



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	341518	TherActive Pain
ARTG entry for	Medicine Listed	
Sponsor	FIT-BioCeuticals Pty Ltd	
Postal Address	Blackmores Limited, PO Box 1725, Warriewood, NSW, 2102 Australia	
ARTG Start Date	14/08/2020	
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 . TherActive Pain

Product Type	Single Medicine Product	Effective Date	27/08/2024
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Permitted Indications

- Traditionally used in Western herbal medicine to anti-inflammatory/relieve inflammation
- Traditionally used in Western herbal medicine to analgesic/Anodyne/relieve pain
- Traditionally used in Western herbal medicine to antispasmodic/spasmolytic
- Traditionally used in Western herbal medicine to decrease/reduce/relieve mild migraine symptoms
- Traditionally used in Western herbal medicine to decrease/reduce/relieve mild nerve pain/neuralgia
- Traditionally used in Western herbal medicine to decrease/reduce/relieve menstruation pain/dysmenorrhoea

Indication Requirements

- Label statement: If symptoms persist, talk to your health professional.
- Product presentation must not imply or refer to serious musculoskeletal or neurological conditions.
- Product presentation must only refer to mild migraine.
- Product presentation must only refer to mild nerve pain/neuralgia.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

In very rare cases, Curcuma species may harm the liver. Stop use and see a doctor if you have yellowing skin/eyes or unusual: fatigue, nausea, appetite loss, abdominal pain, dark urine, or itching.

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1



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Dosage Form Tablet, film coated

Route of Administration Oral

Visual Identification

Active Ingredients

Boswellia serrata sap resin Extract dry concentrate standardised	184.62 mg
Equivalent: Boswellia serrata (Dry)	3.69 g
curcumin	10 mg
Piscidia piscipula stem bark Extract dry concentrate	250 mg
Equivalent: Piscidia piscipula (Dry)	1 g
Salix alba stem bark Extract dry concentrate standardised	100 mg
Equivalent: Salix alba (Dry)	10 g
Zingiber officinale rhizome Extract dry concentrate	60.91 mg
Equivalent: Zingiber officinale (Dry)	670 mg

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate
Carnauba Wax
citric acid
colloidal anhydrous silica
croscarmellose sodium
crospovidone
Ghatti Gum
hypromellose
macrogol 400
magnesium stearate
maltodextrin
maltose
microcrystalline cellulose
povidone
silicon dioxide

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