



**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	236218	Ultra Muscleze Cream
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	FIT-BioCeuticals Pty Ltd	
<b>Postal Address</b>	Care of Blackmores Ltd PO Box 1725, Warriewood, NSW, 2102 Australia	
<b>ARTG Start Date</b>	15/04/2015	
<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 . Ultra Muscleze Cream

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	1/05/2023
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### Permitted Indications

Maintain/support healthy muscle contraction function  
Maintain/support muscle relaxation  
Maintain/support (state vitamin/mineral/nutrient) levels in the body

### Indication Requirements

If product is indicated for supplementation, Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).

### Standard Indications

No Standard Indications included on Record

### Specific Indications

No Specific Indications included on Record

### Warnings

Do not use [this product/insert name of product] in children 6 years of age or less.  
Avoid prolonged exposure in the sun.[or words to that effect]  
Contains sorbates' (or word to this effect) if medicine contains two or more sorbate sources OR 'Contains [insert the approved name of sorbate source used]' (or words to this effect) if medicine contains one sorbate source.  
Contains phenoxyethanol (or words to that effect).  
Contains methyl salicylate  
Avoid contact with eyes (or words to that effect).  
If irritation develops, discontinue use.  
Do not use if pregnant or likely to become pregnant (or words to that effect)  
Application to skin may increase sensitivity to sunlight (or words to that effect).  
If you have sensitive skin, test this product on a small area of skin before applying it to a large area.

### Additional Product information

### Pack Size/Poison information

<b>Pack Size</b>	<b>Poison Schedule</b>
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Components		
1 . Formulation 1		
Dosage Form	Cream	
Route of Administration	Topical	
Visual Identification		
Active Ingredients		
magnesium chloride hexahydrate		167.22 mg/g
Equivalent: magnesium		20 mg/g
Mentha arvensis leaf Oil essential		1 mg/g
Equivalent: Mentha arvensis ()		.7 mg/g
wintergreen oil		1 mg/g
Other Ingredients (Excipients)		
allantoin		
Avocado oil		
C13-14 isoparaffin		
cetostearyl alcohol		
citric acid		
Coconut Oil		
glycerol		
glyceryl monostearate		
hydrogenated vegetable oil		
laureth-7		
Olive Oil		
phenoxyethanol		
polyacrylamide		
polysorbate 80		
potassium sorbate		
purified water		
Simmondsia chinensis		
white beeswax		
xanthan gum		

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