

PROFESSIONAL INFORMATION



38389 PG

USN PURE GLUTAMINE CAPSULES

(capsules)

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 CAPSULES

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

ACTIVE INGREDIENTS:

L-Glutamine

Per Capsule
500 mg

Per 4-Capsule Dose
2 000 mg

Sugar free.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Capsules.

Size 0 white vegi capsules containing a white powder.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

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

4.2 Posology and method of administration

Adults:

- As a health supplement, take 4 vegi capsules of USN PURE GLUTAMINE CAPSULES with 200 – 250 ml water, or drink of your choice.
- Take one dosage prior to workout and another dosage following your workout. For best results, take a last dosage prior to bedtime.
- Ensure to drink enough fluid before, during, and after exercise.
- 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 or to any of the excipients listed in section 6.1.

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 CAPSULES 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.

USN PURE GLUTAMINE CAPSULES should not be taken during pregnancy or lactation.

4.7 Effects on ability to drive and use machines

USN PURE GLUTAMINE CAPSULES 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 CAPSULES are known.

4.8 Undesirable effects

USN PURE GLUTAMINE CAPSULES 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 CAPSULES is important. It allows continued monitoring of the benefit/risk balance of USN PURE GLUTAMINE CAPSULES. 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 CAPSULES contains L-Glutamine to assist in muscle cell repair after exercise and help 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

Magnesium stearate

Vegi capsules.

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

120 capsules are packed in a white HDPE container with a blue screw-on cap and induction seal.

6.6 Special precautions for disposal

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

USN (Pty) Ltd

Unit 4, Louwardia 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 July 2021.

GLU010/PI-PII/A

JOB: SACS_Pure Glutamine_120s	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 CAPSULES

(capsules)

SCHEDULING STATUS: S0

USN PURE GLUTAMINE CAPSULES

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

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

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

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

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

Do not take USN PURE GLUTAMINE CAPSULES:

- If you are hypersensitive (allergic) to L-Glutamine or to any of the other ingredients of USN PURE GLUTAMINE CAPSULES (listed in section 6).

Warnings and precautions

Take special care with USN PURE GLUTAMINE CAPSULES:

- 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 CAPSULES to children younger than 18 years, as the safety and efficacy in children have not yet been established.

Other medicines and USN PURE GLUTAMINE CAPSULES

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 CAPSULES.

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 CAPSULES. Safety in pregnancy and lactation has not been established. Do not take USN PURE GLUTAMINE CAPSULES if you are pregnant or breastfeeding.

Driving and using machines

USN PURE GLUTAMINE CAPSULES 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 CAPSULES affects you.

3. How to take USN PURE GLUTAMINE CAPSULES

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

Adults:

- As a health supplement, take 4 vegi capsules of USN PURE GLUTAMINE CAPSULES with 200 – 250 ml water, or drink of your choice.
- Take one dosage prior to workout and another dosage following your workout. For best results, take a last dosage prior to bedtime.
- Ensure to drink enough fluid before, during, and after exercise.
- Do not exceed the recommended daily dosage.

If you take more USN PURE GLUTAMINE CAPSULES 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 GLUTAMINE CAPSULES

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 CAPSULES can have side effects.

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

If any of the following happens, stop taking USN PURE GLUTAMINE CAPSULES 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 CAPSULES. 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 CAPSULES.

5. How to store USN PURE GLUTAMINE CAPSULES

- 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 CAPSULES contains

ACTIVE INGREDIENTS:	Per Capsule	Per 4-Capsule Dose
L-Glutamine	500 mg	2 000 mg

The other ingredients are magnesium stearate and vegi capsules.

What USN PURE GLUTAMINE CAPSULES looks like and contents of the pack

Size 0 white vegi capsules containing a white powder. 120 capsules are packed in a white HDPE container with a blue screw-on cap and induction seal.

Holder of Certificate of Registration:

USN (Pty) Ltd
Unit 4, Louwardia Logistics Park
cnr Nellmapius Drive & Olievenhoutbosch Road
Centurion, 1683
Pretoria
Tel: 086 111 1876

This leaflet was last revised in

July 2021.

Registration number

Will be allocated by SAHPRA upon registration.

Access to corresponding Professional Information

www.usn.co.za

PASIËNTINLIGTINGSBLAD



USN PURE GLUTAMINE CAPSULES

(kapsules)

SKEDULERINGSSTATUS: S0

USN PURE GLUTAMINE KAPSULES

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

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

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

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

Moenie USN PURE GLUTAMINE CAPSULES neem nie

- Indien jy hipersensitief (allergies) is vir L-Glutamien of vir enige van die ander bestanddele van USN PURE GLUTAMINE CAPSULES (gelys by afdeling 6).

Waarskuwings en voorsorgmaatreëls

Wees veral versigtig met USN PURE GLUTAMINE CAPSULES:

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

Kinders en tieners

Moet nie USN PURE GLUTAMINE CAPSULES 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 GLUTAMINE CAPSULES

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 CAPSULES 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 CAPSULES neem. Die veiligheid tydens swangerskap en borsvoeding is nie bepaal nie. Moenie USN PURE GLUTAMINE CAPSULES neem indien jy swanger is of borsvoed nie.

Bestuur en die gebruik van masjien

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

3. Hoe om USN PURE GLUTAMINE CAPSULES te neem

Gebruik USN PURE GLUTAMINE CAPSULES 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:

- As 'n gesondheidsaanvulling, neem 4 vegikapsules van USN PURE GLUTAMINE CAPSULES met 200 – 250 ml water, of drankie van jou keuse.
- Neem een dosering voor jou oefensessie en nog 'n dosering na afloop van jou oefensessie. Vir beste resultate, neem 'n laaste dosering voor slapenstyd.
- Sorg dat jy genoeg vloeistof drink voor, tydens en na oefening.
- Moenie die aanbevole daaglikse dosering oorskry nie.

Wat om te doen indien jy meer USN PURE GLUTAMINE CAPSULES 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 CAPSULES 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 nuwe-effekte


USN PURE GLUTAMINE CAPSULES kan nuwe-effekte hê.

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

Indien enige van die volgende gebeur, hou op om USN PURE GLUTAMINE CAPSULES 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 nuwe-effekte. Indien jy enige daarvan ondervind, mag jy 'n ernstige allergiese reaksie op USN PURE GLUTAMINE CAPSULES gehad het. Jy mag dringende mediese bystand of hospitalisasie benodig.

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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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