



37680 P4

PROFESSIONAL INFORMATION**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
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). Caution is advised.

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.

| Per capsule | Per dose |
|-------------|----------|
| 1 mg | 5 mg |
| 764.8 mg | 3 824 mg |
| 600 mg | 3 000 mg |
| 20 mg | 100 mg |

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 reactionsReporting 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 life24 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 REGISTRATIONUSN (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: | 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 HCI

37680 P4

(capsules)

SCHEDULING STATUS: **S0**

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

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

1. What USN CREATINE HCI is and what it is used for

USN CREATINE HCI may assist with increased physical performance and lean muscle mass by increasing intramuscular creatine levels.

2. What you need to know before you take USN CREATINE HCI

Do not take USN CREATINE HCI:

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

Warnings and precautions

Take special care with USN CREATINE HCI:

- If you have a bleeding disorder, USN CREATINE HCI 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 HCI 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 a kidney disorder.
- Consult a relevant healthcare provider before long-term use.
- Sufficient protein is provided in normal well-balanced daily meals.

Children and adolescents

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

Other medicines and USN CREATINE HCI

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.

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

Driving and using machines

USN CREATINE HCI 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 HCI affects you.

3. How to take USN CREATINE HCI

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

Adults:

- The usual dose is 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 HCI.
- 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.

If you take more USN CREATINE HCI 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 HCI

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 HCI can have side effects.

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

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

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

Frequency unknown:

- Headache.
- Swelling due to retained fluid.

This is a serious side effect. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequency unknown:

- Stomach pain, heartburn, diarrhoea, nausea (feeling sick), vomiting (being sick).
- Muscle cramps.

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 HCI.

5. How to store USN CREATINE HCI

- 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 HCI contains

| Active ingredients: | Per capsule | Per dose |
|--|-----------------|--------------------|
| BioPerine® Piper nigrum L. (Black Pepper) [fruit, 50:1 extract standardised to Piperine 95 %] | 1 mg | 5 mg |
| Creatine HCI providing Creatine | 764.8 mg | 3 824 mg |
| Alpha-lipoic acid | 600 mg 20 mg | 3 000 mg 100 mg |

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

7. What USN CREATINE HCI looks like and contents of the pack

Size 00 white hard gelatine capsules containing a white powder. Capsules are packed in a black HDPE container with a black screw-on cap. Available in pack sizes of 50 and 100 capsules.

8. 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

9. This leaflet was last revised in

March 2021.

10. Registration number

Will be allocated by SAHPRA upon registration.

11. Access to corresponding Professional Information

www.usn.co.za

PASIËNTINLIGTINGSBLAD



USN CREATINE HCI

(capsules)

SKEDULERINGSTATUS: **S0**

USN CREATINE HCI kapsules

Suikervry.

KOMPLEMENTÈRE MEDISYNE: KOMBINASIEPRODUK (WESTERSE KRUIEMEDISYNE / GESONDHEIDAANVULLING)

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

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

USN CREATINE HCI is beskikbaar sonder 'n dokter se voorskrif, sodat jy jou gesondheid in stand kan hou. Jy moet USN CREATINE HCI 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 HCI met enigeliemand anders deel nie.
- Vir gerus jou apteker indien jy verdere inligting van advies nodig het.

Wat is in hierdie inligtingsblad?

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

1. Wat is USN CREATINE HCI en waarvoor word dit gebruik

USN CREATINE HCI kan help met verbeterde fisiese prestasie en verhoogde maer spiermassa deur intramuskulêre kreatienvlakke te verhoog.

2. Wat jy moet weet voordat jy USN CREATINE HCI neem

Moenie USN CREATINE HCI neem nie.

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

Waarskuwings en voorsorgmaatreels

Wees veral versigtig met USN CREATINE HCI:

- Indien jy 'n bloedingversteuring het of vir 'n operasie moet gaan. Hou twee weke voor enige chirurgiese procedure (operasie) op om USN CREATINE HCI te neem.
- Indien jy diabetes mellitus (hoë bloedsuiker) het en jy medisyne gebruik om jou bloedsuikervlakke te beheer.
- Staak die gebruik van USN CREATINE HCI en raadpleeg 'n gesondheidsorgverskaffer indien jy simptome van lae bloedsuiker, soos sweet, bleekheid, kouekoers, hoofpyn, duiselheid en/of verwarring,ervaar.
- Indien jy 'n niersiekte het.
- Raadpleeg 'n gesondheidsorgverskaffer voor langdurige gebruik.
- Voldoende proteïene word in normale, gebalanseerde maaltye voorsien.

Kinders en tinders

Moenie USN CREATINE HCI 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 HCI

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

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

- Antikoagulantmedisyne (word gebruik om jou bloed deur te hou) of kruie-aanvullings met bloedverdundernde effekte.
- Antidiabetiese medisyne (gebruik om hoë bloedsuikervlakke te behandel) of kruie-aanvullings met bloedsuiker-verlagende effekte.

Swangerskap en borsvoeding

Indien jy swanger is of jy 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 CREATINE HCI neem. Die veiligheid tydens swangerskap en borsvoeding is nie bepaal nie. Moenie USN CREATINE HCI neem indien jy swanger is of jy baba borsvoed.

Bestuur en die gebruik van masjiene

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

3. Hoe om USN CREATINE HCI te neem

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

Volwassenes:

- Die gewone dosering is 5 capsules saam met 'n glas water voor oefening. Kombineer met jou gunsteling protein drankjie om spiersverandering tot 'n groter mate te bevorder. Op nie-oefen dae, neem 5 capsules op 'n leë maag, voor ontbyt.
- Drink genoeg vloeistof voor, tydens en na oefening. Drink ten minste 2 tot 3 liter water per dag tydens die gebruik van USN CREATINE HCI.
- Kreatien in dosisse van 3 g per dag verhoog fisiese prestasie tydens kort en strawwe opeenvolgende oefensessies.
- Vir die beste resultate, volg 'n gepaste eetplan en oefenprogram wat spierbou bevorder.
- Moenie die aanbevolde dagliklike dosering oorskry nie.

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

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

Indien jy vergeet om USN CREATINE HCI 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 CREATINE HCI kan newe-effekte hê.

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

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

- Swelling van jou hande, voete, enkels, gesig, lippe, mond of keel, wat probleme kan veroorsaak met sluk en asemhaling.
- Uitslag of gejuk.
- Floute.

Hierdie is baie ernstige newe-effekte. Indien jy enige daarvan ondervind, mag jy 'n ernstige allergiese reaksie op USN CREATINE HCI gehad het. Jy mag dringende mediese bystand of hospitalisasie benodig.

Sê vir jou dokter of gaan na die ongevalle-effeling in u naaste hospitaal as u een van die volgende opmerk:

Newe-effekte wat met onbekende frekwensie voorkom:

- Swelling as gevolg van behoue vloeistof.

Sê vir jou dokter indien jy enige van die volgende opmerk:

Newe-effekte wat met onbekende frekwensie voorkom: