



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	236218	Ultra Muscleze Cream
ARTG entry for	Medicine Listed	
Sponsor	FIT-BioCeuticals Limited	
Postal Address	Care of Blackmores Ltd PO Box 1725, Warriewood, NSW, 2102 Australia	
ARTG Start Date	15/04/2015	
Product Category	Medicine	
Status	Active	
Approval Area	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.

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.

The sponsor shall not supply the listed medicine after the expiry date of the goods.

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

Product Type	Single Medicine Product	Effective Date	13/03/2020
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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

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.

Do not use if pregnant or likely to become pregnant (or words to that effect)

Do not use [this product/insert name of product] in children 6 years of age or less.

Application to skin may increase sensitivity to sunlight (or words to that effect).

Contains methyl salicylate

If irritation develops, discontinue use.

Avoid contact with eyes (or words to that effect).

Avoid prolonged exposure in the sun.[or words to that effect]

Contains phenoxyethanol (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



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Pack Size/Poison information	
Pack Size	Poison Schedule
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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