



## USN CREATINE X4

(capsules)

## COMPLEMENTARY MEDICINE: COMBINATION PRODUCT (WESTERN HERBAL 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 CREATINE X4 capsules

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

## ACTIVE INGREDIENTS

BioPerine® Piper nigrum L. (Black Pepper)  
[fruit; 50:1 extract standardised to Piperine 95 %]

Creatine HCl

Glycine

Creatine Ethyl Ester HCl

Creatine Nitrate

Creatine Monohydrate

Magnesium Amino Acid Chelate 20 %  
providing Magnesium (elemental)

Beta-Alanine

Taurine

Alpha-Lipoic Acid

\*%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

Capsules.

Size 00 white hard gelatine capsules containing a white powder.

## 4. CLINICAL PARTICULARS

## 4.1 Therapeutic indications

USN CREATINE X4 may assist with increased physical performance and exercise capacity. USN CREATINE X4 may increase lean muscle mass when used in conjunction with a resistance training regimen and improves physical performance in successive bursts of short term, high intensity exercise.

## 4.2 Posology and method of administration

## Adults:

- Take 4 – 6 capsules with a glass of water 30 minutes before a workout. Another dose can be taken post-workout, if required.
- On non-training days, take 6 capsules on an empty stomach first thing in the morning.
- For best results, follow an appropriate muscle gain eating plan and training program.
- Creatine increases physical performance in successive bursts of short term, high intensity exercise when taken in dosage of at least 3 g per day.
- Consume sufficient amounts of fluid before, during and after exercise. Drink at least 2 to 3 litres of water per day while using USN CREATINE X4.
- Do not exceed the recommended daily dosage.

## 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

## Bleeding disorders:

USN CREATINE X4 may have antplatelet effects and may increase the risk of bruising and bleeding when used in patients with bleeding disorders. Patients should be advised to discontinue USN CREATINE X4 at least 2 weeks prior to surgical procedures (see section 4.5).

## Diabetes mellitus:

USN CREATINE X4 may affect blood glucose levels and adjustment of antidiabetic medicine might be necessary (see section 4.5). Diabetic patients should consult a healthcare provider prior to use.

Consumers should discontinue use and consult a relevant healthcare provider if they experience symptoms of low blood sugar such as sweating, paleness, chills, headache, dizziness and/or confusion.

## Hypotension:

USN CREATINE X4 may reduce blood pressure, increasing the risk of blood pressure becoming too low in patients with hypotension. Caution is advised.

## Kidney disorders:

USN CREATINE X4 should be used in caution in patients with a kidney disorder.

## General:

USN CREATINE X4 may cause a flushing, tingling and/or prickling sensation of the skin, in which case the dose must be reduced.

A relevant healthcare provider should be consulted before long-term use.

May result in weight gain.

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

## Anticoagulant/antiplatelet medicines:

USN CREATINE X4 may enhance the effects of anticoagulant/antiplatelet medicines or herbal supplements. Concomitant use may increase the risk of bruising and bleeding (see section 4.4).

## Antidiabetic medicines:

The use of USN CREATINE X4 with antidiabetic medicines or herbal supplements with hypoglycaemic effects may have an additive effect when used concomitantly (see section 4.4). Caution is advised.

## Antihypertensive medicines:

The use of USN CREATINE X4 with antihypertensive medicine or herbal supplements with hypotensive effects may have additive blood pressure-lowering effects when used concomitantly. Caution is advised.

## Lithium:

USN CREATINE X4 might reduce excretion and increase levels of lithium due to its potential diuretic effect. The dose of lithium might need to be decreased.

Per Capsule	Per 6-Capsule Dose	*%NRV
0,8 mg	5 mg	
166,7 mg	1 000 mg	
166,7 mg	1 000 mg	
133 mg	800 mg	
133 mg	800 mg	
66,7 mg	400 mg	
50 mg	300 mg	
10 mg	60 mg	
33,3 mg	200 mg	
32,3 mg	194 mg	
16,7 mg	100 mg	14 %

## 4.6 Fertility, pregnancy and lactation

Safety in pregnancy and lactation has not been established.  
USN CREATINE X4 should not be taken during pregnancy or lactation.

## 4.7 Effects on ability to drive and use machines

USN CREATINE X4 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 CREATINE X4 are known.

## 4.8 Undesirable effects

USN CREATINE X4 is generally well tolerated.

## Immune system disorders:

Frequency unknown: hypersensitivity and/or allergic reactions.

## Nervous system disorders:

Frequency unknown: headache, paraesthesia.

## Vascular disorders:

Frequency unknown: flushing.

## Gastrointestinal disorders:

Frequency unknown: gastrointestinal pain, dyspepsia, diarrhoea, nausea, vomiting.

## Musculoskeletal and connective tissue:

Frequency unknown: muscle cramps.

## Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of USN CREATINE X4 is important. It allows continued monitoring of the benefit/risk balance of USN CREATINE X4. 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 33.7 Combination Product.

USN CREATINE X4 contains Creatine, BioPerine® (Black Pepper) and amino acids which assist with increased physical performance, exercise capacity and lean muscle mass.

## 5.2 Pharmacokinetic properties

Alpha-lipoic acid is readily absorbed from the gut, extensively metabolised in the liver to dihydrolipoic acid (DHLA) and excreted in the urine.

Intestinal absorption of creatine is nearly 100 %. It is mainly stored in muscle, metabolised to creatinine and excreted renally.

Beta-alanine is a nonessential amino acid and a component of pantothenic acid (vitamin B5) and the dipeptides carnosine and anserine. Carnosine (beta-alanyl-L-histidine) is synthesised from beta-alanine and L-histidine in muscles and cells of the CNS by the enzyme carnosine synthetase. Carnosine is concentrated in actively contracting muscle and is thought to play a role in the contractility of muscle tissue. It acts as a buffer to prevent the build-up of hydrogen ions in myocytes which contributes to muscle fatigue.

Glycine is an amino acid. It is rapidly absorbed in the blood with maximal levels about 40 minutes after ingestion. Glycine appears to passively diffuse across the blood-brain barrier and is eliminated within hours after ingestion.

Taurine is an amino acid which is normally synthesised in the human body in adequate amounts by oxidation and decarboxylation of cysteine. Taurine has been reported to decrease oxidative stress and it is possible that it prevents increases in carbonyl protein and lipoperoxide levels which contribute to muscle soreness.

Taurine is conjugated to bile acids, and it is also excreted in the urine.

There is insufficient information available about the pharmacokinetic properties of *Piper nigrum* L. (Black Pepper).

## 6. PHARMACEUTICAL PARTICULARS

## 6.1 List of excipients

Gelatine capsules (bovine)  
Magnesium stearate  
Silicon dioxide.

## 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

Capsules are packed in a white HDPE container with a metallic blue screw-on cap and induction seal.  
Available in pack sizes of 60 and 120 capsules.

## 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 May 2021.

CREA018-004/PI-PIL/A

JOB: SACS_Creatine X4_60s - 120s	SIZE: 300mm x 322mm
STOCK: Foil Substrate: <input type="checkbox"/> Clear Substrate: <input type="checkbox"/> White Substrate: <input 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 CREATINE X4

37946 P3

(capsules)

SCHEDULING STATUS: **[S0]**

## USN CREATINE X4 capsules

Sugar free.

## COMPLEMENTARY MEDICINE: COMBINATION PRODUCT (WESTERN HERBAL 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 CREATINE X4 is available without a doctor's prescription, for you to maintain your health. Nevertheless, you still need to use USN CREATINE X4 carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share USN CREATINE X4 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 CREATINE X4 is and what it is used for.
2. What you need to know before you take USN CREATINE X4.
3. How to take USN CREATINE X4.
4. Possible side effects.
5. How to store USN CREATINE X4.
6. Contents of the pack and other information.

## 1. What USN CREATINE X4 is and what it is used for

USN CREATINE X4 may assist with increased physical performance and exercise capacity. USN CREATINE X4 may increase lean muscle mass when used in conjunction with a resistance training regimen and improves physical performance in successive bursts of short term, high intensity exercise.

## 2. What you need to know before you take USN CREATINE X4

## Do not take USN CREATINE X4:

- If you are hypersensitive (allergic) to any of the ingredients of USN CREATINE X4 (listed in section 6).

## Warnings and precautions

## Take special care with USN CREATINE X4:

- If you have a bleeding disorder, USN CREATINE X4 should be discontinued at least 2 weeks before surgical procedures.
- If you have diabetes mellitus (high blood sugar) and you are taking medicines to control your blood sugar levels.
- Stop taking USN CREATINE X4 and consult a healthcare provider if you experience symptoms of low blood sugar such as sweating, paleness, chills, headache, dizziness and/or confusion.
- If you have low blood pressure.
- If you have a kidney disorder.
- Consult a relevant healthcare provider before long-term use.

## Children and adolescents

Do not give USN CREATINE X4 to children younger than 18 years, as the safety and efficacy in children have not yet been established.

## Other medicines and USN CREATINE X4

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:

- Anticoagulant/antiplatelet medicines (used to thin your blood), or herbal supplements with blood thinning effects.
- Antidiabetic medicines (used to treat high blood sugar levels), or herbal supplements which can influence blood sugar levels.
- Antihypertensive medicines (used to treat high blood pressure), or herbal supplements which lower blood pressure.
- Lithium (used to stabilise your mood).

## 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 CREATINE X4. Safety in pregnancy and lactation has not been established. Do not take USN CREATINE X4 if you are pregnant or breastfeeding.

## Driving and using machines

USN CREATINE X4 is unlikely to affect your ability to drive a vehicle and use machines. Do not drive or operate machinery until you know how USN CREATINE X4 affects you.

## 3. How to take USN CREATINE X4

Always take USN CREATINE X4 exactly as described in this leaflet or as your pharmacist has told you. Check with your pharmacist if you are not sure.

## Adults:

- Take 4 – 6 capsules with a glass of water 30 minutes before a workout. Another dose can be taken post-workout, if required.
- On non-training days, take 6 capsules on an empty stomach first thing in the morning.
- For best results, follow an appropriate muscle gain eating plan and training program.
- Creatine increases physical performance in successive bursts of short term, high intensity exercise when taken in dosage of at least 3 g per day.
- Consume sufficient amounts of fluid before, during and after exercise. Drink at least 2 to 3 litres of water per day while using USN CREATINE X4.
- Do not exceed the recommended daily dosage.

## If you take more USN CREATINE X4 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 CREATINE X4

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 CREATINE X4 can have side effects.

Not all side effects reported for USN CREATINE X4 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking USN CREATINE X4, please consult your healthcare provider for advice.

If any of the following happens, stop taking USN CREATINE X4 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 CREATINE X4. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

## Frequency unknown:

- Headache.
- Stomach pain, heartburn, diarrhoea, nausea, vomiting.

- Muscle cramps.
- Pins and needles sensation.
- Skin and/or face become red and hot.

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 CREATINE X4.

## 5. How to store USN CREATINE X4

- 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 container.
- 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 CREATINE X4 contains

ACTIVE INGREDIENTS	Per Capsule	Per 6-Capsule Dose	*%NRV
BioPerine® <i>Piper nigrum</i> L. (Black Pepper) [fruit; 50:1 extract standardised to Piperine 95 %]	0.8 mg	5 mg	
Creatine HCl	166.7 mg	1 000 mg	
Glycine	166.7 mg	1 000 mg	
Creatine Ethyl Ester HCl	133 mg	800 mg	
Creatine Nitrate	133 mg	800 mg	
Creatine Monohydrate	66.7 mg	400 mg	
Magnesium Amino Acid Chelate 20 % providing Magnesium (elemental)	50 mg	300 mg	
Beta-Alanine	10 mg	60 mg	14 %
Taurine	33.3 mg	200 mg	
Alpha-Lipoic Acid	32.3 mg	194 mg	
	16.7 mg	100 mg	

\*%Nutrient Reference Values (NRVs) for individuals 4 years &amp; older (2010).

The other ingredients are bovine gelatine capsules, magnesium stearate and silicon dioxide.

## What USN CREATINE X4 looks like and contents of the pack

Size 00 white hard gelatine capsules containing a white powder. Capsules are packed in a white HDPE container with a metallic blue screw-on cap and induction seal. Available in pack sizes of 60 and 120 capsules.

## Holder of Certificate of Registration:

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

This leaflet was last revised in May 2021.

## Registration number

Will be allocated by SAHPRA upon registration.

## Access to corresponding Professional Information

[www.usn.co.za](http://www.usn.co.za)

## PASIËNTINLIGTINGSBLAD



## USN CREATINE X4

(capsules)

SKEDULERINGSTATUS: **[S0]**

## USN CREATINE X4 capsules

Suikervry.

## KOMPLEMENTÉRE MEDISYNE: KOMBINASIEPRODUK (WESTERSE KRUIEMEDISYNE / GESONDHEIDSAANVULLING)

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

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

USN CREATINE X4 is beskikbaar sonder 'n dokter se voorskrif, sodat jy jou gesondheid in stand kan hou. Jy moet USN CREATINE X4 nogtans met sorg neem om die beste resultate te verkry.

- Hou hierdie inligtingsblad. Dit mag nodig wees dat jy dit weer lees.
- Moenie USN CREATINE X4 met enigemand anders deel nie.
- Vra gerus jou apoteker indien jy verdere inligting of advies nodig het.

## Wat is in hierdie inligtingsblad

1. Wat is USN CREATINE X4 en waarvoor word dit gebruik.
2. Wat jy moet weet voordat jy USN CREATINE X4 neem.
3. Hoe om USN CREATINE X4 te neem.
4. Moontlike newe-effekte.
5. Hoe om USN CREATINE X4 te bêre.
6. Inhoud van die pak en ander inligting.

## 1. Wat is USN CREATINE X4 en waarvoor word dit gebruik

USN CREATINE X4 kan help met verbeterde fisiese prestasie en oefenvormoë. USN CREATINE X4 verhoog maar spiermassa wanneer dit saam met 'n weerstandsoefening gebruik word en verbeter die fisiese prestasie tydens kort en strawwe opeenvolgende oefensessies.

## 2. Wat jy moet weet voordat jy USN CREATINE X4 neem

Moenie USN CREATINE X4 neem nie

- Indien jy hipersensitief (allergies) is vir enige van die bestanddele van USN CREATINE X4 (gelys by afdeling 6).

## Waarskuwings en voorsorgmaatreels

## Wees veral versigtig met USN CREATINE X4:

- Indien jy 'n bloedingversteuring het of vir 'n operasie moet gaan. Hou twee weke voor enige chirurgiese prosedure (operasie) op om USN CREATINE X4 te neem.
- Indien jy diabetes mellitus (hoë bloedsuiker) het en jy medisyne gebruik om jou bloedsuikervlakke te beheer.
- Staak die gebruik van USN CREATINE X4 en raadpleeg 'n gesondheidsoverskaffer indien jy simptome van lae bloedsuiker, soos swet, bleekheid, kouekoers, hoofpyn, duiselheid en/of verwarring, ervaar.
- Indien jy lae bloeddruk het.
- Indien jy 'n niersiekte het.
- Raadpleeg 'n gesondheidsoverskaffer voor langdurige gebruik.

## Kinders en tieneres

Moenie USN CREATINE X4 aan kinders jonger as 18 jaar gee nie, aangesien die veiligheid en doeltreffendheid by kinders nog nie vasgestel is nie.

## Ander medisyne en USN CREATINE X4

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

Sê vir jou dokter of apoteker indien jy tans die volgende gebruik:

- Antikoagulantmedisyne (word gebruik om jou bloed dun te hou) of kruie-aanvullings met bloedverdunnde effekte.
- Antidiabetiese medisyne (gebruik om hoë bloedsuikervlakke te behandel) of kruie-aanvullings met bloedsuikerverlagende effekte.
- Antihypertensieve middels (word gebruik om hoë bloeddruk te behandel) of kruie-aanvullings wat die bloeddruk verlaag.
- Lithium (word gebruik om die gemoed te stabiliseer).

## Swangerskap en borsvoeding

Indien jy swanger is of jou borsvoeding, dink dat jy swanger mag wees of beplan om swanger te raak, raadpleeg asseblief jou dokter, apoteker of ander gesondheidsoverskaffer voordat jy USN CREATINE X4 neem. Die veiligheid tydens swangerskap en borsvoeding is nie bepaal nie. Moenie USN CREATINE X4 neem indien jy swanger is of jou borsvoeding nie.

## Bestuur en gebruik van masjiene

Dit is onwaarskynlik dat USN CREATINE X4 jou vermoe om 'n voortuig te bestuur en masjiene te gebruik sal belemmer. Moenie 'n voortuig bestuur of masjiener hanteer totdat jy weet hoe USN CREATINE X4 jou affekteer nie.

## 3. Hoe om USN CREATINE X4 te neem

Gebruik USN CREATINE X4 altyd presies soos wat in hierdie inligtingsblad aangedui word, of soos wat jou dokter of apoteker vir jou gesê het. Vra gerus jou dokter of apoteker indien jy onseker is.

## Volwasenes:

- Neem 4 – 6 capsules met 'n glas water 30 minute voor oefening. Nog 'n dosering kan na die oefensessie geneem word, indien nodig.
- 6 capsules kan in die ooggend op 'n leë maag geneem word, op dae wanneer geen oefening gedoen word.
- Drink minstens 2 tot 3 liter water per dag tydens gebruik van hierdie produk.
- Vir beste resultate, volg 'n toepaslike spierbou eetplan en oefenprogram.
- Kreatien in dosis van 3 g per dag verhoog fisiese prestasie tydens kort en strawwe opeenvolgende oefensessies.
- Drink genoeg vloeistof voor, tydens en na oefening. Drink ten minste 2 tot 3 liter water per dag tydens die gebruik van USN CREATINE X4.
- Moenie die aanbevolle daagliks dosering oorskry nie.

## Wat om te doen indien jy meer USN CREATINE X4 geneem het as wat jy moet

In geval van oordroering, raadpleeg jou dokter of apoteker. Indien nie een van hulle beskikbaar is nie, kontak die naaste hospitaal of gifsentrum.

Indien jy vergeet om USN CREATINE X4 te neem

Neem jou volgende dosis op die gewone tyd.&lt;/div