



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	341518	TherActive Pain
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	FIT-BioCeuticals Limited	
<b>Postal Address</b>	Care of Blackmores Ltd PO Box 1725, Warriewood, NSW, 2102 Australia	
<b>ARTG Start Date</b>	14/08/2020	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	Listed Medicines	

### Conditions

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

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	14/08/2020
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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

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

No Warnings included on Record

#### Additional Product information

#### Pack Size/Poison information

<b>Pack Size</b>	<b>Poison Schedule</b>
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#### Components

##### 1 . Formulation 1

<b>Dosage Form</b>	Tablet, film coated
<b>Route of Administration</b>	Oral

#### Visual Identification



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**Active Ingredients**

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