

PROFESSIONAL INFORMATION



36004 PA

USN MULTI-VITAMIN & MINERALS

(capsules)

COMPLEMENTARY MEDICINE: HEALTH SUPPLEMENT

This unregistered medicine has not been evaluated by SAHPRA for its quality, safety or intended use.

SCHEDULING STATUS:

1. NAME OF THE MEDICINE

USN MULTI-VITAMIN & MINERALS soft capsules

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

ACTIVE INGREDIENTS:

	Per Capsule	*%NRV
Zinc Gluconate providing Zinc (elemental)	190 mg 25 mg	227 % 100 %
Ascorbic acid (Vitamin C)	100 mg	100 %
Ferrous fumarate providing Iron (elemental)	23.4 mg 7 mg	39 %
Dl- α -Tocopherol Acetate providing D- α -Tocopherol (Vitamin E)	11 mg 6.5 mg (9.7 I.U.)	43 %
Nicotinamide (Vitamin B ₃)	6.5 mg	41 %
Calcium pantothenate providing Pantothenic acid (Vitamin B ₅)	4.8 mg 3.5 mg	70 %
Pyridoxine HCl providing Pyridoxine (Vitamin B ₆)	1.5 mg 1 mg	59 %
Riboflavin (Vitamin B ₂)	0.8 mg	62 %
Vitamin A palmitate providing Retinol (Vitamin A)	440 µg 200 µg	22 %
Folic acid	100 µg	25 %
Cholecalciferol (Vitamin D ₃)	25 µg (1 000 I.U.)	167 %
Biotin (Vitamin H)	22.5 µg	75 %
Cyanocobalamin (Vitamin B ₁₂)	1.5 µg	63 %

*%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

Soft capsules.

Brown soft gelatine capsules containing a suspension.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

USN MULTI-VITAMIN & MINERALS is a multi-vitamin/mineral health supplement that may assist with bone health and provide antioxidants for the maintenance of good health.

4.2 Posology and method of administration

Adults:

- As a health supplement, take 1 softgel capsule per day.
- 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 MULTI-VITAMIN & MINERALS 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 MULTI-VITAMIN & MINERALS at least 2 weeks prior to surgical procedures.

Renal disease:

USN MULTI-VITAMIN & MINERALS should be used with caution in patients with a kidney disorder or a history of kidney stones.

Gastrointestinal disorders:

USN MULTI-VITAMIN & MINERALS may cause irritation and exacerbate gastrointestinal conditions.

Diabetes mellitus:

USN MULTI-VITAMIN & MINERALS may interfere with blood glucose levels in patients with diabetes mellitus. Dose adjustment of antidiabetic medicine might be necessary. Use with caution.

Paediatric population:

The safety and efficacy of USN MULTI-VITAMIN & MINERALS have not been established in children under the age of 18 years.

4.5 Interaction with other medicinal products and other forms of interaction

Anticoagulant/antiplatelet medicines:

USN MULTI-VITAMIN & MINERALS may enhance the effects of anticoagulant/antiplatelet medicines or herbal supplements. Concomitant use may increase the risk of bruising and bleeding.

Antidiabetic medicines:

Concomitant use of USN MULTI-VITAMIN & MINERALS with antidiabetic medicines may interfere with blood glucose control. Use with caution.

Antibiotic medicines:

Concomitant use of USN MULTI-VITAMIN & MINERALS with antibiotics may reduce absorption. Doses should be separated by at least 2 hours prior, or 4 to 6 hours after taking USN MULTI-VITAMIN & MINERALS.

Levothyroxine:

Concomitant use of USN MULTI-VITAMIN & MINERALS with levothyroxine may reduce absorption. Patients should be advised to take levothyroxine and USN MULTI-VITAMIN & MINERALS at least 4 hours apart.

4.6 Fertility, pregnancy and lactation:

Safety in pregnancy and lactation has not been established. USN MULTI-VITAMIN & MINERALS should not be taken during pregnancy or lactation.

4.7 Effects on ability to drive and use machines:

USN MULTI-VITAMIN & MINERALS 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 MULTI-VITAMIN & MINERALS are known.

4.8 Undesirable effects

USN MULTI-VITAMIN & MINERALS is generally well tolerated.

Immune system disorders:

Frequency unknown: hypersensitivity and/or allergic reactions.

Metabolism and nutrition disorders:

Frequency unknown: loss of appetite.

Psychiatric disorders:

Frequency unknown: insomnia.

Nervous system disorders:

Frequency unknown: headache.

Vascular disorders:

Frequency unknown: flushing.

Gastrointestinal disorders:

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

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of USN MULTI-VITAMIN & MINERALS is important. It allows continued monitoring of the benefit/risk balance of USN MULTI-VITAMIN & MINERALS. 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/>

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 MULTI-VITAMIN & MINERALS contains a variety of vitamins and minerals that may assist with bone health and provide antioxidants for the maintenance of good health.

5.2 Pharmacokinetic properties

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

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 the urine.

Iron's absorption is variable and is enhanced by the presence of ascorbic acid. Most of the iron absorbed is incorporated into haemoglobin and is mostly excreted in the faeces.

D- α -Tocopherol (Vitamin E) is mostly absorbed in the small intestines by passive diffusion and is excreted mainly unchanged via the faeces.

Nicotinamide (Vitamin B₃) is rapidly absorbed from the gastrointestinal tract and is excreted mainly via urine.

Pantothenic acid (Vitamin B₅) is the precursor of coenzyme A (CoA) and is excreted in the urine.

Pyridoxine (Vitamin B₆) is passively absorbed from the upper gastrointestinal tract, converted in the liver to coenzyme pyridoxal phosphate and excreted in the urine.

Oral supplementation with Riboflavin (Vitamin B₂) results in the production of 7-hydroxymethylriboflavin in blood plasma and is excreted in the urine.

Retinol (Vitamin A) is readily absorbed from the gastrointestinal tract and is excreted primarily in the urine.

After absorption, folic acid is reduced to tetrahydrofolate and then converted to L-methylfolate. It is excreted mainly in the urine.

Cholecalciferol (Vitamin D₃) is well absorbed and requires hydroxylation in the body to form the active metabolite, calcitriol.

Biotin (Vitamin H) is completely absorbed after oral administration. Biotin metabolites are formed by beta-oxidation, sulfur oxidation, or both, and is excreted in the urine.

Cyanocobalamin (Vitamin B₁₂) is absorbed in the terminal ileum and has a half-life of about 25 – 30 hours. Absorption also occurs by passive diffusion. Vitamin B₁₂ is stored in the liver, excreted in the bile, and undergoes extensive enterohepatic recycling. Part of a dose is excreted in the urine.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Beeswax

Capsule shell (containing gelatine, glycerine, purified water, titanium oxide, milk chocolate brown and caramel colourants)

Lecithin

Sunflower oil

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

60 capsules are packed in a white HDPE container with a white screw-on cap.

6.6 Special precautions for disposal

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

USN (Pty) Ltd
Unit 4, Louwlandia Logistics Park
cnr Nellipinus 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 August 2021.

WELL008/PI-PIL/A

JOB: SAW_Multivitamin Multimineral_60s	SIZE: 300mm x 355mm
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 checked="" type="checkbox"/> K	<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 <small>Although we endeavour to proof accurately, we cannot accept responsibility for errors once proofs are signed and accepted by our clients.</small>	

**USN MULTI-VITAMIN & MINERALS**

(capsules)

SCHEDULING STATUS: **SO****USN MULTI-VITAMIN & MINERALS soft capsules**

Sugar free.

KOMPLEMENTÆRE MEDISYNE: 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 MULTI-VITAMIN & MINERALS is available without a doctor's prescription, for you to maintain your health. Nevertheless, you still need to take USN MULTI-VITAMIN & MINERALS carefully to get the best results from it.

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

1. What USN MULTI-VITAMIN & MINERALS is and what it is used for

USN MULTI-VITAMIN & MINERALS is a multi-vitamin/mineral health supplement that may assist with bone health and provide antioxidants for the maintenance of good health.

2. What you need to know before you take USN MULTI-VITAMIN & MINERALS**Do not take USN MULTI-VITAMIN & MINERALS:**

- If you are hypersensitive (allergic) to any of the ingredients of USN MULTI-VITAMIN & MINERALS (listed in section 6).

Warnings and precautions

Take special care with USN MULTI-VITAMIN & MINERALS:

- If you have a bleeding disorder. You should stop taking USN MULTI-VITAMIN & MINERALS at least 2 weeks before any operation.
- If you have any kidney problems or a history of kidney stones.
- If you have any condition affecting the stomach or intestines.
- If you have diabetes mellitus (high blood sugar) and you are taking medicines to control your blood sugar levels.

Children and adolescents

Do not give USN MULTI-VITAMIN & MINERALS to children younger than 18 years, as the safety and efficacy in children have not yet been established.

Other medicines and USN MULTI-VITAMIN & MINERALS

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.
- Antibiotics (used to treat a bacterial infection). Take antibiotics at least 2 hours before, or 4 to 6 hours after taking USN MULTI-VITAMIN & MINERALS.
- Levothyroxine (used to treat an underactive thyroid). Take levothyroxine and USN MULTI-VITAMIN & MINERALS at least 4 hours apart.

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 MULTI-VITAMIN & MINERALS. Safety in pregnancy and lactation has not been established.

Driving and using machines

USN MULTI-VITAMIN & MINERALS is unlikely to affect your ability to drive a vehicle and use machines. Do not drive or operate machinery until you know how USN MULTI-VITAMIN & MINERALS affects you.

3. How to take USN MULTI-VITAMIN & MINERALS

Always take USN MULTI-VITAMIN & MINERALS 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 1 softgel capsule per day.
- Do not exceed the recommended daily dosage.

If you take more USN MULTI-VITAMIN & MINERALS 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 MULTI-VITAMIN & MINERALS

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 MULTI-VITAMIN & MINERALS can have side effects.

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

If any of the following happens, stop taking USN MULTI-VITAMIN & MINERALS 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 MULTI-VITAMIN & MINERALS. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequency unknown:

- Loss of appetite.
- Insomnia (difficulty falling or staying asleep).
- Headache.
- Flushing (reddening of the skin).
- Stomach pain or cramps, nausea (feeling sick), vomiting (being sick), heartburn, 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 Reaction 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 MULTI-VITAMIN & MINERALS.

5. How to store USN MULTI-VITAMIN & MINERALS

- 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 MULTI-VITAMIN & MINERALS contains****ACTIVE INGREDIENTS:**

	Per Capsule	*%NRV
Zinc Gluconate providing Zinc (elemental)	190 mg	227 %
Ascorbic acid (Vitamin C)	25 mg	100 %
Ferrous fumarate providing Iron (elemental)	100 mg	39 %
Dl-α-Tocopherol Acetate providing D-α-Tocopherol (Vitamin E)	23,4 mg	11 mg
Nicotinamide (Vitamin B ₃)	7 mg	43 %
Calcium pantothenate providing Pantothenic acid (Vitamin B ₅)	6,5 mg (9,7 I.U.)	6,5 mg
Pyridoxine HCl providing Pyridoxine (Vitamin B ₆)	4,8 mg	41 %
Riboflavin (Vitamin B ₂)	3,5 mg	70 %
Vitamin A palmitate providing Retinol (Vitamin A)	1,5 mg	59 %
Folic acid	0,8 mg	62 %
Cholecalciferol (Vitamin D ₃)	440 µg	22 %
Biotin (Vitamin H)	200 µg	25 %
Cyanocobalamin (Vitamin B ₁₂)	100 µg	167 %
	22,5 µg	75 %
	1,5 µg	63 %

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

The other ingredients are beeswax, the capsule shell (containing gelatine, glycerine, purified water, titanium oxide, milk chocolate brown and caramel colourants), lecithin and sunflower oil.

What USN MULTI-VITAMIN & MINERALS looks like and contents of the pack

Brown soft gelatine capsules containing a suspension.

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

Holder of Certificate of Registration:USN (Pty) Ltd
Unit 4, Louwlandia Logistics Park
cn Nellmapius Drive & Olievenhoutbosch Road
Centurion, 1683
Pretoria
Tel: 086 111 1876**This leaflet was last revised in**

August 2021

Registration number

Will be allocated by SAHPRA upon registration.

Access to corresponding Professional Informationwww.usn.co.za**PASIËNTINLIGTINGSBLAD****USN MULTI-VITAMIN & MINERALS**

(capsules)

SKEDULERINGSTATUS: **SO****USN MULTI-VITAMIN & MINERALS sage capsules**

Suikervry.

KOMPLEMENTÆRE MEDISYNE: GESONDHEIDSAANVULLING

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 MULTI-VITAMIN & MINERALS is beskikbaar sonder 'n dokter se voorskrif, sodat jy jou gesondheid in stand kan hou. Jy moet USN MULTI-VITAMIN & MINERALS nooit sorg neem om die beste resultate te verkry.

- Hou hierdie inligtingsblad. Dit mag nodig wees dat jy dit weer lees.
- Moenie USN MULTI-VITAMIN & MINERALS met enigemand anders deel nie.
- Maak geen gebruik van hierdie inligtingsblad nie.

Wat is hierdie inligtingsblad

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

1. Wat is USN MULTI-VITAMIN & MINERALS en waarvoor word dit gebruik

USN MULTI-VITAMIN & MINERALS is 'n multivitamin-en-mineraal-gesondheidsaanvulling wat kan help met beengesondheid en die verskaffing van antoksidaante vir die handhawing van goede gesondheid.

2. Wat moet jy weet voordat jy USN MULTI-VITAMIN & MINERALS neem**Moenie USN MULTI-VITAMIN & MINERALS neem nie**

- Indien jy hipersensitief (allergies) is vir enige van die bestanddele van USN MULTI-VITAMIN & MINERALS (gevolg van afleiding 6).

Waarskuwings en voorsorgmaatreels

Wees veral versig dat jy USN MULTI-VITAMIN & MINERALS gebruik.

- Indien jy 'n bloedingsversteuring het. Jy moet ten minste 2 weke voor enige operasie ophou om USN MULTI-VITAMIN & MINERALS te neem.
- Indien jy enige nierprobleme of 'n geskiedenis van nierstene het.
- Indien jy enige toestand het wat die maag of ingewande beïnvloed.
- Indien jy diabetes mellitus (hôe bloedsuiker) het en jy medisyne gebruik om jou bloedsuikervlakte te beheer.

Kinders en tiener

Moenie USN MULTI-VITAMIN & MINERALS aan kinders jonger as 18 jaar gee nie, aangesien die veiligheid en doeltreffendheid by kinders nog nie vasgestel is nie.

Ander medisyne en USN MULTI-VITAMIN & MINERALS

Sé altyd vir gesondheidsorgverskaffer indien jy enige ander medisyne neem. (Dit sluit komplementære of tradisionele medisyne in.)

Sé vir jou dokter of apoteker indien jy tans die volgende gebruik:

- Antikoagulant/antiplaatijsjemedisyne (gebruik om jou bloed dun te hou) of kruie-aanvullings met bloedverdunrende effekte.
- Antidiabetiese medisyne (gebruik om hoë bloedsuikervlakte te behandel) of kruie-aanvullings wat jou bloedsuikervlakte kan beïnvloed.
- Antibiotika (gebruik om 'n bakteriële infeksie te behandel). Neem antibiotika minstens 2 ure voor, of 4 tot 6 ure nadat jy USN MULTI-VITAMIN & MINERALS geneem het.
- Levotiroksien (gebruik om 'n onderwerklike skildklier te behandel). Neem levotiroksien en USN MULTI-VITAMIN & MINERALS minstens 4 ure uitmekar.

Swangerskap en borsvoeding

Indien jy swanger is of jou baba borsvoeding, dink dat jy swanger mag wees of beplan om swanger te raak, raadpleeg asseblief jou dokter, apoteker of ander gesondheidsorgverskaffer voordat jy USN MULTI-VITAMIN & MINERALS neem. Die veiligheid van USN MULTI-VITAMIN & MINERALS tydens swangerskap en borsvoeding is nie bepaal nie.

Bestuur en die gebruik van masjiene

Dit is onwaarskynlik dat USN MULTI-VITAMIN & MINERALS jou vermoë om 'n voertuig te bestuur en masjiene te gebruik kan belemmer. Moenie 'n voertuig bestuur of masjienerie hanter totdat jy weet hoe USN MULTI-VITAMIN & MINERALS jou aefekteer nie.

3. Hoe om USN MULTIVITAMIN MULTIMINERAL te neem

Neem USN MULTI-VITAMIN & MINERALS altyd presies soos wat in hierdie inligtingsblad aangedui word, of soos wat jou dokter of apoteker vir jou gesê het. Vra gerus jou dokter of apoteker indien jy onseker is.