

SKEDULERINGSSTATUS: Sal toegeen word sodra geregistreer.

GEREGISTREERDE HANDELSNAAM (en doseringvorm):
Promensil Menopause (tablette)

SAMESTELLING:

Elke tablet bevat: *Trifolium pratense* (Rooiklawer) droë plant-ekstrak 2,5 g, gestandaardiseerd om 40 mg isoflavone te bevat.

FARMAKOLOGIESE KLASSEFIKASIE:

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 estrogene reseptor. Rooiklawer isoflavone het 'n voorkeur affiniteit om die beta estrogene reseptore in die brein, beenstruktuur en in die kardiovaskulêre sisteem te aktiveer. Rooiklawer isoflavone het daarenteen 'n baie lae aktiwiteit op die alpha-reseptore wat in die borste en uterus voorkom. Hierdie medisyne is nog nie deur die Medisyne beheerraad 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 warm gloede en nagswete tydens menopause te verlig.

***Produkspesifieke Kliniese studies met Promensil Menopause:**

<ul style="list-style-type: none">- Decrease in hot flushes of 60%- 73% of women experienced a significant reduction in hot flushes within 6 weeks- Randomised Double Blind placebo-controlled	Isoflavones from red clover (Promensil®) significantly reduced menopausal hot flush symptoms compared to placebo. Vande Weijer PHM & Barentsen R. <i>MATURITAS</i> 2002;42:187-193
Significantly decreased menopausal symptoms (Kupperman) index score. Randomised Double Blind - Placebo controlled	The effect of red clover isoflavones on menopausal symptoms, lipids & vaginal cytology in menopausal women Hidalgo LU et al. <i>Gyn Endo</i> 2005;21(5):257-264

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.

PASIËNTINLIGTING VOUBILJET

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Maak seker dat u op datum is met mammogramme en ginekologiese ondersoek. Raadpleeg u geneesheer indien u: Huidiglik hormoon-
vervangende medikasie (HVT) neem of enige voorskrif of oor die toonbank medikasie neem.

Uitwerking op die vermoë om te bestuur en masjinerie te gebruik: Promensil Menopause behoort nie die vermoë om te bestuur of die gebruik van masjinerie te beïnvloed

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INTERAKSIES:

Tamoxifen

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

SWANGERSKAP EN LAKTASIE:

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

DOSIS EN GEBRUIKSAANWYSINGS:

1-2 tablette 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 nuwe-effekte is gerapporteer met die aanbevole dosis. Daar is geen gewigstoename gevind in 'n dubbelblinde placebo gekontroleerde studie.

BEKENDE SIMPTOME VAN OORDOSERING EN DIE

BEHANDELING DAARVAN:

Behandeling is simptomaties en ondersteunend.

IDENTIFIKASIE:

'n Ronde film bedekte tablet. Beige gekleur.

AANBIEDING:

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

BERGINGSINSTRUKSIES:

Moet nie gebruik indien die stolpakkie gebreek is. Sodra oopgemaak hou dig versêel en moet berging 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, Knysna 6570

Web adres: www.ahealthysa.com

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

Datum van publiseren van hierdie voubiljet:

17 Maart 2017

Pro-Print

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SCHEDULING STATUS: To be allocated once registered.

PROPRIETARY NAME (and dosage form):

Promensil Menopause (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. Red clover 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 receptors found in breast and uterine tissue.

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

INDICATIONS:

May help relieve hot flushes and night sweats during menopause*.

***Product Specific Clinical Trials done with Promensil Menopause:**

<ul style="list-style-type: none">- Decrease in hot flushes of 60%- 73% of women experienced a significant reduction in hot flushes within 6 weeks- Randomised Double Blind placebo controlled	Isoflavones from red clover (Promensil*) significantly reduced menopausal hot flush symptoms compared to placebo. Vande Weijer PHM & Barentsen R. <i>MATURITAS</i> 2002;42:187-193
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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 Menopause is not likely to impair your ability to drive vehicles or operate machinery. However do take care if you take **Promensil Menopause** until you know how it will affect you.

INTERACTIONS:

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

PREGNANCY AND LACTATION:

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

DOSAGE AND DIRECTIONS FOR USE:

1-2 tablets 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.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF TREATMENT:

Treatment is symptomatic and supportive.

IDENTIFICATION:

A round shaped, film coated beige 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,
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DATE OF PUBLICATION OF THE PACKAGE INSERT

17th March 2017

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17th March 2017



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THE PROFESSIONALS IN PRINT

REPRO

Date: 24th March 2017
Operator: Elizabeth Choudree
Customer: KCP Products cc
Product Name: Promensil Menopause Tablets Leaflet
Product Code: --
Dimensions: 120 x 210 mm
Fold Size: 120 x 27 mm
Font Size: 6 point Helvetica Condensed
Colours: (1) Black
--
Barcode: --
Pharmacode: (Ref. 10) 100
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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