar pH to stomach acid

Warnings

No Warnings included on Record

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Bottle	Not recorded	2 Years	Store below 30 degrees Celsius	Not recorded	Protect from direct sunlight Protect from Heat

Pack Size/Poison information

Pack Size	Poison Schedule
60 tablets	Not scheduled. Not considered by committee

Components

1 . -

Dosage Form	Tablet, film coated
Route of Administration	Oral
Visual Identification	Large capsule shaped white to off white coloured clear film coated tablet

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Active Ingredients

betaine hydrochloride	400 mg
glutamic acid	100 mg
Pepsin	100 mg

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate
colloidal anhydrous silica
crospovidone
glucose monohydrate
hypromellose
macrogol 400
magnesium stearate
microcrystalline cellulose
povidone

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