



**Australian Government**  
**Department of Health and Aged Care**  
 Therapeutic Goods Administration

**Public Summary**

<b>Summary for ARTG Entry:</b>	19973	Orthoplex D.E.F. Tablets
<b>ARTG entry for</b>	Medicine Registered	
<b>Sponsor</b>	Bio Concepts Pty Ltd	
<b>Postal Address</b>	PO Box 190, Banyo, Brisbane, QLD, 4014 Australia	
<b>ARTG Start Date</b>	4/10/1991	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	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**

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	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 . -	
<b>Dosage Form</b>	Tablet, film coated
<b>Route of Administration</b>	Oral
<b>Visual Identification</b>	Medium round bi-convex off white to beige coloured tablets with clear film coating

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**Active Ingredients**

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

**Other Ingredients (Excipients)**

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

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