



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	19973	Orthoplex D.E.F. Tablets
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 D.E.F. Tablets

Product Type	Single Medicine Product	Effective Date	31/01/2006
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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; Digestive Enzyme Formula; Contains pancreatic enzymes which are important in maintaining healthy digestive function; Bromelain has been shown to have proteolytic activity; Synergistic formula of proteolytic enzymes;

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 Heat Protect from direct sunlight

Pack Size/Poison information

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

Components

1 . -

Dosage Form	Tablet, film coated
Route of Administration	Oral
Visual Identification	Medium round bi-convex off white to beige coloured tablets with clear film coating



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Active Ingredients

bromelains	100 mg
Pancreatin	200 mg
Equivalent: protease	280 BP Unit
Equivalent: lipase	4000 BP Unit
Equivalent: Amylase	4800 BP Unit
Trypsin	30 mg

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate
crospovidone
glucose monohydrate
hypromellose
macrogol 400
magnesium stearate
maltodextrin
microcrystalline cellulose
povidone

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