

PROFESSIONAL INFORMATION



37718 P10

USN TESTO gH ULTRA

(capsules)

COMPLEMENTARY MEDICINE: COMBINATION PRODUCT (WESTERN HERBAL 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 TESTO gH ULTRA capsules

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredients:

Table with 4 columns: Active ingredients, Per capsule, Per 4 capsule dosage, %NRV. Lists ingredients like Tribulus terrestris L., Magnesium Amino Acid Chelate (AAC), Cucurbita moschata, etc.

*%Nutrient Reference Values (NRVs) for individuals 4 years & older (2010). Sugar free.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Capsules.

Size 00 white hard bovine gelatine capsules containing an off-white to light brown powder.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

USN TESTO gH ULTRA promotes lean muscle development and supports male performance. USN TESTO gH ULTRA has anti-oestrogenic properties.

4.2 Posology and method of administration

- Adults: Take 4 capsules once daily at bedtime, or in 2 divided doses of 2 capsules before training and at bedtime. Adhere to cycles lasting 4 - 8 weeks followed by a 2 - 4 week break. 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

Surgery: Patients should be advised to discontinue USN TESTO gH ULTRA at least 2 weeks prior to surgical procedures.

Diabetes mellitus: USN TESTO gH ULTRA may increase insulin levels and/or decrease blood glucose levels and cause hypoglycaemia. Dose adjustment of antidiabetic medicine might be necessary (see section 4.5).

Hypotension: USN TESTO gH ULTRA may reduce blood pressure, increasing the risk of blood pressure becoming too low in patients with hypotension. Caution is advised.

Liver conditions: Caution is advised with USN TESTO gH ULTRA if you have a liver deficiency.

Prostate conditions: USN TESTO gH ULTRA should be used with caution in patients with prostate conditions. Consult a healthcare provider before use to exclude a diagnosis of prostate cancer.

Cross-sensitivity: USN TESTO gH ULTRA is not recommended in case of allergy to soybeans, peanuts, green peas or to other plants of the Fabaceae (legume) family, due to a possible cross-sensitivity with fenugreek.

Paediatric population: The safety and efficacy of USN TESTO gH ULTRA in children under the age of 18 years have not been established. USN TESTO gH ULTRA should not be used in children under 18 years.

4.5 Interaction with other medicines and other forms of interaction

Anticoagulant/antiplatelet medicines: USN TESTO gH ULTRA may reduce platelet aggregation and may enhance the effects of anticoagulant/antiplatelet medicines. Concomitant use may increase the risk of bleeding and caution is advised (see section 4.4).

Antidiabetic medicines: The use of USN TESTO gH ULTRA with antidiabetic medicines or herbal supplements with hypoglycaemic effects may have an additive effect when used concomitantly (see section 4.4). Caution is advised.

Antihypertensive medicines: The use of USN TESTO gH ULTRA with antihypertensive medicine or herbal supplements with hypotensive effects may have additive blood pressure-lowering effects when used concomitantly. Caution is advised.

Lithium: USN TESTO gH ULTRA might reduce excretion and increase levels of lithium due to its potential diuretic effect. The dose of lithium might need to be decreased.

4.6 Fertility, pregnancy and lactation:

USN TESTO gH ULTRA is not indicated for women. USN TESTO gH ULTRA should not be taken during pregnancy or lactation as the safety has not been established.

4.7 Effects on ability to drive and use machines:

USN TESTO gH ULTRA may cause side effects such as dizziness and fatigue 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 TESTO gH ULTRA are known.

4.8 Undesirable effects

USN TESTO gH ULTRA is generally well tolerated.

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

Nervous system disorders: Frequency unknown: dizziness, headache, fatigue.

Gastrointestinal disorders: Frequency unknown: nausea, vomiting, abdominal pain, abdominal distension, diarrhoea, constipation, dyspepsia, flatulence.

Renal and urinary disorders: Frequency unknown: diuresis.

Reproductive system and breast disorders: Frequency unknown: decreased libido.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of USN TESTO gH ULTRA is important. It allows continued monitoring of the benefit/risk balance of USN TESTO gH ULTRA. 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

Category and class:

D 33.7 Combination Product.

Tribulus terrestris is a plant extract that has been suggested to stimulate luteinizing hormone (LH), which stimulates the natural production of testosterone.

Magnesium is an essential mineral that helps to metabolise carbohydrates, fats and proteins. It also contributes to tissue formation and the maintenance of normal muscle function. Magnesium is absorbed throughout the gastrointestinal tract, is distributed in the skeleton and soft tissue, and excreted primarily via the kidneys.

Pumpkin seeds are rich in cucurbitin and carotenoids. The seed oil is rich in vitamin E and unsaturated fatty acids, including linoleic acid, oleic acid, palmitic acid and stearic acid. The seeds and seed oil might improve bladder and urethral function, reduce prostate weight and have anti-inflammatory effects.

Fenugreek extract has been shown to improve testosterone levels in both men and women. In women, fenugreek extract increases both estradiol and luteinising hormone (LH) levels.

Eurycoma longifolia extract, known as tongkat ali, enhances testosterone production by the Leydig cells of the testes and frees bound testosterone for use by muscles.

Zinc is an essential trace element in the body which helps to metabolise carbohydrates, fats and proteins, assists with connective tissue formation and contributes to the maintenance of normal testosterone levels in the blood. Zinc is absorbed in the small intestines and is distributed in the body in skeletal muscle and bone. It is mainly excreted through the faeces.

Saw palmetto has antiandrogenic, antiproliferative and anti-inflammatory properties and displays antiestrogenic activity in prostatic tissue of men with benign prostatic hypertrophy (BPH). After intake, saw palmetto reaches peak plasma levels at about 1,5 hours, and has a half-life of about 19 hours.

After absorption, boron is distributed to all tissues with the highest concentration in bone and lowest in adipose tissue. 90 % of the boron is excreted unchanged in the urine.

Vitamin B6 (pyridoxine hydrochloride) helps to metabolise carbohydrates, fats and proteins and contributes to tissue formation. Vitamin B6 is passively absorbed from the upper gastrointestinal tract, converted in the liver to coenzyme pyridoxal phosphate and excreted in the urine.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Gelatine (bovine) capsules, Magnesium stearate, 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 black HDPE container with a black lid, induction seal and silica gel sachet.

6.6 Special precautions for disposal

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

USN (PTY) LTD, Unit 4, Louwlandia 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/RENEWAL OF THE AUTHORISATION

Will be allocated by SAHPRA upon registration.

10. DATE OF REVISION OF THE TEXT

This leaflet was last revised in April 2021.

TES017/PI-PI/A

Order form for USN TESTO gH ULTRA. Includes fields for JOB (SAHC_USN Testo gH Ultra_120s), STOCK (Foil Substrate, Clear Substrate, White Substrate, Paper, Other), COLOURS (K), FINISHING (Foil/Holographic Foil, Matte, Gloss, Spot UV, Doming, Embossing), and a PLEASE CHECK CAREFULLY section with a disclaimer.

PATIENT INFORMATION LEAFLET



37718 P10

USN TESTO gH ULTRA

(capsules)

SCHEDULING STATUS: S0

USN TESTO gH ULTRA capsules

Sugar free.

COMPLEMENTARY MEDICINE: COMBINATION PRODUCT (WESTERN HERBAL 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 TESTO gH ULTRA is available without a doctor's prescription, for you to maintain your health. Nevertheless, you still need to use USN TESTO gH ULTRA carefully to get the best results from it.

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

1. What USN TESTO gH ULTRA is and what it is used for
USN TESTO gH ULTRA promotes lean muscle development and supports male performance. USN TESTO gH ULTRA has anti-estrogenic properties.

2. What you need to know before you take USN TESTO gH ULTRA

Do not take USN TESTO gH ULTRA:

- If you are hypersensitive (allergic) to any of the ingredients (listed in section 6).

Warnings and precautions

Take special care with USN TESTO gH ULTRA:

- If you are having any surgical procedure done. You should stop taking USN TESTO gH ULTRA at least 2 weeks before any operation.
- If you have diabetes mellitus (high blood sugar) and you are taking medicines to control your blood sugar levels.
- If you have low blood pressure.
- If you have any liver problems.
- If you have any prostate problems.
- If you are allergic to soybeans, peanuts, green peas or to other plants of the Fabaceae (legume) family.

Children and adolescents

Do not give USN TESTO gH ULTRA to children younger than 18 years, as the safety and efficacy in children have not yet been established.

Other medicines and USN TESTO gH ULTRA

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.
- Antihypertensive medicine (used to treat high blood pressure) or herbal supplements with a blood pressure-lowering effect.
- Lithium (used to stabilise your mood).

Pregnancy, breastfeeding and fertility

USN TESTO gH ULTRA is not indicated for women. Do not take USN TESTO gH ULTRA if you are pregnant or breastfeeding.

Driving and using machines

USN TESTO gH ULTRA may cause side effects, such as dizziness and tiredness 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 TESTO gH ULTRA affects you.

3. How to take USN TESTO gH ULTRA

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

Adults:

- Take 4 capsules once daily at bedtime, or in 2 divided doses of 2 capsules before training and at bedtime.
- Adhere to cycles lasting 4 - 8 weeks followed by a 2 - 4 week break.
- Do not exceed the recommended daily dosage.

If you take more USN TESTO gH ULTRA 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 TESTO gH ULTRA

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 TESTO gH ULTRA can have side effects.

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

If any of the following happens, stop taking USN TESTO gH ULTRA 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 TESTO gH ULTRA. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

Frequency unknown:

- If you pass more urine than is normal for you.

This is a serious side effect. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequency unknown:

- Nausea, vomiting, stomach pain, diarrhoea, constipation, bloating, heartburn.
- Dizziness, headache, tiredness.
- Decreased sex drive.

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 TESTO gH ULTRA.

5. How to store USN TESTO gH ULTRA

- 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 TESTO gH ULTRA contains

Active ingredients:	Per capsule	Per 4 capsule dosage	%NRV
<i>Tribulus terrestris</i> L. [herb; extract standardised to 40 % saponins]	312,5 mg	1 250 mg	
Magnesium Amino Acid Chelate (AAC) providing Magnesium (elemental)	131,3 mg 26,3 mg	525 mg 105 mg	25 %
<i>Cucurbita moschata</i> Duchesne (Pumpkin Seed) [seed; 4:1 extract providing 500 mg dried herb equivalent]	125 mg	500 mg	
<i>Trigonella foenum-graecum</i> L. (Fenugreek) [seed; 4:1 extract providing 500 mg dried herb equivalent]	125 mg	500 mg	
<i>Eurycoma longifolia</i> Jack (Tongkat Ali) [root; 200:1 extract providing 7,5 g dried herb equivalent]	37,5 mg	150 mg	
Zinc Monomethionine providing Zinc (elemental)	10,2 mg 3,1 mg	40,8 mg 12,5 mg	114 %
<i>Serenoa repens</i> (W.Bartram) Small (Saw Palmetto) [fruit powder]	25 mg	100 mg	
Boron Citrate providing Boron (elemental)	13,9 mg 0,8 mg	55,6 mg 3 mg	
Pyridoxine HCl providing Pyridoxine (Vitamin B ₆)	3,2 mg 2,6 mg	12,8 mg 10,5 mg	618 %

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

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

7. What USN TESTO gH ULTRA looks like and contents of the pack

Size 00 white hard bovine gelatine capsules containing an off-white to light brown powder. 120 capsules are packed in a black HDPE container with a black lid, induction seal and silica gel sachet.

8. Holder of Certificate of Registration:

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

9. This leaflet was last revised in

April 2021.

10. Registration number

Will be allocated by SAHPRA upon registration.

11. Access to corresponding Professional Information

www.usn.co.za

PASIENTINLIGTINGSBLAD



USN TESTO gH ULTRA

(kapsules)

SKEDULERINGSSTATUS: S0

USN TESTO gH ULTRA kapsules

Suikervry.

KOMPLEMENTÊRE MEDISYNE: KOMBINASIEPRODUK (WESTERSE KRUIEMEDISYNE / GESONDHEIDSAANVULLING)

Hierdie ongeregistreerde medisyne is nie vir gehalte, veiligheid of beoogde gebruik deur SAHPRA geëvalueer nie.

Lees hierdie hele inligtingsblad aandagtig deur wat dit bevat inligting wat belangrik is vir jou.

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

- Hou hierdie inligtingsblad. Dit mag nodig wees dat jy dit weer lees.
- Moenie USN TESTO gH ULTRA 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 TESTO gH ULTRA en waarvoor word dit gebruik.
2. Wat jy moet weet voordat jy USN TESTO gH ULTRA neem.
3. Hoe om USN TESTO gH ULTRA te neem.
4. Moontlike newe-effekte.
5. Hoe om USN TESTO gH ULTRA te bêre.
6. Inhoud van die pak en ander inligting.

1. Wat is USN TESTO gH ULTRA en waarvoor word dit gebruik

USN TESTO gH ULTRA bevorder die ontwikkeling van spiere en ondersteun manlike prestasie. USN TESTO gH ULTRA het ook anti-estrogeniese eienskappe.

2. Wat jy moet weet voordat jy USN TESTO gH ULTRA neem

Moenie USN TESTO gH ULTRA neem nie

- Indien jy hipersensitief (allergies) is vir enige van die bestanddele (gelys by afdeling 6).

Waarskuwings en voorsorgmaatreëls

Wees veral versigtig vir USN TESTO gH ULTRA:

- Indien jy vir 'n operasie moet gaan. Hou twee weke voor enige chirurgiese prosedure (operasie) op om USN TESTO gH ULTRA te neem.
- Indien jy 'n diabeet is (hoë bloedsuiker) en medisyne neem om jou bloedsuikervlakke te beheer.
- Indien jy lae bloeddruk het.
- Indien jy enige lewerprobleme het.
- Indien jy enige prostaatprobleme het.
- Indien jy hipersensitief (allergies) is vir sojabone, grondbone, erbies of ander plante van die Fabaceae (peulgewas) familie.

Kinders en tieners

Moenie USN TESTO gH ULTRA aan kinders jonger as 18 jaar gee nie, aangesien die veiligheid en effektiwiteit by kinders nog nie vasgestel is nie.

Ander medisyne en USN TESTO gH ULTRA

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 bloedverduinnende effekte.
- Antidiabetiese medisyne (gebruik om hoë bloedsuikervlakke te behandel) of kruie-aanvullings met bloedsuikerverlagende effekte.
- Antihypertensiewe medisyne (gebruik om hoë bloeddruk te behandel) of kruie-aanvullings met bloeddrukverlagende effekte.
- Litium (gebruik om jou gemoed te stabiliseer).

Swangerskap en borsvoeding

USN TESTO gH ULTRA is nie aangedui vir vroue nie. Moenie USN TESTO gH ULTRA gebruik indien jy swanger is of borsvoed nie.

Bestuur en die gebruik van masjiene

USN TESTO gH ULTRA kan duiseligheid en moegheid veroorsaak wat jou vermoë om 'n voertuig te bestuur en masjiene te gebruik kan belemmer (sien afdeling 4). Moenie 'n voertuig bestuur of masjinerie hanteer totdat jy weet hoe USN TESTO gH ULTRA jou affekteer nie.

3. Hoe om USN TESTO gH ULTRA te neem

Gebruik USN TESTO gH ULTRA 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:

- Neem 4 kapsules daaglik met slapenstyd, of in 2 verdeelde dosisse van 2 kapsules voor oefening en met slapenstyd.
- Voldoen aan siklusse wat 4 - 8 weke duur, gevolg deur 'n 2 - 4 weke onderbreking.
- Moenie die aanbevole daaglikse dosering oorskry nie.

Wat om te doen indien jy meer USN TESTO gH ULTRA 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 TESTO gH ULTRA 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 TESTO gH ULTRA kan newe-effekte hê.

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

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

Sê dadelik vir jou dokter of gaan na die ongevalle-afdeling van die naaste hospitaal indien jy die volgende opmerk:

Newe-effekte wat met onbekende frekwensie voorkom:

- Indien jy meer urineer as wat normaal is vir jou.

Hierdie is 'n ernstige newe-effek. Jy mag dringende mediese bystand benodig.

Sê vir jou dokter indien jy enige van die volgende opmerk:

Newe-effekte wat met onbekende frekwensie voorkom:

- Naarheid, braking, maagpyn, diarree, hardtygigheid, opgeblasenheid, sooibrand.
- Verlaagde seksdrang.

Indien jy enige newe-effekte opmerk wat nie in hierdie inligtingsblad genoem word nie, sê asseblief vir jou dokter of apteker daarvan.

JOB: SAHC_USN Testo gH Ultra_120s	SIZE: 300mm x 305mm
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: <input checked="" type="checkbox"/> 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.

TES017/PI-PI/LA