

SKEDULERINGSSTATUS: Sal toegeken word sodra geregistreer.

Geregistreeerde Handelsnaam (en doseringvorm):

Promensil Menopause Dubbelsterkte (tablette)

SAMESTELLING:

Elke tablet bevat:

Trifolium pratense droë plant 5.0 g, gestandaardiseerd om 80 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. Rooiklawer isoflavone mimiek wat die liggaamse estrogene doen. As gevolg hiervan is daar 'n interaksie met die liggaamse estrogeenreseptor. Rooiklawer isoflavone het 'n voorkeur affiniteit om die beta-estrogeenreseptore in die brein, beensstruktuur en in die kardiovaskulêre sisteem te aktiveer. Rooiklawer isoflavone het egter 'n baie lae aktiwiteit op die alpha-reseptore wat in die borste en uterus voorkom. 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:

Promensil Menopause Dubbelsterkte vir pasiënte wat meer erg simptome ervaar. Mag help om warmgloede, nagswete en matige angs tydens menopause te verlig.*

***Produk Spesifieke Kliniese Toetse met Promensil Dubbelsterkte:**

- Significant average decrease of 74% in daily hot flush / night sweat frequency and Kupperman index was achieved in the red clover groups. Red Clover 80mg used in study - Promensil Double Strength. - Randomised double blind placebo controlled	"The effect of red clover isoflavone supplementation over vasomotor & menopausal symptoms in postmenopausal women" Markus Lipovac et al - Gynecological Endocrinology 2011,1-5
- Symptoms of anxiety & depression were reduced by 76.9% in the total HADS score (Hospital Anxiety & Depression Scale) & 80.6% in the total ZDS score (Zung's self-rating depression scale). These results were significant!! - Randomised double blind, placebo controlled.	Improvement of postmenopausal depressive & anxiety symptoms after treatment with isoflavones derived from red clover 80mg (Promensil Double Strength) Lipovac M, Chedraui P, Gruenhut C, Gocan A Stammier et al : Maturitas 65 (2010) 258-264

KONTRA-INDIKASIES:

Hipersensitieweit teenoor enige van die bestanddele. Swangerskap en laktasie omdat veiligheid nog nie bo alle twyfel vasgestel is nie.

WAARSKUWINGS EN SPESIALE VOORSORGMATREËLS:

Maak seker dat u op datum is met mammogramme en

ginekologiese ondersoek.

Raadpleeg u geneesheer indien u: Huidglik hormoonvervanging medikasie (HVT) neem of enige voorskrif of oor die toonbank medikasie neem.

Uitwerking op die vermoë om te bestuur en masjinerie te gebruik: Promensil Dubbelsterkte behoort nie die vermoë om te bestuur of die gebruik van masjinerie te beïnvloed nie. Dit is egter altyd raadsaam om bedagsaam te wees vir bogenoemde totdat u seker is daar is nie newe-effekte nie.

INTERAKSIES:

Tamoxifen

Rooiklawer isoflavone ('n phyto-estrogene) mag die effektiwiteit van tamoxifen beïnvloed. Raadpleeg u onkoloog indien u **Promensil Menopause Dubbelsterkte** saam met tamoxifen wil neem.

SWANGERSKAP EN LAKTASIE:

Die veiligheid met die neem van **Promensil Menopause Dubbelsterkte** tydens swangerskap en borsvoeding is nog nie bo alle twyfel bewys nie.

DOSIS EN GEBRUIKSAANWYSINGS:

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

NEWE-EFFEKTE:

Geen newe-effekte is gerapporteer met die aanbevole dosis. Daar is geen gewigstoename gevind in 'n dubbelblinde placebo gekontroleerde 12-weke studie.

BEKEUDE SIMPTOME VAN OORDOSERING EN DIE

BEHANDELING DAARVAN:

Behandeling is simptomaties en ondersteunend.

IDENTIFIKASIE:

'n Ovaal film bedekte tablet. Bruin gekleur.

AANBIEDING:

Promensil Menopause Dubbelsterkte is beskikbaar in 'n deurskynende stolkpakkie van 30 tablette verpak binne in 'n kartonhouer.

BERGINGSINSTRUKSIES:

Moet nie gebruik indien die stolkpakkie gebreek is. Sodra oopgemaak hou dit versêel 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 HOER VAN DIE

REGISTRASIESERTIFIKAAT:

KCP Products cc,

Posbus 1072

Krystna 6570

Web adres: www.ahealthysa.com

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

DATUM VAN PUBLISERING VAN HIERDIE VOUBILJET:

17 Maart 2017

Pro-Print



PASIËNTINLIGTING VOUBILJET

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INDIKASIES:

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***Produk Spesifieke Kliniese Toetse met Promensil Dubbelsterkte:**

- Significant average decrease of 74% in daily hot flush / night sweat frequency and Kupperman index was achieved in the red clover groups. Red Clover 80mg used in study - Promensil Double Strength. - Randomised double blind placebo controlled	"The effect of red clover isoflavone supplementation over vasomotor & menopausal symptoms in postmenopausal women" Markus Lipovac et al - Gynecological Endocrinology 2011,1-5
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DATUM VAN PUBLISERING VAN HIERDIE VOUBILJET:

17 Maart 2017

Pro-Print

SCHEDULING STATUS: To be allocated once registered.

PROPRIETARY NAME (and dosage form):

Promensil Menopause Double Strength (tablets)

COMPOSITION

Each tablet contains:
Trifolium pratense dry herb 5.0 g, standardised to contain 80 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 mimic the human body's natural estrogen. As a result, red clover isoflavones interact with the human estrogen receptor. Red clover isoflavones preferentially activate the beta estrogen receptors found in the brain, bones and cardiovascular system. Red clover isoflavones show very little activity on the alpha estrogen receptors found in breast and uterine tissue.

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

INDICATIONS:

Promensil Menopause Double Strength for patients experiencing more severe symptoms. May help relieve hot flushes, night sweats and mild anxiety during menopause*.

***Product Specific Clinical Trials with Promensil Double Strength:**

- Significant average decrease of 74% in daily hot flush / night sweat frequency and Kupperman index was achieved in the red clover groups. Red Clover 80mg used in study - Promensil Double Strength. - Randomised double blind placebo controlled	"The effect of red clover isoflavone supplementation over vasomotor & menopausal symptoms in postmenopausal women" Markus Lipovac et al - Gynecological Endocrinology 2011,1-5
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CONTRAINDICATIONS:

Hypersensitivity to any of the ingredients.
Pregnancy or lactation as safety has not been established.

WARNINGS AND SPECIAL PRECAUTIONS:

Ensure you are up to date on mammograms and gynaecological evaluations.

If you are currently taking hormone replacement therapy (HRT), any prescription or over counter medicine consult your healthcare professional.

Effects on ability to drive and use machines

Promensil Double Strength is not likely to impair your ability to drive vehicles or operate machinery. However do take care if you take **Promensil Double Strength** until you know how it will affect you.

INTERACTIONS:

Tamoxifen: Red Clover isoflavones (a phyto-estrogen) can affect the effectiveness of tamoxifen. Consult your oncologist if you wish to use **Promensil Menopause Double Strength** whilst taking tamoxifen.

PREGNANCY AND LACTATION:

The safety of **Promensil Menopause Double Strength** during pregnancy and whilst breastfeeding has not been established.

DOSAGE AND DIRECTIONS FOR USE:

One tablet daily with a meal. While individual responses vary many women will notice a difference in symptoms within 3 to 8 weeks of initiating therapy.

SIDE-EFFECTS:

No side-effects have been reported with the recommended dosage. No weight gain was seen in a double blind placebo-controlled 12 weeks study.

INTERACTIONS:

No known symptoms with the use of **Promensil Menopause Double Strength**.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF TREATMENT:

Treatment is symptomatic and supportive.

IDENTIFICATION:

An oblong shaped, film coated, brown tablet.

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,
PO Box 1072
Knysna 6570
Web address: www.ahhealthysa.com
email: kcinfo@mwweb.co.za
Tel no: +27(0)44 382 0382

DATE OF PUBLICATION OF THE PACKAGE INSERT

17 March 2017

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DATE OF PUBLICATION OF THE PATIENT INFORMATION LEAFLET:

17 March 2017



PRO-PRINT (PTY) LTD
THE PROFESSIONALS IN PRINT

REPRO

Date: 27th March 2017
Operator: Elizabeth Choudree
Customer: KCP Products cc
Product Name: Promensil Menopause Tablets Leaflet
Product Code: --
Dimensions: 240 x 120 mm
Fold Size: 120 x 30 mm
Font Size: 6 point Helvetica Condensed
Colours: (1) Black
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Barcode: --
Pharmacode: (Ref. 12) 010
Stock: 50 gsm Aviator
Proof Status: 1st (First)
Proof read by:

Reset: Alterations: Disk/Possie:
No alterations – proceed as soon as possible
Note alterations – Further proof is required

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