

PROFESSIONAL INFORMATION



37680 P4

USN CREATINE HCl

(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 HCl capsules

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredients:

BioPerine® *Piper nigrum* L. (Black Pepper)
[fruit, 50:1 extract standardised to Piperine 95 %]
Creatine HCl
providing Creatine
Alpha-lipoic acid

Per capsule	Per dose
1 mg	5 mg
764,8 mg	3 824 mg
600 mg	3 000 mg
20 mg	100 mg

Sugar free.

For the 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 HCl may assist with increased physical performance and lean muscle mass by increasing intramuscular creatine levels.

4.2 Posology and method of administration

Adults:

- Take 5 capsules with a glass of water before training. Combine with your favourite protein drink to improve muscle saturation to an even greater extent. On non-training days, take 5 capsules on an empty stomach, before breakfast.
- 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 HCl.
- Creatine increases physical performance in successive bursts of short term, high intensity exercise when taken in dosages of at least 3 g per day.
- For best results, follow an appropriate muscle gain eating plan and training program.
- 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 HCl 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 HCl at least 2 weeks prior to surgical procedures (see section 4.5).

Diabetes mellitus:

USN CREATINE HCl may affect blood glucose levels and adjustment of antidiabetic medicine might be necessary (see section 4.5). 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.

Kidney disorders:

A relevant healthcare provider should be consulted before long-term use and in patients with a kidney disorder.

Sufficient protein is provided in normal well-balanced daily meals.

4.5 Interaction with other medicines and other forms of interaction

Anticoagulant/antiplatelet medicines:

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

4.6 Fertility, pregnancy and lactation:

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

4.7 Effects on ability to drive and use machines:

USN CREATINE HCl 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 HCl are known.

4.8 Undesirable effects

USN CREATINE HCl is generally well tolerated.

Immune system disorders:

Frequency unknown: hypersensitivity and/or allergic reactions.

Nervous system disorders:

Frequency unknown: headache.

Gastrointestinal disorders:

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

Musculoskeletal and connective tissue:

Frequency unknown: muscle cramps.

Renal and urinary disorders:

Frequency unknown: oedema.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of USN CREATINE HCl is important. It allows continued monitoring of the benefit/risk balance of USN CREATINE HCl. 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 HCl contains Alpha-lipoic acid, BioPerine® *Piper nigrum* L. (Black Pepper) and Creatine HCl to assist with increased physical performance and lean muscle mass by increasing intramuscular creatine levels.

5.2 Pharmacokinetic properties

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

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

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

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 cool dry place.

6.5 Nature and contents of container

Capsules are packed in a black HDPE container with a black screw-on cap. Available in pack sizes of 50 and 100 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/RENEWAL OF THE AUTHORISATION

Will be allocated by SAHPRA upon registration.

10. DATE OF REVISION OF THE TEXT

This leaflet was last revised in March 2021.

CREA027-041/PI-PIL/A

JOB: SAHC_USN CREATINE HCl_50s+100s	SIZE: 300mm x 285mm
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:  K	FINISHING: <input type="checkbox"/> Foil / Holographic Foil <input type="checkbox"/> Matte <input type="checkbox"/> Gloss <input type="checkbox"/> Spot UV <input type="checkbox"/> Dorning <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.

