



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	394691	SaffroPEA
ARTG entry for	Medicine Listed	
Sponsor	FIT-BioCeuticals Limited	
Postal Address	Level 4 / 64 Kippax Street, Surry Hills, NSW, 2010 Australia	
ARTG Start Date	25/08/2022	
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 . SaffroPEA

Product Type	Single Medicine Product	Effective Date	5/12/2022
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Permitted Indications

Anti-inflammatory/relieve inflammation
Analgesic/Anodyne/relieve pain
Decrease/reduce/relieve mild joint pain/soreness
Maintain/support immune system health
Maintain/support healthy immune system function
Maintain/support muscle function
Maintain/support nervous system function
Support healthy emotional/mood balance
Enhance/improve/promote/increase sleep quality/deep sleep

Indication Requirements

Product presentation must not imply or refer to serious immunological diseases.
Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis.
Product presentation must not imply or refer to mental illnesses, disorders or conditions.
Label statement: If symptoms persist, talk to your health professional.
Product presentation must only refer to mild joint symptoms.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Adults only.
The medicine may interact with other prescription analgesic medicines, please consult your healthcare practitioner before use.
Not to be used for more than 21 consecutive days.

Additional Product information



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Pack Size/Poison information		
Pack Size		Poison Schedule
Components		
1 . Formulation 1		
Dosage Form	Capsule, hard	
Route of Administration	Oral	
Visual Identification		
Active Ingredients		
colecalfiferol		.0125 mg
Crocus sativus stigma Extract dry concentrate		12.6 mg
Equivalent: Crocus sativus (Dry)		42 mg
palmidrol		299.9997 mg
Other Ingredients (Excipients)		
Acacia		
calcium hydrogen phosphate dihydrate		
colloidal anhydrous silica		
dextrin		
disodium edetate		
dl-alpha-tocopherol		
dl-alpha-tocopheryl acetate		
gellan gum		
hypromellose		
lecithin		
Lime Oil Coldpressed		
magnesium stearate		
maize starch		
medium chain triglycerides		
microcrystalline cellulose		
Olive Oil		
PEG-35 castor oil		
potable water		
potassium acetate		
silicon dioxide		
sucrose		

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