



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	314850	Orthoplex Iodine
ARTG entry for	Medicine Listed	
Sponsor	Bio Concepts Pty Ltd	
Postal Address	PO Box 190, Banyo, Brisbane, QLD, 4014 Australia	
ARTG Start Date	27/02/2019	
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.

Products

1 . Orthoplex Iodine

Product Type	Single Medicine Product	Effective Date	25/01/2023
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Permitted Indications

Maintain/support body metabolism/metabolic rate
Maintain/support general health and wellbeing
Maintain/support healthy thyroid gland function for pregnancy
Aid/assist healthy thyroid hormone production for pregnancy
Maintain/support maternal health
Maintain/support healthy pregnancy
Maintains/support healthy foetal development
Helps maintains/support healthy foetal CNS/brain development
Maintain/support (state vitamin/mineral/nutrient) levels in the body
Maintain/support thyroid gland health
Maintain/support healthy thyroid hormones
Maintain/support healthy thyroid gland function

Indication Requirements

Indication can only be used for medicines that contain iodine as a mandatory component of one or more permitted active ingredients and the recommended daily dose of the medicine provides a minimum of 150 micrograms of iodine.

Product presentation must not imply or refer to any thyroid related diseases.

If product is indicated for weight loss, label statement: When used in conjunction with a program of reduced intake of dietary calories and increased physical activity.

If directed to women, Label statement: Advise your doctor of any medicine you take during pregnancy, particularly in your first trimester.

Label statement: If you are concerned about the health of yourself or your baby, talk to your health practitioner.

Label statement: If you have pre-existing thyroid conditions, seek advice from your medical practitioner before taking this medicine.

Label statement: Advise your doctor of any medicine you take during pregnancy, particularly in your first trimester.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record



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Warnings		
No Warnings included on Record		
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		
potassium iodide		294 microgram
Equivalent: iodine		225 microgram
Other Ingredients (Excipients)		
colloidal anhydrous silica		
disodium edetate		
gellan gum		
glycine		
hypromellose		
leucine		
potable water		
potassium acetate		

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