



39800 P3

USN PURE CREATINE MONOHYDRATE

(powder)

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 PURE CREATINE MONOHYDRATE powder

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each teaspoon (5 g) contains:

Creatine monohydrate 5 g
Sugar free.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Powder.
A white unflavoured crystal-like powder.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

USN PURE CREATINE MONOHYDRATE assist with boosting muscle training intensity and endurance, power and strength. Accelerates stamina and an increase in lean muscle gain when used in conjunction with a resistance training regimen.

4.2 Posology and method of administration

Adults:

- *Creatine Loading:* For the first 5 days of use, take 1 teaspoon 4 times daily with 250 ml of your favourite protein-/carbohydrate drink or grape juice.
- *Creatine Level Maintenance:* After 5 consecutive days of loading, take 1 teaspoon 1 to 2 times daily with 250 ml of your favourite protein-/carbohydrate drink or grape juice.
- Ensure to drink enough fluid before, during and after exercise.
- During loading and maintenance, one of the dosages should be taken before and/or after training.
- Do not exceed the recommended daily dosage.

Children:

Not suitable for children under the age of 18 years.

4.3 Contraindications

Hypersensitivity to Creatine monohydrate.

4.4 Special warnings and precautions for use

Kidney disorders:

A relevant healthcare provider should be consulted before use in patients with a kidney disorders.

General:

A relevant healthcare provider should be consulted before long-term use.
May result in weight gain.
Sufficient protein is provided in normal well-balanced daily meals.

4.5 Interaction with other medicinal products and other forms of interaction

No known interactions.

4.6 Fertility, pregnancy and lactation

Safety in pregnancy and lactation has not been established. A healthcare provider should be consulted prior to use during pregnancy or lactation.

4.7 Effects on ability to drive and use machines

USN PURE CREATINE MONOHYDRATE 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 PURE CREATINE MONOHYDRATE are known.

4.8 Undesirable effects

USN PURE CREATINE MONOHYDRATE is generally well tolerated.

Gastrointestinal disorders:

Frequency unknown: abdominal pain or cramps, dyspepsia, bloating, diarrhoea, constipation, nausea, vomiting.

Musculoskeletal and connective tissue disorders:

Frequency unknown: muscle cramps.

Renal and urinary disorders:

Frequency unknown: oedema / water retention.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of USN PURE CREATINE MONOHYDRATE is important. It allows continued monitoring of the benefit/risk balance of USN PURE CREATINE MONOHYDRATE. 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 34.1 Amino acids.

USN PURE CREATINE MONOHYDRATE contains Creatine monohydrate to assist with increased physical performance and lean muscle mass by increasing intramuscular creatine levels.

5.2 Pharmacokinetic properties

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

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

None.

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

Pack sizes: 200 g, 300 g and 410 g.
200 g of powder is packed in a white PP container with a blue PP screw-on lid.
300 g of powder is packed in a blue aluminium foil pouch.
410 g of powder is packed in a white HDPE container with a blue PP screw-on lid.

6.6 Special precautions for disposal

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Pro-acti Pharma (Pty) Ltd
Unit 4, Louwleria Logistics Park
cnr Nellmapius Road & Olievenhoutbosch Avenue
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 March 2022.

JOB: SACS_Pure Creatine_200g - 410g		SIZE: 180mm x 314mm	
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:	
 K		<input type="checkbox"/> Foil / Holographic Foil <input type="checkbox"/> Matte <input type="checkbox"/> Gloss <input type="checkbox"/> Spot UV <input type="checkbox"/> Doring <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.			

PATIENT INFORMATION LEAFLET



39800 P2

USN PURE CREATINE MONOHYDRATE

SCHEDULING STATUS: **S0**

USN PURE CREATINE MONOHYDRATE powder

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

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

1. What USN PURE CREATINE MONOHYDRATE is and what it is used for

USN PURE CREATINE MONOHYDRATE 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 PURE CREATINE MONOHYDRATE

Do not take USN PURE CREATINE MONOHYDRATE:

- If you are hypersensitive (allergic) to Creatine monohydrate.

Warnings and precautions

Take special care with USN PURE CREATINE MONOHYDRATE:

- If you have a kidney disorder.
- Consult a relevant healthcare provider before long-term use.
- May result in weight gain.
- Sufficient protein is provided in normal well-balanced daily meals.

Children and adolescents

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

Other medicines and USN PURE CREATINE MONOHYDRATE

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

PASIENTINLIGTINGSBLAD



USN PURE CREATINE MONOHYDRATE

SKEDULERINGSSTATUS: **S0**

USN PURE CREATINE MONOHYDRATE poeier

Suikervry.

KOMPLEMENTÊRE MEDISYNE: GESONDHEIDSAANVULLING

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

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

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

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

Wat is in hierdie inligtingsblad

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

1. Wat is USN PURE CREATINE MONOHYDRATE en waarvoor word dit gebruik

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

2. Wat jy moet weet voordat jy USN PURE CREATINE MONOHYDRATE neem

Moenie USN PURE CREATINE MONOHYDRATE neem nie

- Indien jy hipersensitief (allergies) is vir Kreatienmonohidraat.

Waarskuwings en voorsorgmaatreëls

Wees veral versigtig met USN PURE CREATINE MONOHYDRATE:

- Indien jy 'n niersiekte het.
- Raadpleeg 'n gesondheidsorgverskaffer voor langdurige gebruik.
- Kan gewigstoename veroorsaak.
- Voldoende proteïene word in normale, gebalanseerde maaltye voorsien.

Kinders en tieners

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

Ander medisyne en USN PURE CREATINE MONOHYDRATE

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

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 PURE CREATINE MONOHYDRATE. Safety in pregnancy and lactation has not been established. Consult a relevant healthcare provider prior to use if you are pregnant or breastfeeding.

Driving and using machines

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

3. How to take USN PURE CREATINE MONOHYDRATE

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

Adults:

- **Creatine Loading:** For the first 5 days of use, take 1 teaspoon 4 times daily with 250 ml of your favourite protein-/carbohydrate drink or grape juice.
- **Creatine Level Maintenance:** After 5 consecutive days of loading, take 1 teaspoon 1 to 2 times daily with 250 ml of your favourite protein-/carbohydrate drink or grape juice.
- Ensure to drink enough fluid before, during and after exercise.
- During loading and maintenance, one of the dosages should be taken before and/or after training.
- Do not exceed the recommended daily dosage.

If you take more USN PURE CREATINE MONOHYDRATE than you should

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

If you forget to take USN PURE CREATINE MONOHYDRATE

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 PURE CREATINE MONOHYDRATE can have side effects.

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

If any of the following happens, stop taking USN PURE CREATINE MONOHYDRATE 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 PURE CREATINE MONOHYDRATE. 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:

- 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 PURE CREATINE MONOHYDRATE.

5. How to store USN PURE CREATINE MONOHYDRATE

- 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 PURE CREATINE MONOHYDRATE contains

Each teaspoon (5 g) contains:

Creatine monohydrate 5 g

There are no other ingredients.

What USN PURE CREATINE MONOHYDRATE looks like and contents of the pack

A white flavoured crystal-like powder.

Pack sizes: 200 g, 300 g and 410 g.

200 g of powder is packed in a white PP container with a blue PP screw-on lid.

300 g of powder is packed in a blue aluminium foil pouch.

410 g of powder is packed in a white HDPE container with a blue PP screw-on lid.

Holder of Certificate of Registration:

Pro-acti Pharma (Pty) Ltd
Unit 4, Louwardia Logistics Park
cnr Nellmapius Road & Olievenhoutbosch Avenue
Centurion, 1683
Pretoria
Tel: 086 111 1876

This leaflet was last revised in

March 2022.

Registration number

Will be allocated by SAHPRA upon registration.

Access to corresponding Professional Information

www.usn.co.za

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 PURE CREATINE MONOHYDRATE neem. Die veiligheid tydens swangerskap en borsvoeding is nie bepaal nie. Raadpleeg eers jou gesondheidsorgverskaffer voor gebruik indien jy swanger is of borsvoed.

Bestuur en die gebruik van masjiene

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

3. Hoe om USN PURE CREATINE MONOHYDRATE te neem

Gebruik USN PURE CREATINE MONOHYDRATE 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.

Volwasse nes:

- **Kreatienlading:** Vir die eerste 5 dae van gebruik, neem 1 teelepel 4 keer daagliks met 250 ml van jou gunsteling proteïen-/koolhidraatdrankie of vrugtesap.
- **Instandhouding van Kreatienvlakke:** Na 5 opeenvolgende dae van lading, neem 1 teelepel 1 tot 2 keer daagliks met 250 ml van jou gunsteling proteïen-/koolhidraatdrankie of vrugtesap.
- Maak seker dat jy genoeg vloeistof word, tydens en na oefening drink.
- Tydens lading en onderhoud moet een van die dosisse voor en/of na oefening geneem word.
- Moenie die aanbevole daaglikse dosis oorskry nie

Wat om te doen indien jy meer USN PURE CREATINE MONOHYDRATE 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 hospitaal of giftsentrum.

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

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

Indien enige van die volgende gebeur, hou op om USN PURE CREATINE MONOHYDRATE te neem en sê dadelik vir jou dokter, of gaan na die ongevalle-afdeling 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 gejeuk.
- Floute.

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

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

Newe-effekte wat met onbekende frekwensie voorkom:

- Swelling as gevolg van vloeistof wat teruggehou word.

Dit is 'n ernstige newe-effek. Jy benodig moontlik dringende mediese hulp.

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

Newe-effekte wat met onbekende frekwensie voorkom:

- Maagpyn, sooibrand, diarree, naarheid, braking.
- Spierkrampe.

Indien jy enige newe-effekte opmerk wat nie in hierdie inligtingsblad genoem word nie, sê asseblief vir jou dokter of apteker daarvan.

Aanmelding van newe-effekte

Indien enige newe-effekte ondervind word, bespreek dit met jou dokter of apteker. Jy kan ook newe-effekte aan SAHPRA rapporteer via die vorm om ongunstige geneesmiddellekies te rapporteer, wat aanlyn by SAHPRA se publikasies beskikbaar is: <http://www.sahpra.org.za/Publications/Index/8>.

Deur newe-effekte te rapporteer kan jy help om meer inligting rakende die veiligheid van USN PURE CREATINE MONOHYDRATE te verskaf.

5. Hoe om PURE CREATINE MONOHYDRATE te bêre

- Bêre by of onder 25 °C.
- Bêre op 'n droë plek.
- Bêre alle medisyne buite bereik van kinders.
- Moenie gebruik na die vervaldatum wat op die houder gedruk is nie.
- Neem alle ongebruikte medisyne terug na jou apteker.
- Moenie ongebruikte medisyne in dreine en rioolstelsels (bv. toilet) weggooi nie.

6. Inhoud van die pak en ander inligting

Wat PURE CREATINE MONOHYDRATE bevat

Elke teelepel (5 g) bevat:

Kreatienmonohidraat 5 g

Daar is geen ander bestanddele nie.

Hoe USN PURE CREATINE MONOHYDRATE lyk en inhoud van die verpakking

'n Wit ongegeure kristalagtige poeier.

Verpakingsgroottes: 200 g, 300 g en 410 g.

200 g poeier word verpak in 'n wit PP-houer met 'n blou PP skroefop.

300 g poeier word in 'n blou aluminiumfoeliesak verpak.

410 g poeier word verpak in 'n wit HDPE-houer met 'n blou PP skroefop.

Houer van die Registrasiesertifikaat

Pro-acti Pharma (Edms) Bpk
Eenheid 4, Louwardia Logistieke Park
h/v Nellmapiusstraat & Olievenhoutboschrylaan
Centurion, 1683
Pretoria
Tel: 086 111 1876

Hierdie inligtingsblad is laas hersien in

Maart 2022.

Registrasienuommer

Moet deur SAHPRA toegeken word.

Toegang tot die ooreenstemmende Professionele Inligtingsblad

www.usn.co.za

JOB: SACS_Pure Creatine_200g - 410g	SIZE: 180mm x 314mm
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"/>	
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