

SKEDULERINGSSTATUS: Sal toegeken word sodra geregistreer.

GEREGISTREERDE HANDELSNAAM (en doseringvorm):

Trinovin (tablette)

SAMESTELLING:

Elke tablet bevat:

Trifolium pratense (Rooiklawer) droë plant-ekstrak 2,5 g, gestandaardiseer tot 40 mg isoflavone te bevat.

FARMAKOLOGIESE KLASSIFIKASIE:

Kategorie D Komplimentêre Medisyne.

FARMAKOLOGIESE WERKING:

Rooiklawer isoflavone is natuurlike bestaande molekules met 'n chemiese struktuur soortgelyk aan steroid-estrogene. Isoflavone kan baie van die chemiese ontstaan-meganismes reguleer, wat gebruik word om normale, gesonde prostaatfunksie te onderhou. Een ensiem wat Isoflavone kan inhibeer is 5 alpha-reduktase*. Hierdie ensiem beheer die omskakeling van testosteroon na di-hidrotesteroon. DHT is die meer potente (sterker) vorm van testosteroon en is die hoof hormoon in die prostaat. Daar word vermoed dat te veel DHT verantwoordelik is vir prostaatvergroting soos mans verouder. Isoflavone help met die regulering van DHT-produksie vir normale prostaatfunksie.

**** BAJ Evans, K Griffiths & MS Morton "Inhibition of 5-alpha-reductase in genital skin fibroblasts and prostate tissue by dietary lignans and Isoflavonoids" 1995 Dept of Child Health & Tenovous Cancer Research Centre, University of Wales College of Medicine, Health Park, Cardiff CF4, 4XN, UK**

Hierdie medisyne is nog nie deur die Medisynebeheerraad ge-evalueer nie, en is nie bedoel om 'n diagnose te maak, 'n siektetoestand te behandel, te voorkom of om as kuur gebruik te word nie.

INDIKASIES:

Mag help om urinêresimptome in mans met BPH (prostaatvergroting) te verlig*.

*Produksiespesifieke kliniese studie gedoen met Trinovin:

Three months of supplementation with Trinovin improved lower urinary tract symptoms (LUTS) in men who have clinical BPH. IPPS, nocturnal frequency & importantly quality of life were all significantly influenced from baseline.	The Use of Standardized Extract of Red Clover Isoflavones (Trinovin) for the alleviation of BPH Symptoms. Glen S Gerber, Franklin C Lowe, & Sameul Spigelman. Endo 2000
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PASIËNTINLIGTING VOUBILJET

SKEDULERINGSSTATUS: Sal toegeken word sodra geregistreer.

GEREGISTREERDE HANDELSNAAM (en doseringvorm):

Trinovin (tablette)

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Elke tablet bevat:

Trifolium pratense (Rooiklawer) droë plant ekstrak 2,5 g, gestandaardiseer tot 40 mg isoflavone te bevat.

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KONTRA-INDIKASIES:

Hipersensitiwiteit teenoor enige van die bestanddele.

WAARSKUWINGS EN SPESIALE VOORSORGMATREËLS:

Maak seker dat u op datum is met prostaatondersoek. Raadpleeg u geneesheer indien u huidige enige voorskrif of oor die toonbankmedikasie gebruik.

Uitwerking op die vermoë om te bestuur en masjinerie te gebruik:

Trinovin behoort nie die vermoë om te bestuur of die gebruik van masjinerie te beïnvloed nie. Dit is egter altyd raadsaam

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INTERAKSIES:

Daar is geen interaksies bekend met die gebruik van Trinovin.

DOSIS EN GEBRUIKSAANWYSINGS:

Een tablet daaglik met 'n maaltyd. Individuele resultate mag verskil, maar meeste mans sal 'n verbetering in simptome ervaar binne 3-8 weke se daaglikse dosering.

NEWE-EFFEKTE:

Geen nuwe-effekte is gerapporteer met die aanbevole dosis.

BEKENDE SIMPTOME VAN OORDOSERING EN DIE BEHANDELING DAARVAN:

Behandeling is simptomaties en ondersteunend.

IDENTIFIKASIE:

'n Gespikkelde groen/grys ronde bikonveksgevormde tablet.

Rooibruin gekleur.

AANBIEDING:

Trinovin is beskikbaar in 'n deursynende stolpakkie van 30 tablette verpak binne in 'n kartonhouer.

BERGINGSINSTRUKSIES:

Moet nie gebruik indien die stolpakkie gebreek is. Sodra oopgemaak hou dit verseël en moet geberg word in 'n droë omgewing onder 30 °C. Hou buite die bereik van kinders.

REGISTRASIONOMMER:

Sal toegeken word.

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE REGISTRASIESERTIFIKAAI:

KCP Products cc,

No 9 Groen Straat,

Krystna 6570 Suid Afrika

Web adres: www.ahealthysa.com // www.trinovin.com.au

epos: kcpinfo@mweb.co.za Tel no: +27 (0) 44 382 0382

DATUM VAN PUBLISERING VAN HIERDIE VOUBILJET:

15 Mei 2014

Pro-Print

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SCHEDULING STATUS: To be allocated once registered.

PROPRIETARY NAME (and dosage form):

Trinovin (Tablets)

COMPOSITION:

Each tablet contains:
Trifolium pratense (Red Clover) dry herb extract 2.5 g, standardised to contain 40 mg isoflavones.

PHARMACOLOGICAL CLASSIFICATION:

Category D Western herbal complementary medicine.

PHARMACOLOGICAL ACTION:

Red clover isoflavones are naturally occurring molecules with a chemical structure similar to that of steroidal estrogens. Isoflavones can modulate many of the chemical pathways that are involved in maintaining normal function & health in the prostate. One enzyme isoflavones are known to inhibit is 5-Alpha Reductase*. This enzyme converts testosterone to DHT (Di Hydro Testosterone). DHT is the more potent form of testosterone and is the main male hormone in the prostate. It is thought that an increase in DHT is responsible for prostate growth as men age. Isoflavones help to regulate DHT production to maintain normal prostate function.

** **BAJ Evans, K Griffiths & MS Morton "Inhibition of 5-alpha-reductase in genital skin fibroblasts & prostate tissue by dietary lignans & Isoflavonoids" 1995 Dept of Child Health & Tenovus Cancer Research Centre, University of Wales College of Medicine, Health Park, Cardiff CF4, 4XN, UK**

This medicine has not been evaluated by the Medicines Control Council and is not intended to diagnose, treat, cure or prevent any disease.

INDICATIONS:

A patented clinically proven extract which may help relieve BPH symptoms*.

*Product Specific Clinical Trial done with Trinovin:

Three months of supplementation with Trinovin improved lower urinary tract symptoms (LUTS) in men who have clinical BPH. IPPS, nocturnal frequency & importantly quality of life were all significantly influenced from baseline.	The Use of Standardized Extract of Red Clover Isoflavones (Trinovin) for the alleviation of BPH Symptoms. Glen S Gerber, Franklin C Lowe, & Sameul Spigelman. Endo 2000
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CONTRAINDICATIONS:

Hypersensitivity to any of the ingredients.

WARNINGS AND SPECIAL PRECAUTIONS:

Ensure you are up to date with prostate examinations. If you are currently taking any prescription or over counter medicine consult your healthcare professional.

Effects on ability to drive and use machines: Trinovin is not likely to impair your ability to drive vehicles or operate machinery. However do take care if you take Trinovin until you know how it will affect you.

INTERACTIONS:

No known interactions.

DOSAGE AND DIRECTIONS FOR USE:

One tablet daily with a meal.

SIDE-EFFECTS:

No side-effects have been reported with the recommended dosage.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF TREATMENT:

Treatment is symptomatic and supportive.

IDENTIFICATION:

A mottled green/grey round biconvex shaped tablet coated beige

PRESENTATION:

30 tablets in a transparent PVC/PVDC blister in an outer carton.

STORAGE INSTRUCTIONS:

Store at or below 30 °C in a cool dry place. Keep out of reach of children.

REFERENCE NUMBER:

To be allocated.

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

KCP Products cc,
No 9 Green Street
Knysna 6570 South Africa
Web address: www.ahealthysa.com // www.trinovin.com.au
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Tel no: +27 (0) 44 382 0382

DATE OF PUBLICATION OF THE PACKAGE INSERT:

15 May 2014



PATIENT INFORMATION LEAFLET

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Date: 20th October 2014
Operator: Elizabeth Choudree
Customer: KCP Products cc
Product Name: Trinovin Tablets Leaflet
Product Code: --
Dimensions: 120 x 210 mm
Fold Size: 120 x 27 mm
Font Size: 6 point Helvetica Condensed
Colours: (1) Black
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Barcode: --
Pharmacode: (Ref. 9) 101
Stock: 50 gsm Aviator
Proof Status: 4th (Fourth)
Proof read by: _____

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No alterations – proceed as soon as possible
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