



3831924

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 providing Sodium	150 mg 41 mg
Magnesium carbonate providing Magnesium (elemental)	125 mg 32 mg
Calcium carbonate providing Calcium (elemental)	75 mg 30 mg
Taurine	50 mg
Di-potassium phosphate providing Potassium (elemental)	25 mg 11 mg
Phosphorus (elemental)	4,5 mg
Pyridoxine HCl providing Pyridoxine (Vitamin B ₆)	3 mg 2,5 mg

*%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 D₃, which plays a role in maintaining blood levels of both calcium and phosphorus. It is mostly distributed to bone.Pyridoxine (Vitamin B₆) 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 blanched
 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.

CRA001/PI-PIL/A

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



USN CRAMP BLOCK

(tablets)

SCHEDULING STATUS:

USN CRAMP BLOCK tablets

Sugar free.

COMPLEMENTARY MEDICINE: HEALTH SUPPLEMENT

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

Read all of this leaflet carefully because it contains important information for you.

USN CRAMP BLOCK is available without a doctor's prescription, for you to maintain your health. Nevertheless, you still need to use USN CRAMP BLOCK carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share USN CRAMP BLOCK with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.

What is in this leaflet

1. What USN CRAMP BLOCK is and what it is used for.
2. What you need to know before you take USN CRAMP BLOCK.
3. How to take USN CRAMP BLOCK.
4. Possible side effects.
5. How to store USN CRAMP BLOCK.
6. Contents of the pack and other information.

1. What USN CRAMP BLOCK is and what it is used for

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.

2. What you need to know before you take USN CRAMP BLOCK

Do not take USN CRAMP BLOCK:

- If you are hypersensitive (allergic) to any of the ingredients of USN CRAMP BLOCK (listed in section 6).

Warnings and precautions

Take special care with USN CRAMP BLOCK:

- If you have a heart disease such as high blood pressure.
- If you have any kidney problems.

Children and adolescents

Do not give USN CRAMP BLOCK to children younger than 18 years, as the safety and efficacy in children have not yet been established.

Other medicines and USN CRAMP BLOCK

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Tell your doctor or pharmacist if you are currently taking:

- Antibiotics (used to treat a bacterial infection). Take antibiotics at least 2 hours before, or 4 to 6 hours after taking USN CRAMP BLOCK.
- Levothyroxine (used to treat an underactive thyroid). Take levothyroxine and USN CRAMP BLOCK at least 4 hours apart.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking USN CRAMP BLOCK. Safety in pregnancy and lactation has not been established. Do not take USN CRAMP BLOCK if you are pregnant or breastfeeding.

Driving and using machines

USN CRAMP BLOCK is unlikely to affect your ability to drive a vehicle and use machines. Do not drive or operate machinery until you know how USN CRAMP BLOCK affects you.

USN CRAMP BLOCK contains sodium

USN CRAMP BLOCK contains 41 mg sodium (main component of cooking/table salt) in each tablet. This is equivalent to 2 % of the recommended maximum daily dietary intake of sodium for an adult.

3. How to take USN CRAMP BLOCK

Always take USN CRAMP BLOCK exactly as described in this leaflet or as your pharmacist has told you. Check with your pharmacist if you are not sure.

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.

If you take more USN CRAMP BLOCK than you should

In the event of an overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take USN CRAMP BLOCK

Take your next dose at the normal time.

Do not take a double dose to make up for individual forgotten doses.

4. Possible side effects

USN CRAMP BLOCK can have side effects.

Not all side effects reported for USN CRAMP BLOCK are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking USN CRAMP BLOCK, please consult your healthcare provider for advice.

If any of the following happens, stop taking USN CRAMP BLOCK and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to USN CRAMP BLOCK. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequency unknown:

- Loss of appetite.
- Headache.
- Upset stomach, nausea (feeling sick), vomiting (being sick), heartburn, stomach pain, diarrhoea, burping, gas, constipation.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the 6.04 Adverse Drug Reactions Reporting Form, found online under SAHPRA's publications: <http://www.sahpra.org.za/Publications/Index/8>.

By reporting side effects, you can help provide more information on the safety of USN CRAMP BLOCK.

5. How to store USN CRAMP BLOCK

- Store at or below 25 °C.
- Store in a dry place.
- Store all medicines out of reach of children.
- Do not use after the expiry date printed on the carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What USN CRAMP BLOCK contains

Each tablet contains:

Sodium bicarbonate	150 mg	*%NRV
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 ₆)	2,5 mg	147 %

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

The other ingredients are magnesium stearate (E572), maize starch, microcrystalline cellulose (PH102) (E460), povidone K25, silicon dioxide (E551), stearic acid (E570), talc (E553b), castor oil (E1530), shellac blonded and white base PHA2013.

What USN CRAMP BLOCK looks like and contents of the pack

Oval shaped white film coated tablets.
30 tablets are packed in aluminium/PVC blister strips containing 10 tablets each. 3 blister strips are packed inside a carton.

Holder of Certificate of Registration:

USN (Pty) Ltd
Unit 4, Louwlandia Logistics Park
cnr Nellmapius Drive & Olievenhoutbosch Road
Centurion, 1683
Pretoria
Tel: 086 111 1876

This leaflet was last revised in July 2021.

Registration number
Will be allocated by SAHPRA upon registration.Access to corresponding Professional Information
www.usn.co.za

PASIËNTINLIGTINGSBLAD



USN CRAMP BLOCK

(tablete)

SKEDULERINGSTATUS:

USN CRAMP BLOCK tablette

Suikervry.

KOMPLEMENTÉRE MEDISYNE: GESONDHEIDAANVULLING

Hierdie ongeregistreerde medisyne is nie vir gehalte, veiligheid of beoogde gebruik deur SAHPRA geëvalueer nie.

Lees hierdie hele inligtingsblad aandagdig deur want dit bevat inligting wat belangrik is vir jou.

USN CRAMP BLOCK is beskikbaar sonder 'n dokter se voorskrif, sodat jy jou gesondheid in stand kan hou. Jy moet USN CRAMP BLOCK nogtans met sorg neem om die beste resultate te verkry.

- Hou hierdie inligtingsblad. Dit mag nodig wees dat jy dit weer lees.
- Moenie USN CRAMP BLOCK met enigemand anders deel nie.
- Vra gerus jou apteker indien jy verdere inligting of advies nodig het.

Wat is in hierdie inligtingsblad

1. Wat is USN CRAMP BLOCK en waarvoor word dit gebruik
2. Wat jy moet weet voordat jy USN CRAMP BLOCK neem
3. Hoe om USN CRAMP BLOCK te neem
4. Moontlike newe-effekte
5. Hoe om USN CRAMP BLOCK te bêre.
6. Inhoud van die pak en ander inligting

1. Wat is USN CRAMP BLOCK en waarvoor word dit gebruik

USN CRAMP BLOCK verskaf minerale en elektrolyte vir optimale fisiiese prestasie tydens intense fisiiese aktiwiteit. USN CRAMP BLOCK kan ook help met verhoogde uitlhouvermoë en verminderde spierkramp en moegheid.

2. Wat jy moet weet voordat jy USN CRAMP BLOCK neem

Moenie USN CRAMP BLOCK neem nie

- Indien jy hypersensitief (allergie) is vir enige van die bestanddele van USN CRAMP BLOCK (gelys by afdeling 6).

Waarskuwings en voorsorgmaatreëls

Wees veral versigtig met USN CRAMP BLOCK:

- Indien jy aan 'n hartsiekte ly soos hoë bloeddruk.
- Indien jy enige nierprobleme het.

Kinders en tiens

Moenie USN CRAMP BLOCK aan kinders jonger as 18 jaar gee nie, aangesien die veiligheid en doeltreffendheid by kinders nog nie vasgestel is nie.

Ander medisyne en USN CRAMP BLOCK

Sé altyd vir jou gesondheidsorgverskaffer indien jy enige ander medisyne neem. (Dit sluit komplementäre of tradisionele medisyne in.)

Sé vir jou dokter indien jy tans die volgende gebruik:

- Antibiotika (gebruik om 'n bakteriële infeksie te behandel). Neem antibiotika minstens 2 ure voor, of 4 tot 6 ure nadat jy USN CRAMP BLOCK geneem het.
- Levotiroksien (gebruik om 'n onderaktiewe skildklier te behandel). Neem levotiroksien en USN CRAMP BLOCK minstens 4 ure uitmekar.

Swangerskap en borsvoeding

Indien jy swanger is of jou baba borsvoed, dink dat jy swanger mag wees of beplan om swanger te raak, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer voordat jy USN CRAMP BLOCK neem. Die veiligheid tydens swangerskap en borsvoeding is nie bepaal nie. Moenie USN CRAMP BLOCK neem indien jy swanger is of jou baba borsvoed nie.

Bestuur en die gebruik van masjiene

Dit is onwaarskynlik dat USN CRAMP BLOCK jou vermoë om 'n voertuig te bestuur en masjiene te gebruik sal belemmer. Moenie 'n voertuig bestuur of masjiene hanter totdat jy weet hoe USN CRAMP BLOCK jou effekue nie.

USN CRAMP BLOCK bevat natrium

USN CRAMP BLOCK bevat 41 mg natrium (vernaamste bestanddeel van tafelsout) in elke tablet. Dit is gelykstaande aan 2 % van die aanbevolke maksimum daagliks innname van sout uit die dieet vir 'n volwassene.

3. Hoe om USN CRAMP BLOCK te neem

Gebruik USN CRAMP BLOCK altyd presies soos wat in hierdie inligtingsblad aangedui word, of soos wat jou apteker vir jou gesê het. Vra gerus jou apteker indien jy onseker is.

Volwassenes:

- VOOR- EN GEDURENSE OEFENSESSIE: Neem 2 tablette 30 minute voor die begin van die oefensessie en 1 tablette elke uur tydens die oefensessie.
- NA OEFENSESSIE: Neem 2 tablette 30 minute na die voltooiing van die oefensessie, asook 2 tablette voor slapenstyd.
- DAAGLIKSE AANVULLING (ONDERHOUDING): Neem 2 – 4 tablette voor slapenstyd vir optimale absorpsie.
- FOSFATLADING VOOR OEFENSESSIES: Neem 3 tablette tweemaal daagliks gedurende die 3 dae voor die oefensessie.
- Moenie 'n daagliks innname van 7 tablette oorskry nie.
- Maak seker dat jy genoeg vloeistof drink voor, tydens en na oefening.

Wat om te doen indien jy meer USN CRAMP BLOCK geneem het as wat jy moet

In geval van oordosering, raadpleeg jou dokter of apteker. Indien nie een van hulle beskikbaar is nie, kontak die naaste apotheker of gifsentrum.

Indien jy vergeet om USN CRAMP BLOCK te neem

Neem jou volgende dosis op die gewone tyd. Moenie 'n dubbele dosis neem om te vergoed vir die individuele dosisse wat vergeet is nie.

4. Moontlike newe-effekte

USN CRAMP BLOCK kan newe-effekte hê.

Nie alle newe-effekte wat vir USN CRAMP BLOCK gerapporteer is, word in hierdie inligtingsblad ingesluit nie. Indien jou algemene gesondheid verswak of jy enige ongunstige effekte ondervind terwyl USN CRAMP BLOCK geneem word, raadpleeg asseblief jou gesondheidsorgverskaffer.

Indien enige van die volgende gebeur, hou op om USN CRAMP BLOCK te neem en sê dadelik vir jou dokter, of gaan na die ongevalle-afdeling by jou naaste hospitaal:

<li