

SCHEDULING STATUS: Not scheduled

PROPRIETARY NAME (and dosage form)



35735 P15

USN TESTO TRIBULUS

(capsule)

COMPOSITION

Active ingredients:	Per Capsule	Per Dose	*%NRV
<i>Tribulus terrestris</i> L. extract (herb; extract standardised to saponins 40 %)	150 mg	300 mg	
Magnesium L-Aspartate Providing Magnesium	415 mg 30,6 mg	830 mg 61,2 mg	15 %
Zinc Methionine Providing Zinc	12,2 mg 2,1 mg	24,4 mg 4,2 mg	38 %
Pyridoxine (Vitamin B ₆)	0,7 mg	1,4 mg	82 %

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

Sugar free

Other ingredients: Bovine gelatine capsules, magnesium stearate, silicon dioxide.

CATEGORY AND CLASS

D 33.7 Combination Product

PHARMACOLOGICAL ACTION

Tribulus terrestris (also known as puncture weed/vine or caltrop) is a plant extract that has been suggested to stimulate luteinising hormone (LH) which stimulates the natural production of testosterone. Current research indicates that the dominant furostanolic saponin, protodioscin, is the active ingredient in *Tribulus* that affords it its testosterone-boosting effects. This steroidal saponin appears to stimulate the release of luteinizing hormone (LH) from the pituitary gland. LH then travels via the bloodstream to the testicles, where it stimulates testosterone production. Protodioscin is also believed to increase dehydroepiandrosterone (DHEA) production by the adrenal glands. This steroid precursor becomes testosterone. Consequently, *Tribulus* could potentially increase testosterone levels and promote greater gains in strength and muscle mass during training.

Magnesium is a ubiquitous element that plays a fundamental role in many cellular reactions. More than 300 metabolic reactions require magnesium as a cofactor. Some important examples include glycolysis, fat and protein metabolism. Magnesium also contributes to tissue formation and the maintenance of normal muscle function.

Zinc is a trace mineral essential for the functioning of enzymatic and other cellular processes, including the regulation of gene expression, protein folding, and immunity. Zinc helps the body to metabolise carbohydrates, fats and proteins and helps in connective tissue formation. Zinc also contributes to the maintenance of normal testosterone levels in the blood.

Vitamin B₆ (pyridoxine) helps to metabolise carbohydrates, fats and proteins and assists with tissue formation. Vitamin B₆ also contributes to normal energy-yielding metabolism and the reduction of tiredness and fatigue as well as the normal function of the immune system.

INDICATION

Indicated as an aid to normal protein synthesis and muscle function, and to assist with a reduction in tiredness and fatigue.

CONTRA-INDICATIONS

Avoid with a known allergy/hypersensitivity to *Tribulus terrestris*, any of its parts, or other members of the *Zygophyllaceae* family.

Do not use if you are pregnant or lactating.

WARNINGS AND SPECIAL PRECAUTIONS

Not recommended for use in children under the age of 18 years.

Tribulus has been found to have a hypotensive action, and may affect hypotension/hypertension medicine.

Use cautiously in patients using beta-blockers or calcium channel blockers, as *Tribulus* may increase their effects due to its negative chronotropic activity in cardiac muscle.

Please discuss with your healthcare professional before taking this medicine.

PREGNANCY AND LACTATION

Do not take this medicine during pregnancy or lactation.

INTERACTIONS

Always tell your healthcare professional if you are taking any other medicine.

DOSAGE AND DIRECTIONS FOR USE

Adults: Best taken at bedtime. During high intensity training an additional serving can be taken before training. The dosage can vary between 2 and 7 capsules per day depending on the intensity of training.

Capsules can be taken either at bedtime or divided between before training and bedtime.

Adhere to a five-days-on/two-days-off regime for a period of eight weeks where-after a two week break should be taken.

Do not exceed the daily recommended dose. In the event of over dosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

Do not share medicines prescribed for you with any other person.

SIDE-EFFECTS

The following side-effects may be associated with the use of **USN TESTO TRIBULUS**, especially if taken on a regular basis, and are listed under their corresponding body-organ class:

Gastro-intestinal disorders: Abdominal discomfort, flatulence, diarrhoea, constipation, nausea, vomiting, heartburn, gastralgia, dyspepsia.

Immune system disorders: Hypersensitivity and/or allergic reactions.

Cardiovascular disorders, general: Hypotensive effect.

Neurological system disorders: Headache, dizziness, agitation, sleeplessness, insomnia, depression.

Not all side-effects reported for this medicine are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

None known. Treatment is symptomatic and supportive.

IDENTIFICATION

Clear bovine gelatine capsule containing a brown powder.

PRESENTATION

Blue PET plastic container with a white USN lid, containing 100 capsules.

STORAGE INSTRUCTIONS

Store in a cool (below 25 °C), dry place.

STORE OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

To be allocated by the Authority.

NAME AND BUSINESS ADDRESS OF THE APPLICANT

USN Pty (Ltd)

Building C, Southdowns Office Park, 2nd Floor, 21 Karee Street, Irene Ext.54, 0157. Tel: 0861 111 876

DATE OF PUBLICATION OF THIS PACKAGE INSERT

July 2014

COMPLEMENTARY MEDICINE:

Discipline: Combination Product – Western Herbal Medicine & Health Supplement.

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

TES004/PI/B

JOB: USN_SACS_TestoTribulus_100s_PI		SIZE: 205mm x 150mm	
STOCK: Foil Substrate: <input type="checkbox"/> Clear Substrate: <input type="checkbox"/> White Substrate: <input type="checkbox"/> Other: <input checked="" type="checkbox"/>			
COLOURS:		FINISHING:	
<input checked="" type="checkbox"/> K	<input type="checkbox"/> Available Slot	<input type="checkbox"/> Available Slot	<input type="checkbox"/> Available Slot
<input type="checkbox"/> Available Slot	<input type="checkbox"/> Available Slot	<input type="checkbox"/> Available Slot	<input type="checkbox"/> Available Slot
<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	

SKEDULERINGSSTATUS: Nie geskeduleerd

EIENDOMSNAAM (en doseervorm)



USN TESTO TRIBULUS

(kapsule)

SAMESTELLING

Aktiewe bestanddele:	Per Kapsule	Per Dosering	*%NWW
<i>Tribulus terrestris</i> L. ekstrak [plant; ekstrak gestandaardiseer tot saponiene 40 %]	150 mg	300 mg	
Magnesium L-Asparaat	415 mg	830 mg	
Verskaf Magnesium	30,6 mg	61,2 mg	15 %
Sinkmetionien	12,2 mg	24,4 mg	
Verskaf Sink	2,1 mg	4,2 mg	38 %
Piridoksien (Vitamiën B ₆)	0,7 mg	1,4 mg	82 %

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

Suikervry

Ander bestanddele: Beesgelatienkapsules, magnesiumstearaat, silikondioksied.

KATEGORIE EN KLAS

D 33.7 Kombinasie Produk

FARMAKOLOGIESE AKSIE

Tribulus terrestris is 'n plant ekstrak wat na bewering luteïniserende hormoon (LH) stimuleer, wat die natuurlike produksie van testosteroon stimuleer. Huidige navorsing dui daarop dat die dominante furostanoliese saponiene, protodiosiene, die aktiewe bestanddeel in *Tribulus* is wat testosteroon-bevorderings effekte bied. Dit blyk dat die steroïdale saponieninhoud die vrylating van luteïniseringshormoon (LH) van die pituitêre klier stimuleer. LH reis dan via die bloedstroom na die testikels, waar dit testosteroonproduksie stimuleer. Daar word geglo dat protodiosien dehidroepiandrosteron (DHEA) produksie deur die biniere verhoog. Hierdie steroïde voorloper word dan testosteroon. Gevolglik kan *Tribulus* potensieel testosteroonvlakke verhoog en dus 'n groter toename in krag en spiermassa tydens oefening bevorder.

Magnesium is 'n alomteenwoordige element wat 'n belangrike rol in baie sellulêre reaksies speel. Meer as 300 metaboliese reaksies vereis magnesium as 'n kofaktor. Sommige belangrike voorbeelde sluit glikolise, vet en proteïenmetabolisme in. Magnesium dra ook by tot weefselvorming en die handhawing van normale spierfunksie.

Sink is 'n spoorn mineraal wat noodsaaklik is vir die funksionering van ensiematiese en ander sellulêre prosesse, insluitende die regulering van geen-uitdrukking, proteïenvouing en immuniteit. Sink help die liggaam met die metabolisering van koolhidrate, vette en proteïene en help met hielike weefselvorming. Sink dra ook by tot die handhawing van normale testosteroonvlakke in die bloed.

Vitamiën B₆ (piridoksien) help met die metabolisering van koolhidrate, vette en proteïene asook met weefselvorming. Vitamiën B₆ dra ook by tot normale energieopbrengende metaboliese en die vermindering van moegheid en uitputting, en die normale funksionering van die immuunstelsel.

INDIKASIES

Aangedui as 'n hulpmiddel om by te dra tot die normale proteïensintese en spierfunksie, asook om moegheid en uitputting te verminder.

KONTRA-INDIKASIES

Vermey met 'n bekende allergie/hipersensitiwiteit vir *Tribulus terrestris*, enige van sy bestanddele, of ander lede van die *Zygophyllaceae* familie.

Moenie gebruik tydens swangerskap of borsvoeding nie.

WAARSKUWINGS EN SPESIALE VOORSORGMATREËLS

Nie aanbeveel vir gebruik in kinders jonger as 18 jaar nie.

Daar is gevind dat *Tribulus* 'n bloeddrukverlagende effek het, en dus hipotensie/hipertensie medikasie kan beïnvloed.

Gebruik versigtig in pasiënte wat gebruik maak van beta-blokkeerders of kalsiumkanaalblokkeerders, aangesien *Tribulus* hul effekte kan verhoog as gevolg van die negatiewe chronotropiese aktiwiteit in hartspiere.

Bespreek asseblief met jou gesondheidspraktisyn voordat jy hierdie medisyne gebruik.

SWANGERSKAP EN LAKTASIE

Vermey die gebruik van hierdie produk tydens swangerskap en laktasie.

INTERAKSIES

Lig altyd jou professionele gesondheidspraktisyn in as jy enige ander medisyne neem.

DOSIS EN GEBRUIKSAANWYSINGS

Volwassenes: Neem verkieklik met slapenstyd. Tydens hoë-intensiteit oefening kan 'n addisionele dosis voor oefening geneem word.

Die dosis kan wissel tussen 2 en 7 kapsules per dag, afhange van die intensiteit van oefening.

Kapsules kan met slapenstyd geneem word of verdeel word tussen voor oefening en slapenstyd.

Voldoen aan 'n vyf-dag-aan/twee-dag-af regime vir 'n tydperk van agt weke, waarna 'n twee weke breek geneem moet word.

Moenie die aanbevole dosis oorskry nie. In die geval van oordosering skakel dringend u dokter of apteker. Indien hul nie beskikbaar is nie, kontak u naaste hospitaal of gifbeheersentrum.

Moenie medisyne wat vir jou voorgeskryf is met ander mense deel nie.

NEWE-EFFEKTE

Die volgende newe-effekte kan geassosieer word met die gebruik van **USN TESTO TRIBULUS**, veral as dit op 'n gereelde grondslag geneem word, en word onder hulle ooreenstemmende liggaamsorgaan klas gelys:

Gastro-intestinale versteurings: Buik-ongemak, winderigheid, diarree, hardlywigheid, naarheid, vomering, soolbrand, gastralgie, dispepsie.

Immuunstelsel versteuring: Hipersensitiwiteit en/of allergiese reaksies.

Kardiovaskulêre stelsel versteurings: Hipotensiewe effek.

Neurologiese stelsel versteurings: Hoofpyn, duiseligheid, onrustigheid, slapeloosheid, insomnie, depressie.

Nie alle newe-effekte wat vir hierdie medisyne aangemeld is, word in hierdie voubiljet genoem nie. Indien jou algemene gesondheid agteruitgaan of jy enige ongunstige effekte ervaar terwyl jy hierdie medisyne neem, raadpleeg asseblief jou dokter, apteker of ander gesondheidspraktisyn.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING
Gen. Behandeling is simptomaties en ondersteunend van aard.

IDENTIFIKASIE

Deurskynende beesgelatienkapsule wat bruin poeier bevat.

AAANBIEDING

Blou PET plastiekhouer met 'n wit USN-deksel, wat 100 kapsules bevat.

BERGINGSAAANWYSINGS

Bêre op koel (beneede 25 °C), droë plek.
STOOR BUITE DIE BEREIK VAN KINDERS.

REGISTRASIE NOMMER

Vir toekennings deur die Raad.

NAAM EN BESIGHEIDSADRES VAN DIE APPLIKANT

USN (Edms) Bpk
Gebou C, Southdowns Besigheidspark, 2de Vloer, Kareestraat 21, Irene Uitb. 54, 0157.
Tel: 0861 111 876

DATUM VAN PUBLIKASIE VAN HIERDIE VOUBILJET

Julie 2014

KOMPLEMENTÊRE MEDISYNE:

Dissipline: Kombinasie Produk - Westerse Kruiemidisyne & Gesondheidsaanvulling.

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

TES004/PI/B

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