PROFESSIONAL INFORMATION

USN®

38007 P3

USN ZMA+

(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 ZMA+ capsules

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

ACTIVE INGREDIENTS:	Per Capsule	Per Dose	*%NRV
ZMA®	305,6 mg	1 222,5 mg	
providing Magnesium (from Magnesium Citrate and Magnesium Oxide)	62,4 mg	250 mg	60 %
Zinc (from Zinc Mono-L-Methionine)	4,2 mg	17 mg	155 %
Vitamin B_6 (from Pyridoxine HCl)	1,5 mg	6 mg	353 %
Beta-alanine	12,5 mg	50 mg	
Ascorbic acid (Vitamin C)	10 mg	40 mg	40 %
Vitamin E acetate (50 %)	5 mg	20 mg	
providing Vitamin E	2,5 mg	10 mg	67 %

*%Nutrient Reference Values (NRVs) for individuals 4 years and older (2010).

Sugar free.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Capsules.

Size 0, white and light blue, hard gelatine capsules containing a white powder.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

USN ZMA+ is indicated as an anabolic recovery aid for optimal athletic performance. USN ZMA+ may improve physical performance and exercise capacity and help to delay muscle fatigue during physical activity.

4.2 Posology and method of administration

Adults:

- MEN: Take 2 – 4 capsules daily, preferably on an empty stomach 30 – 60 minutes before bedtime.
- WOMEN: Take 2 – 3 capsules daily, preferably on an empty stomach 30 – 60 minutes before bedtime.
- For best results, avoid taking with dairy or other calcium-containing foods or supplements.
- 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 ZMA+ 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 ZMA+ at least 2 weeks prior to surgical procedures (see section 4.5).

Renal disease:

USN ZMA+ should be used with caution in patients with existing renal disease.

Flushing and/or tingling sensation:

USN ZMA+ may cause a flushing, tingling and/or prickling sensation of the skin, in which case, the dose should be reduced.

4.5 Interaction with other medicinal products and other forms of interaction

Anticoagulant/antiplatelet medicines:

USN ZMA+ 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).

Antibiotic medicines:

USN ZMA+ may decrease the absorption of antibiotics. Doses should be separated by at least 2 hours prior, or 4 to 6 hours after taking USN ZMA+.

4.6 Fertility, pregnancy and lactation

Safety in pregnancy and lactation has not been established.

USN ZMA+ should not be taken during pregnancy or lactation.

4.7 Effects on ability to drive and use machines

USN ZMA+ may cause side effects, such as somnolence, which can affect the ability to drive a vehicle and use machines (see section 4.8).

Caution is advised before driving a vehicle or operating machinery until the effects of USN ZMA+ are known.

4.8 Undesirable effects

USN ZMA+ is generally well tolerated.

Immune system disorders:
Frequency unknown: hypersensitivity and/or allergic reactions.

Psychiatric disorders:
Frequency unknown: insomnia, somnolence.

Nervous system disorders:
Frequency unknown: paraesthesia, headache.

Vascular disorders:
Frequency unknown: flushing.

Gastrointestinal disorders:
Frequency unknown: gastrointestinal irritation, abdominal pain or cramps, nausea, vomiting, dyspepsia, diarrhoea.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of USN ZMA+ is important. It allows continued monitoring of the benefit/risk balance of USN ZMA+. 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 34.12 Multiple Substance Formulation.

USN ZMA+ contains vitamins, minerals and beta-alanine to improve physical/athletic performance and exercise capacity and help to delay muscle fatigue during physical activity.

5.2 Pharmacokinetic properties

Magnesium requires both parathyroid hormone and vitamin D for absorption. Magnesium is absorbed throughout the gastrointestinal tract, is distributed in the skeleton and soft tissue, and excreted primarily via the kidneys.

Zinc is absorbed in the small intestines, distributed in the body in skeletal muscle and bone and mainly excreted through the faeces.

Pyridoxine (Vitamin B_6) is passively absorbed from the upper gastrointestinal tract, converted in the liver to coenzyme pyridoxal phosphate and excreted in the urine.

After supplementation with beta-alanine, muscle carnosine levels are increased. When beta-alanine is taken orally, the plasma half-life is about 25 minutes. Small amounts are excreted unchanged in the urine.

Ascorbic acid (Vitamin C) is readily absorbed from the gastrointestinal tract and is widely distributed in the body. The main route of elimination is through urine.

Vitamin E is mostly absorbed in the small intestines by passive diffusion and is excreted mainly unchanged via the faeces.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Gelatine capsules (bovine)
Magnesium stearate
Potato starch
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 dry place.

6.5 Nature and contents of container

120 capsules are packed in a cobalt blue PET container with a white 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, Louwlardia 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 June 2021.

ZMA001/PI-PIL/A

JOB: SACS_ZMA Plus_120s	**SIZE:** 300mm x 295mm
STOCK: Foil Substrate: ☐ Clear Substrate: ☐ White Substrate: ☐ Paper: ☒ Other: ☐	
COLOURS: ■ K	**FINISHING:** ☐ Foil / Holographic Foil ☐ Matte ☐ Gloss ☐ Spot UV ☐ Doming ☐ 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®

38007 P3

USN ZMA+

(capsules)

SCHEDULING STATUS: S0

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

- Keep this leaflet. You may need to read it again.
- Do not share USN ZMA+ 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 ZMA+ is and what it is used for
USN ZMA+ is indicated as an anabolic (muscle building) recovery aid for optimal athletic performance. USN ZMA+ may improve physical performance and exercise capacity and help to delay muscle fatigue during physical activity.

2. What you need to know before you take USN ZMA+

Do not take USN ZMA+:
- If you are hypersensitive (allergic) to any of the ingredients (listed in section 6).

Warnings and precautions
Take special care with USN ZMA+:
- If you have a bleeding disorder, USN ZMA+ should be discontinued at least 2 weeks before surgical procedures.
- If you have any kidney problems.
- USN ZMA+ may cause a flushing, tingling and/or prickling sensation of the skin, in which case, reduce the dose.

Children and adolescents
Do not give USN ZMA+ to children younger than 18 years, as the safety and efficacy in children have not yet been established.

Other medicines and USN ZMA+
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.
- Antibiotic medicines (used to treat bacterial infections). Take antibiotics at least 2 hours before, or 4 to 6 hours after taking USN ZMA+.

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 ZMA+. Safety in pregnancy and lactation has not been established.

Driving and using machines
USN ZMA+ may cause side effects, such as sleepiness, and can affect your ability to drive a vehicle and use machines (see section 4). Do not drive or operate machinery until you know how USN ZMA+ affects you.

3. How to take USN ZMA+
Always take USN ZMA+ exactly as described in this leaflet or as your pharmacist has told you. Check with your pharmacist if you are not sure.

Adults:
- MEN: The usual dose is 2 – 4 capsules daily, preferably on an empty stomach 30 – 60 minutes before bedtime.
- WOMEN: The usual dose is 2 – 3 capsules daily, preferably on an empty stomach 30 – 60 minutes before bedtime.
- For best results, avoid taking with dairy or other calcium-containing foods or supplements.
- Do not exceed the recommended daily dosage.

If you take more USN ZMA+ 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 ZMA+
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 ZMA+ can have side effects.

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

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

Tell your doctor if you notice any of the following:
Frequency unknown:
- Stomach pain or cramps, nausea (feeling sick), vomiting (being sick), heartburn, diarrhoea.
- Tingling and/or prickling sensation of your skin ("pins-and-needles"), headache.
- Insomnia (difficulty falling or staying asleep), sleepiness.
- Reddening of the skin (flushing).

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 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 ZMA+.

5. How to store USN ZMA+
- 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 ZMA+ contains

ACTIVE INGREDIENTS:	**Per Capsule**	**Per Dose**	***%NRV**
ZMA®	305,6 mg	1 222,5 mg	
providing Magnesium (from Magnesium Citrate and Magnesium Oxide)	62,4 mg	250 mg	60 %
Zinc (from Zinc Mono-L-Methionine)	4,2 mg	17 mg	155 %
Vitamin B_6 (from Pyridoxine HCl)	1,5 mg	6 mg	353 %
Beta-alanine	12,5 mg	50 mg	
Ascorbic acid (Vitamin C)	10 mg	40 mg	40 %
Vitamin E acetate (50 %)	5 mg	20 mg	
providing Vitamin E	2,5 mg	10 mg	67 %

*%Nutrient Reference Values (NRVs) for individuals 4 years and older (2010).

Sugar free.

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

What USN ZMA+ looks like and contents of the pack
Size 0, white and light blue, hard gelatine capsules containing a white powder.
120 capsules are packed in a cobalt blue PET container with a white screw-on cap and induction seal.

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

This leaflet was last revised in
June 2021.

Registration number
Will be allocated by SAHPRA upon registration.

Access to corresponding Professional Information
www.usn.co.za

PASIËNTINLIGTINGSBLAD

USN®

USN ZMA+

(kapsules)

SKEDULERINGSTATUS: S0

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

- Hou hierdie inligtingsblad. Dit mag nodig wees dat jy dit weer lees.
- Moenie USN ZMA+ 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 ZMA+ en waarvoor word dit gebruik
USN ZMA+ is aangedui as 'n anaboliese (spieropbouende) herstelhulpmiddel vir optimale atletiese prestasie. USN ZMA+ kan fisieke prestasies en oefenvermoë verbeter en spiervermoeidheid tydens fisieke aktiwiteit help vertraag.

2. Wat jy moet weet voordat jy USN ZMA+ neem

Moenie USN ZMA+ neem nie
- Indien jy hipersensitief (allergies) is vir enige van die bestanddele (gelys by afdeling 6).

Waarskuwings en voorsorgmaatreëls
Wees veral versigtig met USN ZMA+:
- Indien jy 'n bloedingsversteuring het, hou twee weke voor enige chirurgiese prosedure (operasie) op om USN ZMA+ te neem.
- Indien jy enige nierprobleme het.
- USN ZMA+ kan rooiheid, tinteling en/of prikkelende gevoel van die vel veroorsaak, in welke geval, verminder die dosis.

Kinders en tieners
Moet nie USN ZMA+ aan kinders jonger as 18 jaar gee nie, aangesien die veiligheid en doeltreffendheid by kinders nog nie vasgestel is nie.

Ander medisyne en USN ZMA+
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 dun te hou) of kruie-aanvullings met bloedverdunnende effekte.
- Antibiotika (gebruik vir die behandeling van bakteriële infeksies). Neem antibiotika minstens 2 ure voor, of 4 – 6 ure na USN ZMA+.

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 ZMA+ neem. Die veiligheid tydens swangerskap en borsvoeding is nie bepaal nie.

Bestuur en die gebruik van masjiene
USN ZMA+ kan slaperigheid veroorsaak wat 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 ZMA+ jou affekteer nie.

3. Hoe om USN ZMA+ te neem
Gebruik USN ZMA+ 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:
- MANS: Die gewone dosering is 2 – 4 kapsules daagliks, verkieslik op 'n leë maag, 30 – 60 minute voor slapenstyd.
- VROUE: Die gewone dosering is 2 – 3 kapsules daagliks, verkieslik op 'n leë maag, 30 – 60 minute voor slapenstyd.
- Vir die beste resultate, vermy gepaardgaande inname van suiwelprodukte of ander kalsiumbevattende voedsel of aanvullings.
- Moenie die aanbevole daaglikse dosering oorskry nie.

Wat om te doen indien jy meer USN ZMA+ 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 ZMA+ 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 ZMA+ kan newe-effekte hê.

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

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

Sê vir jou dokter indien jy enige van die volgende opmerk:
Newe-effekte wat met onbekende frekwensie voorkom:
- Maagpyn of -krampe, naarheid, braking, sooibrand, diarree.
- Tinteling en/of prikkelende gevoel van die vel ("naalde-en-spelde"), hoofpyn.
- Slapeloosheid, slaperigheid.
- Rooi word van die vel.

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 geneesmiddelreaksies 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 ZMA+ te verskaf.

5. Hoe om USN ZMA+ 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 houer gedruk is nie.
- Neem alle ongebruikte medisyne terug na jou apteker.
- Moenie ongebruikte medisyne in dreine en rioolstelsels (bv. toilette) weggooi nie.

6. Inhoud van die pak en ander inligting

Wat USN ZMA+ bevat

AKTIEWE BESTANDDELE:	**Per Kapsule**	**Per Dosering**	***%NVW**
ZMA®	305,6 mg	1 222,5 mg	
verskaf Magnesium (van Magnesiumsitraat en Magnesiumoksied)	62,4 mg	250 mg	60 %
Sink (van Sinkmono-L-Metionien)	4,2 mg	17 mg	155 %
Vitamien B_6 (van Piridoksien HCl)	1,5 mg	6 mg	353 %
Beta-alanien	12,5 mg	50 mg	
Askorbiensuur (Vitamien C)	10 mg	40 mg	40 %
Vitamien E asetaat (50 %)	5 mg	20 mg	
verskaf Vitamien E	2,5 mg	10 mg	67 %

*%Nutriëntverwysingswaardes (NVWs) vir individue 4 jaar en ouer (2010).

Die ander bestanddele is beesgelatienkapsules, magnesiumstearaat, aartappelstysel en silikondioksied.

Hoe USN ZMA+ lyk en inhoud van die verpakking
Grootte 0, wit en ligblou, harde gelatienkapsules wat 'n wit poeier bevat.
120 kapsules word verpak in 'n kobaltblou PET-houer met 'n wit skroefdop en induksie seël.

Houer van die Registrasiesertifikaat
USN (Edms) Bpk.
Eenheid 4, Louwlardia Logistieke Park
h/v Nellmapiusrylaan & Olievenhoutboschweg
Centurion, 1683
Pretoria
Tel: 086 111 1876

Hierdie inligtingsblad is laas hersien in
Junie 2021.

Registrasienommer
Moet deur SAHPRA toegeken word.

Toegang tot die ooreenstemmende Professionele Inligtingsblad
www.usn.co.za

ZMA001/PI-PIL/A

JOB: SACS_ZMA Plus_120s	**SIZE:** 300mm x 295mm
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COLOURS: ■ K	**FINISHING:** ☐ Foil / Holographic Foil ☐ Matte ☐ Gloss ☐ Spot UV ☐ Doming ☐ 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.	