

PROFESSIONAL INFORMATION



37848 P3

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

Table with 4 columns: Ingredient, Per Capsule, Per 6-Capsule Dose, and %NRV. Includes BioPerine, Creatine HCl, Glycine, Creatine Ethyl Ester HCl, Creatine Nitrate, Creatine Monohydrate, Magnesium Amino Acid Chelate, Beta-Alanine, Taurine, and 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 antiplatelet 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.

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-PI/A

Form for printing specifications including JOB: SACS_Creatine X4_60s - 120s, SIZE: 300mm x 322mm, STOCK options, COLOURS, FINISHING options, and a PLEASE CHECK CAREFULLY warning.

