Public Summary

Summary for ARTG Entry:	300714 Orthoplex Intestaclear
ARTG entry for	Medicine Listed
Sponsor	Bio Concepts Pty Ltd
Postal Address	PO Box 190, Banyo, Brisbane, QLD, 4014 Australia
ARTG Start Date	13/03/2018
Product Category	Medicine
Status	Active
Approval Area	Listed Medicines

Conditions

Colouring agents used in listed medicine for ingestion, other than those listed for export only under section 25 of the Act, shall be only those included in the list of 'Colourings permitted in medicines for oral use'.

The sponsor shall keep records relating to this listed medicine as are necessary to: (a) Expedite recall if necessary of any batch of the listed medicine, (b) Identify the manufacturer(s) of each batch of the listed medicine. Where any part of or step in manufacture in Australia of the listed medicine is sub-contracted to a third party who is not the sponsor, copies of relevant Good Manufacturing Practice agreements relation to such manufacture shall be kept.

The sponsor shall retain records of the distribution of the listed medicine for a period of five years and shall provide the records or copies of the records to the Complementary Medicines Branch, Therapeutic Goods Administration, upon request.

Where a listed medicine is distributed overseas as well as in Australia, product recall or any other regulatory action taken in relation to the medicine outside Australia which has or may have relevance to the quality, safety or efficacy of the goods distributed in Australia, must be notified to the National Manager Therapeutic Goods Administration, immediately the action or information is known to the sponsor.

The warning statement 'Do not use if pregnant or likely to become pregnant' must be displayed on the medicine label.

Products

1 . Orthoplex Intestaclear

Product Type Single Medicine Product **Effective Date** 4/02/2021

Permitted Indications

Maintain/support general health and wellbeing

Traditionally used in Western herbal medicine to maintain/support digestive system health

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

Not for prolonged use. May harm liver.

If symptoms persist, seek the advice of a healthcare professional.

Additional Product information

Pack Size/Poison information

Pack Size **Poison Schedule**

Components

1 . Formulation 1

Dosage Form	Capsule, hard
Route of Administration	Oral
Visual Identification	

Active Ingredients

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Allium sativum bulb Extract dry concentrate	**14.4 mg**
Equivalent: Allium sativum (Dry)	720 mg
Artemisia annua herb Extract dry concentrate	**40 mg**
Equivalent: Artemisia annua (Dry)	400 mg
Berberis vulgaris stem bark Extract dry concentrate standardised	**36 mg**
Equivalent: Berberis vulgaris (Dry)	360 mg
Clove Bud Oil	**50 mg**
Handroanthus impetiginosus stem bark inner Extract dry concentrate	**20 mg**
Equivalent: Handroanthus impetiginosus (Dry)	200 mg
Juglans nigra fruit hull Extract dry concentrate	**40 mg**
Equivalent: Juglans nigra (Dry)	400 mg
Origanum Oil Spanish	**50 mg**
Thyme Oil	**50 mg**

Other Ingredients (Excipients)

ascorbyl palmitate
calcium hydrogen phosphate dihydrate
colloidal anhydrous silica
gellan gum
hypromellose
microcrystalline cellulose

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