



USN MULTI-VITAMIN & MINERALS

38604 PA

(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 MULTI-VITAMIN & MINERALS soft capsules

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

ACTIVE INGREDIENTS:	Per Capsule	*%NRV
Zinc Gluconate	190 mg	
providing Zinc (elemental)	25 mg	227 %
Ascorbic acid (Vitamin C)	100 mg	100 %
Ferrous fumarate	23,4 mg	
providing Iron (elemental)	7 mg	39 %
Dl- α -Tocopherol Acetate	11 mg	
providing D- α -Tocopherol (Vitamin E)	6,5 mg (9,7 I.U.)	43 %
Nicotinamide (Vitamin B ₃)	6,5 mg	41 %
Calcium pantothenate	4,8 mg	
providing Pantothenic acid (Vitamin B ₅)	3,5 mg	70 %
Pyridoxine HCl	1,5 mg	
providing Pyridoxine (Vitamin B ₆)	1 mg	59 %
Riboflavin (Vitamin B ₂)	0,8 mg	62 %
Vitamin A palmitate	440 μ g	
providing Retinol (Vitamin A)	200 μ g	22 %
Folic acid	100 μ g	25 %
Cholecalciferol (Vitamin D ₃)	25 μ g (1 000 I.U.)	167 %
Biotin (Vitamin H)	22,5 μ g	75 %
Cyanocobalamin (Vitamin B ₁₂)	1,5 μ g	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 or herbal supplements 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/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 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, Louwardia Logistics Park
cnr Nellmapius Drive & Olivevouthbosch 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.

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 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"/> Dorning <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.			

