

PROFESSIONAL INFORMATION



40086 P3

USN PURE GLUTAMINE POWDER

(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 GLUTAMINE powder

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each scoop (2,5 g) contains:

L-Glutamine 2,5 g
Sugar free.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Powder.

An unflavoured free-flowing white powder.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

USN PURE GLUTAMINE contains a pure free-form anti-catabolic amino acid to assist in muscle cell repair after exercise and helps speed up muscle recovery. USN PURE GLUTAMINE helps reduce exercise related muscle breakdown and may also assist with increased muscle stamina and strength.

4.2 Posology and method of administration

Adults:

- Mix one teaspoon of USN PURE GLUTAMINE powder with 200 – 250 ml water, protein drink or juice of your choice.
- Take one dosage prior to your workout, and another dosage within 90 minutes following your workout.
- Ensure to drink enough fluid before, during and after exercise.
- For best results, take a last dosage prior to bedtime.
- Do not exceed the recommended daily dosage.

Children:

Not suitable for children under the age of 18 years.

4.3 Contraindications

Hypersensitivity to L-Glutamine.

4.4 Special warnings and precautions for use

Diet:

Patients that are following a low protein diet should consult a relevant healthcare provider prior to use. Sufficient protein is provided in normal well-balanced daily meals.

Paediatric population:

USN PURE GLUTAMINE is not suitable for children under the age of 18 years.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

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 and breastfeeding.

4.7 Effects on ability to drive and use machines

USN PURE GLUTAMINE 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 GLUTAMINE are known.

4.8 Undesirable effects

USN PURE GLUTAMINE is generally well tolerated.

Nervous system disorders:

Frequency unknown: headache.

Gastrointestinal disorders:

Frequency unknown: gastrointestinal pain, belching, bloating, flatulence, nausea, vomiting, diarrhoea, constipation.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of USN PURE GLUTAMINE is important. It allows continued monitoring of the benefit/risk balance of USN PURE GLUTAMINE. 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 GLUTAMINE contains L-Glutamine to assist in muscle cell repair after exercise and helps speed up muscle recovery. It may also assist with increased muscle stamina and strength.

5.2 Pharmacokinetic properties

L-Glutamine is a non-essential amino acid involved in muscle protein synthesis. L-Glutamine is absorbed in the jejunum and primarily oxidised. A small portion is used for gluconeogenesis, is metabolised to glutamate and ammonia in the body and is eliminated in the urine.

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

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

6.6 Special precautions for disposal

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Pro-acti Pharma (Pty.) Ltd.
Unit 4, Louwlandia 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 April 2022.

JOB: SACS_Pure Glutamine_150g - 300g	SIZE: 300mm x 276mm
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"/> 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.

PATIENT INFORMATION LEAFLET



USN PURE GLUTAMINE POWDER

(powder)

SCHEDULING STATUS: S0

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

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

1. What USN PURE GLUTAMINE is and what it is used for

USN PURE GLUTAMINE contains a pure free-form anti-catabolic amino acid to assist in muscle cell repair after exercise and helps speed up muscle recovery, USN PURE GLUTAMINE helps reduce exercise related muscle breakdown and may also assist with increased muscle stamina and strength.

2. What you need to know before you take USN PURE GLUTAMINE

Do not take USN PURE GLUTAMINE

- If you are hypersensitive (allergic) to L-Glutamine.

Warnings and precautions

Take special care with USN PURE GLUTAMINE

- If you are following a low protein diet.
- Sufficient protein is provided in normal well-balanced daily meals.

Children and adolescents

Do not give USN PURE GLUTAMINE to children younger than 18 years.

Other medicines and USN PURE GLUTAMINE

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

There are no known interactions with USN PURE GLUTAMINE.

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 GLUTAMINE. Safety in pregnancy and lactation has not been established.

Driving and using machines

USN PURE GLUTAMINE 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 GLUTAMINE affects you.

3. How to take USN PURE GLUTAMINE

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

Adults:

- Mix one teaspoon of USN PURE GLUTAMINE powder with 200 – 250 ml water, protein drink or juice of your choice.
- Take one dosage prior to your workout, and another dosage within 90 minutes following your workout.
- Ensure to drink enough fluid before, during and after exercise.
- For best results, take a last dosage prior to bedtime.
- Do not exceed the recommended daily dosage.

If you take more USN PURE GLUTAMINE 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 PURE GLUTAMINE

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 GLUTAMINE can have side effects.

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

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

Tell your doctor if you notice any of the following:

Frequency unknown:

- Headache.
- Stomach pain, burping, feeling bloated, flatulence (gas), nausea (feeling sick), vomiting (being sick), diarrhoea, constipation.

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 GLUTAMINE.

5. How to store USN PURE GLUTAMINE

- 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 GLUTAMINE contains

Each scoop (2,5 g) contains:

L-Glutamine 2,5 g

There are no other ingredients.

What USN PURE GLUTAMINE looks like and contents of the pack

An unflavoured free-flowing white powder.

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

Holder of Certificate of Registration:

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

This leaflet was last revised in

April 2022.

Registration number

Will be allocated by SAHPRA upon registration.

Access to corresponding Professional Information

www.usn.co.za

PASIËNTINLIGTINGSBLAD



USN PURE GLUTAMINE POWDER

(poeier)

SKEDULERINGSSTATUS: S0

USN PURE GLUTAMINE 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 GLUTAMINE is beskikbaar sonder 'n dokter se voorskrif, sodat jy jou gesondheid in stand kan hou. Jy moet USN PURE GLUTAMINE 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 GLUTAMINE 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 GLUTAMINE en waarvoor word dit gebruik.
2. Wat jy moet weet voordat jy USN PURE GLUTAMINE neem.
3. Hoe om USN PURE GLUTAMINE te neem.
4. Moontlike newe-effekte.
5. Hoe om USN PURE GLUTAMINE te bêre.
6. Inhoud van die pak en ander inligting.

1. Wat is USN PURE GLUTAMINE en waarvoor word dit gebruik

USN PURE GLUTAMINE bevat 'n suiwer vrye-vorm anti-kataboliese aminosuur om te help met spiersel herstel na oefening en om spiere vinniger te verbeter. USN PURE GLUTAMINE help of oefeningverwante spierafbraak te verminder en kan ook help met verhoogde spier uithouvermoë en krag.

2. Wat jy moet weet voordat jy USN PURE GLUTAMINE neem

Moenie USN PURE GLUTAMINE neem nie

- Indien jy hipersensitief (allergies) is vir L-Glutamien.

Waarskuwings en voorsorgmaatreëls

Wees veral versigtig met USN PURE GLUTAMINE

- Indien jy 'n lae proteïendieet volg.
- Voldoende proteïene word in normale, goed-gebalanseerde maaltye voorsien.

Kinders en tieners

Moet nie USN PURE GLUTAMINE aan kinders jonger as 18 jaar gee nie.

Ander medisyne en USN PURE GLUTAMINE

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

Daar is geen interaksies met USN PURE GLUTAMINE bekend nie.

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 GLUTAMINE neem. Die veiligheid tydens swangerskap en borsvoeding is nie bepaal nie.

Bestuur en die gebruik van masjiene

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

3. Hoe om USN PURE GLUTAMINE te neem

Gebruik USN PURE GLUTAMINE 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:

- Meng een teelepel USN PURE GLUTAMINE met 200 – 250 ml water, proteïendrankie of sap van jou keuse.
- Neem een dosis voor oefening, en nog 'n dosis binne 90 minute na oefening.
- Maak seker dat jy genoeg vloeistof voor, tydens en na oefening drink.
- Vir beste resultate, neem 'n laaste dosis voor slapenstyd.
- Moenie die aanbevole daaglikse dosering oorskry nie.

Wat om te doen indien jy meer USN PURE GLUTAMINE 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 gifsentrum.

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

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

Indien enige van die volgende gebeur, hou op om USN PURE GLUTAMINE 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 GLUTAMINE gehad het. Jy mag dringende mediese bystand of hospitalisasie benodig.

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