



38319 PA

# USN CRAMP BLOCK

(tablets)

## COMPLEMENTARY MEDICINE: HEALTH SUPPLEMENT

This unregistered medicine has not been evaluated by SAHPRA for its quality, safety or intended use.

**SCHEDULING STATUS:** S0

### 1. NAME OF THE MEDICINE

USN CRAMP BLOCK tablets

### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:		%NRV
Sodium bicarbonate	150 mg	
providing Sodium	41 mg	
Magnesium carbonate	125 mg	
providing Magnesium (elemental)	32 mg	8 %
Calcium carbonate	75 mg	
providing Calcium (elemental)	30 mg	2 %
Taurine	50 mg	
Di-potassium phosphate	25 mg	
providing Potassium (elemental)	11 mg	
Phosphorus (elemental)	4,5 mg	
Pyridoxine HCl	3 mg	
providing Pyridoxine (Vitamin B <sub>6</sub> )	2,5 mg	147 %

\*%Nutrient Reference Values (NRVs) for individuals 4 years and older (2010).  
Sugar free.

For a full list of excipients, see section 6.1.

### 3. PHARMACEUTICAL FORM

Tablets.

Oval shaped white film coated tablets.

### 4. CLINICAL PARTICULARS

#### 4.1 Therapeutic indications

USN CRAMP BLOCK provides minerals and electrolytes for optimal physical performance during intense physical activity. USN CRAMP BLOCK may also assist with increased stamina and reduced muscle cramps and fatigue.

#### 4.2 Posology and method of administration

*Adults:*

- PRE- AND DURING EVENT: Take 2 tablets 30 minutes before the start of the event and 1 tablet per hour of exercise thereafter.
- POST EVENT: Take 2 tablets 30 minutes after the completion of the event, as well as 2 tablets before bedtime.
- DAILY SUPPLEMENTATION (MAINTENANCE): Take 2 – 4 tablets before bedtime to optimise absorption.
- PHOSPHATE LOADING PRIOR TO EVENTS: Take 3 tablets twice daily in the 3 days prior to an event.
- Do not exceed a daily intake of 7 tablets.
- Ensure to drink enough fluid before, during, and after exercise.

*Children:*

Not suitable for children under the age of 18 years.

#### 4.3 Contraindications

Hypersensitivity to any of the active ingredients or to any of the excipients listed in section 2 or 6.1.

#### 4.4 Special warnings and precautions for use

##### Cardiovascular disorders:

USN CRAMP BLOCK should be used with caution in patients with cardiovascular disorders such as hypertension.

##### Kidney disorders:

USN CRAMP BLOCK may worsen kidney dysfunction in patients with existing kidney disease. Use with caution.

##### Contains sodium

USN CRAMP BLOCK contains 41 mg sodium per tablet, equivalent to 2 % of the WHO recommended maximum daily intake of 2 g sodium for an adult.

##### Paediatric population

USN CRAMP BLOCK is not suitable for children under the age of 18 years.

#### 4.5 Interaction with other medicinal products and other forms of interaction

##### Antibiotic medicines:

Concomitant use of USN CRAMP BLOCK with antibiotics may reduce absorption. Doses should be separated by at least 2 hours prior, or 4 to 6 hours after taking USN CRAMP BLOCK.

##### Levothyroxine:

Concomitant use of USN CRAMP BLOCK with levothyroxine may reduce absorption. Patients should be advised to take levothyroxine and USN CRAMP BLOCK at least 4 hours apart.

#### 4.6 Fertility, pregnancy and lactation

Safety in pregnancy and lactation has not been established. USN CRAMP BLOCK should not be taken during pregnancy or lactation.

#### 4.7 Effects on ability to drive and use machines

USN CRAMP BLOCK is unlikely to affect the ability to drive a vehicle and use machines.

Caution is advised before driving a vehicle or operating machinery until the effects of USN CRAMP BLOCK are known.

#### 4.8 Undesirable effects

USN CRAMP BLOCK is generally well tolerated.

##### Immune system disorders:

*Frequency unknown:* hypersensitivity and/or allergic reactions.

##### Metabolism and nutrition disorders:

*Frequency unknown:* loss of appetite.

##### Nervous system disorders:

*Frequency unknown:* headache.

##### Gastrointestinal disorders:

*Frequency unknown:* stomach upset, nausea, vomiting, dyspepsia, abdominal pain, diarrhoea, belching, flatulence, constipation.

##### Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of USN CRAMP BLOCK is important. It allows continued monitoring of the benefit/risk balance of USN CRAMP BLOCK. Healthcare providers are asked to report any suspected adverse reactions to the South African Health Products Regulatory Authority (SAHPRA) via the 6.04 Adverse Drug Reaction Reporting Form, found online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8>.

#### 4.9 Overdose

In overdose, side effects can be precipitated and/or be of increased severity (see section 4.8).

In the event of overdose, treatment should be symptomatic and supportive.

## 5. PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

#### Category and class:

D 34.12 Multiple Substance Formulation.

USN CRAMP BLOCK is a multi-vitamin/mineral supplement with taurine that provides electrolytes for optimal physical performance during intense physical activity. USN CRAMP BLOCK may also assist with increased stamina and reduced muscle cramps and fatigue.

### 5.2 Pharmacokinetic properties

Sodium is absorbed by the small intestines, distributed to extracellular compartments, and is excreted in the urine and sweat.

Magnesium is absorbed throughout the gastrointestinal tract, is distributed in the skeleton and soft tissue, and excreted primarily via the kidneys.

Calcium absorption is affected by several factors like age, race, environmental and dietary conditions. Calcium is distributed in the bones and teeth and excreted via the urine and faeces.

Taurine is distributed to the liver and kidneys, and in low amounts to the brain and muscle. Taurine is conjugated to bile acids and is also excreted in the urine.

Potassium in the body is regulated by the kidneys and distribution in intracellular and extracellular fluid influences serum potassium levels without changing the total body potassium. Potassium is excreted mainly in the urine.

Phosphorus absorption from the gut is partially regulated by vitamin D<sub>3</sub>, which plays a role in maintaining blood levels of both calcium and phosphorus. It is mostly distributed to bone.

Pyridoxine (Vitamin B<sub>6</sub>) is passively absorbed from the upper gastrointestinal tract, converted in the liver to the coenzyme pyridoxal phosphate and excreted in the urine.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

#### Tablet core:

Magnesium stearate (E572)  
Maize starch  
Microcrystalline cellulose (PH102) (E460)  
Povidone K25  
Silicon dioxide (E551)  
Stearic acid (E570)  
Talc (E553b)

#### Film coating:

Castor oil (E1530)  
Shellac blonded  
White base PHA2013.

### 6.2 Incompatibilities

Not applicable

### 6.3 Shelf life

24 months.

Store at or below 25 °C.

### 6.4 Special precautions for storage

Store in a dry place.

### 6.5 Nature and contents of container

30 tablets are packed in aluminium/PVC blister strips containing 10 tablets each. 3 blister strips are packed inside a carton.

### 6.6 Special precautions for disposal

No special requirements.

## 7. HOLDER OF CERTIFICATE OF REGISTRATION

USN (Pty) Ltd  
Unit 4, Louwlandia Logistics Park  
cnr Nellmapius Drive & Olievenhoutbosch Road  
Centurion, 1683  
Pretoria

## 8. REGISTRATION NUMBER


Will be allocated by SAHPRA upon registration.

## 9. DATE OF FIRST AUTHORISATION

Will be allocated by SAHPRA upon registration.

## 10. DATE OF REVISION OF THE TEXT

This leaflet was last revised in July 2021.

<b>JOB:</b> SAPF_CrampBlock_30s		<b>SIZE:</b> 300mm x 320mm	
<b>STOCK:</b> Foil Substrate: <input type="checkbox"/> Clear Substrate: <input type="checkbox"/> White Substrate: <input type="checkbox"/> Paper: <input checked="" type="checkbox"/> Other: <input type="checkbox"/>			
<b>COLOURS:</b>		<b>FINISHING:</b>	
 K		<input type="checkbox"/> Foil / Holographic Foil <input type="checkbox"/> Matte <input type="checkbox"/> Gloss <input type="checkbox"/> Spot UV <input type="checkbox"/> Doming <input type="checkbox"/> Embossing	
<b>PLEASE CHECK CAREFULLY</b> Although we endeavour to proof accurately, we cannot accept responsibility for errors once proofs are signed and accepted by our clients.			

