

**PROFESSIONAL INFORMATION**



38131 P3

# USN TESTO gH

(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 capsules

**2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

**Active ingredients:**

*Cucurbita moschata* Duchesne (Pumpkin Seed)  
[seed; 4:1 extract providing 500 mg dried herb equivalent]  
*Tribulus terrestris* L.  
[herb; extract standardised to 40 % saponins]  
*Epimedium sagittatum* (Siebold & Zucc.) Maxim. (Horny Goat Weed)  
[powder]  
Gamma Aminobutyric Acid (GABA)  
L-Arginine  
Magnesium L-Aspartate  
providing Magnesium (elemental)  
Zinc DL-Monomethionine  
providing Zinc (elemental)  
Pyridoxine (Vitamin B<sub>6</sub>)

Per capsule	Per dose	*%NRV
166,7 mg	500 mg	
100 mg	300 mg	
33,3 mg	100 mg	
66,7 mg	200 mg	
66,7 mg	200 mg	
276,5 mg	829,5 mg	15 %
20,4 mg	61,2 mg	
8,1 mg	24,4 mg	
1,4 mg	4,2 mg	38 %
0,5 mg	1,5 mg	88 %

\*%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.

White size 00 hard bovine gelatine capsules containing a light brown powder.

**4. CLINICAL PARTICULARS**

**4.1 Therapeutic indications**

USN TESTO gH is an aid to normal protein synthesis and muscle function, and to assist with reduction in tiredness and fatigue.

**4.2 Posology and method of administration**

*Adults:*

- Take 6 capsules once daily at bedtime, or in 2 individual doses of 3 capsules before training and at bedtime.
- Adhere to a five-days-on/two-days-off regime for a period of eight weeks followed by a two-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 6.1.

**4.4 Special warnings and precautions for use**

**Surgery:**

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

**Diabetes mellitus:**

USN TESTO gH may decrease blood glucose levels and cause hypoglycaemia. Dose adjustment of antidiabetic medicine might be necessary (see section 4.5).

**Hypotension:**

USN TESTO gH 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 if you have a liver deficiency.

**Paediatric population**

The safety and efficacy of USN TESTO gH in children under the age of 18 years have not been established. USN TESTO gH 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 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 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 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 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 is not indicated for women. USN TESTO gH 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 may cause side effects such as dizziness 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 are known.

**4.8 Undesirable effects**

USN TESTO gH is generally well tolerated.

**Immune system disorders:**

*Frequency unknown:* hypersensitivity and/or allergic reactions.

**Nervous system disorders:**

*Frequency unknown:* dizziness, headache, insomnia.

**Gastrointestinal disorders:**

*Frequency unknown:* nausea, vomiting, abdominal pain, cramping, bloating, diarrhoea, heartburn, constipation.

**Renal and urinary disorders:**

*Frequency unknown:* diuresis.

**Reporting of suspected adverse reactions**

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

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.

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

Horny goat weed constituents are absorbed in the intestinal tract. Peak plasma levels of the metabolite, icaraside II, occurred at 4,1 – 4,3 hours after intake. The accumulation of the metabolite, desmethylcaritin, was biphasic with small and large peaks, respectively, after 5 and 24 hours. Peak levels lasted for up to 48 hours. The half-life of the icariin metabolite icaraside II after oral intake of horny goat weed was 12 – 15 hours.

Gamma-aminobutyric acid (GABA) is a non-protein amino acid which does not cross the blood-brain barrier. GABA is primarily catabolised in the liver.

L-arginine has an oral bioavailability of 68 % and is broken down into nitric oxide and L-citrulline. L-arginine has a half-life of approximately 80 minutes and is excreted via the renal route.

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 primary via the kidneys.

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.

Vitamin B<sub>6</sub> helps to metabolise carbohydrates, fats and proteins and contributes to tissue formation. Vitamin B<sub>6</sub> 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 (E572)  
Potato starch  
Silicon dioxide (E551).

**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, LouwIardia 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.

<b>JOB: SAHC_USN Testo gH_120s</b>	<b>SIZE:</b> 300mm x 317mm
<b>STOCK:</b> Foil Substrate: <input type="checkbox"/> Clear Substrate: <input type="checkbox"/> White Substrate: <input type="checkbox"/> Paper: <input checked="" type="checkbox"/> Other: <input type="checkbox"/>	
<b>COLOURS:</b>  K	<b>FINISHING:</b> <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
<b>PLEASE CHECK CAREFULLY</b>	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 TESTO gH

(capsules)

**SCHEDULING STATUS:** S0

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

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

#### 1. What USN TESTO gH is and what it is used for

USN TESTO gH is an aid to normal protein synthesis and muscle function, and to assist with reduction in tiredness and fatigue.

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

##### Do not take USN TESTO gH:

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

#### Warnings and precautions

##### Take special care with USN TESTO gH:

- If you are having any surgical procedure done. You should stop taking USN TESTO gH 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.

#### Children and adolescents

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

#### Other medicines and USN TESTO gH

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

#### Driving and using machines

USN TESTO gH may cause side effects such as dizziness 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 affects you.

#### 3. How to take USN TESTO gH

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

##### Adults:

- Take 6 capsules once daily at bedtime, or in 2 individual doses of 3 capsules before training and at bedtime.
- Adhere to a five-days-on/two-days-off regime for a period of eight weeks followed by a two-week break.
- Do not exceed the recommended daily dosage.

#### If you take more USN TESTO gH 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 TESTO gH

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 can have side effects.

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

If any of the following happens, stop taking USN TESTO gH 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. 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 (feeling sick), vomiting (being sick), stomach pain, cramping, bloating, diarrhoea, heartburn, constipation (difficulty in passing stools).
- Dizziness, headache, sleeplessness.

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.

#### 5. How to store USN TESTO gH

- 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 contains

Active ingredients:	Per capsule	Per dose	***NRV
<i>Cucurbita moschata</i> Duchesne (Pumpkin Seed) [seed; 4:1 extract providing 500 mg dried herb equivalent]	166,7 mg	500 mg	
<i>Tribulus terrestris</i> L. [herb; extract standardised to 40 % saponins]	100 mg	300 mg	
<i>Epimedium sagittatum</i> (Siebold & Zucc.) Maxim. (Horny Goat Weed) [powder]	33,3 mg	100 mg	
Gamma Aminobutyric Acid (GABA)	66,7 mg	200 mg	
L-Arginine	66,7 mg	200 mg	
Magnesium L-Aspartate providing Magnesium (elemental)	276,5 mg 20,4 mg	829,5 mg 61,2 mg	114 %
Zinc DL-Monomethionine providing Zinc (elemental)	8,1 mg 1,4 mg	24,4 mg 4,2 mg	38 %
Pyridoxine (Vitamin B <sub>6</sub> )	0,5 mg	1,5 mg	88 %

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

The other ingredients are bovine gelatine capsules, magnesium stearate (E572), potato starch and silicon dioxide (E551).

##### What USN TESTO gH looks like and contents of the pack

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

#### 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](http://www.usn.co.za)

PASİËNTINLİGİNGSBLAD



# USN TESTO gH

(kapsules)

**SKEDULERINGSTATUS:** S0

## USN TESTO gH 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 want dit bevat inligting wat belangrik is vir jou.**

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

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

USN TESTO gH is 'n hulpmiddel vir normale proteïensintese en spierfunksie, en help met die vermindering van moegheid.

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

##### Moenie USN TESTO gH 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:

- Indien jy vir 'n operasie moet gaan. Hou twee weke voor enige chirurgiese prosedure (operasie) op om USN TESTO gH 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.

#### Kinders en tieners

Moenie USN TESTO gH 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

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 bloedverdunde effekte.
- Antidiabetiese medisyne (gebruik om hoë bloedsuikervlakke te behandel) of kruie-aanvullings met bloedsuikerverlagende effekte.
- Antihipertensiewe 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 is nie aangedui vir vroue nie. Moenie USN TESTO gH gebruik indien jy swanger is of borsvoed nie.

#### Bestuur en die gebruik van masjiene

USN TESTO gH kan duiseligheid 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 jou afkteer nie.

#### 3. Hoe om USN TESTO gH te neem

Gebruik USN TESTO gH 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 6 kapsules daagliks met slapenstyd, of in 2 verdeelde dosisse van 3 kapsules voor oefening en met slapenstyd.
- Voldoen aan 'n vyf-dag-aan/twee-dag-af regime vir 'n tydperk van agt weke, gevolg deur 'n rusperiode van twee weke.
- Moenie die aanbevole daaglikse dosering oorskry nie.

#### Wat om te doen indien jy meer USN TESTO gH 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 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 TESTO gH kan nuwe-effekte hê.

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

Indien enige van die volgende gebeur, hou op om USN TESTO gH 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 TESTO gH 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: **Neuwe-effekte wat met onbekende frekwensie voorkom:**

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

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

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

##### Neuwe-effekte wat met onbekende frekwensie voorkom:

- Naarheid, braking, maagpyn, krampe, opgeblasenheid, diarree, sooibrand, hardlywigheid.
- Duiseligheid, hoofpyn, slaaploosheid.

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

<b>JOB:</b> SAHC_USN Testo gH_120s	<b>SIZE:</b> 300mm x 317mm
<b>STOCK:</b> Foil Substrate: <input type="checkbox"/> Clear Substrate: <input type="checkbox"/> White Substrate: <input type="checkbox"/> Paper: <input checked="" type="checkbox"/> Other: <input type="checkbox"/>	
<b>COLOURS:</b> K	<b>FINISHING:</b> <input type="checkbox"/> Foil / Holographic Foil <input type="checkbox"/> Matte <input type="checkbox"/> Gloss <input type="checkbox"/> Spot UV <input type="checkbox"/> Dornimg <input type="checkbox"/> Embossing
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