PROFESSIONAL INFORMATION
CRAMPEASE® ORAL SPRAY

• Complementary Medicine
• Discipline: D34.12 Complementary Medicines: Health Supplements – Multiple substance formulation.
• Health Supplements are intended only to complement health or supplement the diet.
• This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.

SCHEDULING STATUS
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1. NAME OF THE MEDICINE
CRAMPEASE® ORAL SPRAY

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredients	Per 10 sprays (1,25 ml)	% NRV# per 10 sprays (max dose)
Fulvic acid	750 mg	*
Sodium	45,83 mg	*
Provided by:		
Sodium bicarbonate	41,67 mg	*
Sodium citrate	4,17 mg	*
Magnesium (magnesium glycerophosphate)	20,83 mg	4,96 %
Potassium (potassium citrate)	10,42 mg	*

Nutrient reference values for adults and children older than 4 years.
* NRV not established
CrampEase® Oral Spray contains sugar: dextrose 0,19 g/ 1,25 ml.
CrampEase® Oral Spray contains artificial sweetener: sucralose 0,825 mg/ 1,25 ml.
For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM
Oral spray.
CrampEase® Oral Spray is a clear light yellow liquid with a characteristic fruity odour and taste.

4. CLINICAL PARTICULARS
4.1 Therapeutic indications
CrampEase® Oral Spray may help in the recovery and reduce the discomfort of exercise–associated muscle cramps and episodes of involuntary muscle cramps at night-time. Minerals in conjunction with fulvic acid are absorbed directly into the bloodstream when used under the tongue.
4.2 Posology and method of administration
The recommended daily dosage is:
Adults and children 12 years and older:
6 - 10 sprays under the tongue when necessary.
Children 6 - 12 years:
3 - 5 sprays under the tongue when necessary.
Advise patients not to exceed the daily dose.
Advise the patient to consult a healthcare provider if the symptoms do not improve within one (1) week of the use of this medicinal product.
4.3 Contraindications
• Hypersensitivity to the any of the ingredients in CrampEase® Oral Spray (see 6.1 List of excipients).
4.4 Special warnings and precautions for use
• No special warnings or precautions associated with CrampEase® Oral Spray.
Porphyria
Safety has not been established.
4.5 Interaction with other medicinal products and other forms of interaction
No relevant interactions with other medications are anticipated when considering the small quantity of the dose and the method of administration.
4.6 Fertility, pregnancy and lactation
Pregnancy
Use during pregnancy is not recommended as safety during pregnancy has not been established.
Breastfeeding
Use is not recommended as safety during lactation has not been established.
Fertility
There are no known effects of CrampEase® Oral Spray on fertility.
4.7 Effects on the ability to drive and use machines.
Based on the side effect profile, CrampEase® Oral Spray is not expected to affect the ability to drive or operate machinery.
4.8 Undesirable effects
Advice patients to discontinue use and consult a healthcare provider if they experience any side effects or sensitivity to any of the ingredients.

System Organ Class	Frequency	Adverse Event
Gastrointestinal disorders	frequency unknown	diarrhoea, gastrointestinal irritation, nausea, and vomiting.
Nervous system disorders	frequency unknown	Headache

Advise patient to consult a healthcare provider if symptoms persist, or if any adverse reactions occur.
Reporting of suspected adverse reactions
Reporting of suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**," found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8
4.9 Overdose
Symptoms
See **4.8 Undesirable effects**
In overdose, side effects can be precipitated and/or be of increased severity.
Treatment
If an accidental overdose occurs, treatment is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic properties
Category and class: D34.12 Complementary Medicines: Health Supplements – Multiple substance formulation.
Other drugs for disorders of the musculo-skeletal systems.
ATC- code: M09AX
Fulvic acid:
Carbohydrate -derived fulvic acid has antioxidant effects, resulting in reduced hydroxyl radical formation, potentially aiding muscle recovery, and anti-inflammatory properties to protect cells against oxidation during stress with a high affinity to COX-1.
Research suggests that fulvic acid can reduce the release of tumor necrosis factor-alpha form differentiated U937 cells.
Sodium:
The body requires sodium for normal neuron and muscle function, and for fluid and electrolyte balance.
Magnesium:
Extracellular magnesium is essential to maintaining nerve and muscle electrical potentials. Oral magnesium has been reported to reduce pregnancy-related leg cramps brought on by low serum levels of magnesium.
Potassium:
Potassium is essential for the normal functioning of physiological processes, including nerve impulse transmission and cardiac, smooth, and skeletal muscle contraction.
5.2 Pharmacokinetic properties
Fulvic acid:
Absorption: Fulvic acid is well absorbed from the gastrointestinal tract. Oral administration of carbohydrate-derived fulvic acid is rapidly absorbed and well distributed, with an oral bioavailability of 78%.
Excretion: Fulvic acid is eliminated from the body within hours of administration.
Sodium:
Absorption: Oral administration of sodium chloride results in approximately 98 % of the sodium being absorbed in the small intestines.
Distribution: Sodium is distributed to extracellular compartments, including plasma, interstitial fluid, plasma water, and muscle.
Excretion: Individuals with a steady sodium and fluid balance display a urinary sodium excretion equal to their sodium intake.
Magnesium:
Magnesium:
Absorption: The absorption of magnesium is dependent on both vitamin D and parathyroid hormone, it is absorbed throughout the gastrointestinal tract with an approximate dietary bioavailability of 30 %. Plasma levels of magnesium generally peak 4 hours after oral administration.
Distribution: The body stores an approximate amount of 25 grams of magnesium, which is equally divided between the skeleton and soft tissues. Approximately 30 % of skeletal magnesium is stored at the surface of bone structures and acts as a reserve for the replenishing of extracellular magnesium levels. In plasma, magnesium is 55 % ionised or free, 30 % plasma protein bound, and 15 % complexed to anions.
Excretion: Magnesium is primarily excreted via the kidneys and urine. Excretion can range from 10 to 5000 mg over a 24-hour period.
Potassium:
Distribution: The total potassium content of the body is regulated by the kidneys. Serum potassium levels are extensively affected by the intracellular and extracellular potassium distribution without a change in total body potassium.

6. PHARMACEUTICAL PARTICULARS
6.1 List of excipients
Water.
Flavourant (tutti fruity).
Dextrose.
Sucralose.
6.2 Incompatibilities
None known
6.3 Shelf life
24 Months
6.4 Special precautions for storage
• Store in a dry place at or below 25 °C.
• Protect from light and moisture.
• Keep in original packaging until required for use.
6.5 Nature and contents of container
CrampEase® Oral Spray is a clear light yellow liquid with a characteristic fruity odour and taste.
CrampEase® Oral Spray is packaged in a white 30 ml polyethylene terephthalate container with a white spray cap, in a unit carton that includes a patient information leaflet.
6.6 Special precautions for disposal and other handling
No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION
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8. REGISTRATION NUMBER(S)
To be allocated

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
February 2021

10. DATE OF REVISION OF THE TEXT

PPIL311/01