

FEMOLENE

MENOPAUSE SR

SCHEDULING STATUS:

Will be allocated upon registration.

PROPRIETY NAME AND DOSAGE FORM:

Femolene Menopause SR 30 Capsules.

COMPOSITION:

Each capsule contains:

Active ingredients:

Ingredients	Quantity per Capsules
Vitamin B6	9.4 mg
Soya Isoflavones 40%	50 mg

In-active ingredients: Calcium Carbonate, Magnesium Stearate, Aerosil 200

Possible allergen: Soya

PHARMACOLOGICAL CLASSIFICATION:

D 21.8 Female sex hormones.

PHARMACOLOGICAL ACTION:

Vitamin B6 - Co-factor in the regulation of the action of steroid hormones.

Soya Isoflavones - Contains isoflavone glucosides genistein and daidzin which are metabolised in the bowel by β -glucosidase enzymes into aglycones which are then absorbed. Soya Isoflavones are heterocyclic phenols with structural similarity to estradiol-17 β and selective estrogen receptor ER β modulators.

The metabolite of daidzin, equol however also displays ER α receptor activity.

Soya isoflavones helps to reduce hot flushes and memory loss associated with menopause.

INDICATIONS:

FEMOLENE Menopause SR helps alleviate the symptoms of menopause.

CONTRAINDICATIONS:

Do not use if you currently have or previously had breast cancer and / or breast tumors or if you are predisposed to breast cancer, as indicated by abnormal mammogram and/or biopsy, or family member with breast cancer. Thyroid disorders, bleeding disorders, surgery (anti-platelet effects), anaemia, liver disorders, schizophrenia, antioplasty, Leber's disease, diabetes, haemochromatosis, hypercalcaemia, renal osteodystrophy with hyperphosphataemia, epilepsy, kidney stones, cardiac conditions.

WARNINGS AND SPECIAL PRECAUTIONS:

See CONTRAINDICATIONS.

Caution is advised if any hypersensitivity to the ingredients.

Consult your doctor or healthcare practitioner if your symptoms do not improve.

INTERACTIONS:

Hormone replacement therapy (HRT), anti-coagulants, tetracycline antibiotics, MAO, anticonvulsants, chemotherapy, statins.

PREGNANCY AND LACTATION:

Not recommended during pregnancy or lactation.

DOSAGE AND DIRECTION FOR USE:

Take one capsule in the morning, after breakfast

SIDE EFFECTS:

Headaches, nausea, vomiting, diarrhoea, yellow-orange discolouration of the urine.

IDENTIFICATION:

Maroon coloured oblong capsule.

PRESENTATION:

30 capsules packed in white 225 ml plastic bottle in an outer carton.

STORAGE INSTRUCTIONS:

Store in a cool, dry place at or below 25 °C.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

Will be allocated by the Council upon registration.

NAME AND BUSINESS ADDRESS OF THE CERTIFICATE HOLDER:

Kenza Health (Pty) Ltd, 51 APD Office Park, Kelvin Street, Kya Sands, South Africa.

Customer Care: 0860 103 359 | www.femolene.co.za

DATE OF PUBLICATION OF THIS PACKAGE INSERT:

March 2017

DISCLAIMER:

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

FEMOLENE

MENOPAUSE SR

SKEDULERINGSSTATUS:

Sal toegeken word met registrasie.

EIENDOMSNAAM EN DOSEERVORM:

Femolene Menopause SR 30 Kapsules

SAMESTELLING:

Elke kapsule bevat:

Aktiewe bestanddele:

Bestanddeel	Hoeveelheid per kapsule
Vitamine B6	9.4 mg
Soja Isoflavone 40%	50 mg

Onaktiewe bestanddele: Kalsiumkarbonaat, Magnesiumstearaat, Aerosil 200

Moontlike allergeen: Soja

FARMAKOLOGIESE KLASSIFIKASIE:

D 21.8 Vroulike seks hormone.

FARMAKOLOGIESE AKSIES:

Vitamine B6 – Ko-faktor vir die regulering van die aksie van steroïedhormone.

Soja Isoflavone – Bevat isoflavoonglukosiede genisteïen en diadseïen wat in die derm deur β -glukosidase ensieme in aglikone gemetaboliseer word wat dan geabsorbeer word. Soja isoflavone is heterosikliese fenole wat strukturele ooreenkomste met oestradiol-17 β en die selektiewe estrogeen reseptor-ER β -moduleerders toon. Die metaboliet van diadseïen, equol, vertoon ook ER α -reseptor aktiwiteit. Soja isoflavone help met geheueverlies en verminder warmgloede wat met menopouse geassosieer word.

INDIKASIES:

FEMOLENE Menopause SR help om simptome van menopouse te verlig.

KONTRA-INDIKASIES:

Moenie gebruik as jy tans of voorheen borskanker en/of borsgewasse gehad het nie, of as jy vatbaar vir borskanker is, soos aangedui deur 'n abnormale mammogram en/of biopsie, of familielid met borskanker het nie.

Skildklierversteurings, bloedingversteurings, sjirurgie (anti-plaatjie effekte), anemie, lewerversteurings, skisofrenie, angioplastie, Leber se siekte, suikersiekte, heamochromatose, hiperkalsemia, renale osteodistrofie met hiperfosfatemia, epilepsie, nierstene, harttoestande.

WAARSKUWINGS EN SPESIALE VOORSORGMATREËLS:

Sien KONTRA-INDIKASIES.

Versigtigheid moet aan die dag gelê word indien 'n persoon hipersensitief is vir enige van die bestanddele.

Raadpleeg jou dokter of gesondheidsorgkundige as jou simptome nie verbeter nie.

INTERAKSIES:

Hormoonvervangingsterapie (HVT), anti-koagulante, tetrasiklien antibiotika, mono-amienoksidase-inhibeerders, antikonvulsante, chemoterapie, statiene.

SWANGERSKAP EN BORSVOEDING:

Nie aanbeveel gedurende swangerskap en borsvoeding nie

DOSIS EN GEBRUIKSAANWYSINGS:

Neem een kapsule in die oggend na ontbyt.

NEWE EFFEKTE:

Hoofpyn, naarheid, braking, diaree, geel-oranje verkleuring van uriene.

IDENTIFIKASIE:

Maroenkleurige langwerpige Kapsule.

AANBIEDING:

30 kapsules verpak in 'n wit 225 ml bottel in 'n buite karton.

BERGINGSINSTRUKSIES:

Bewaar in 'n koel, droë plek teen of benede 25 °C.

HOU BUIITE BEREIK VAN KINDERS.

REGISTRASIENOMMER:

Sal toegeken word met registrasies deur Raad.

NAAM EN BESIGHEIDSADRES VAN HOUER VAN**REGISTRASIESERTIFIKAAT:**

Kenza Health (Edms) Bpk, ADP Kantoorpark no 51, Kelvin Straat, Kya Sands, Suid-Afrika.
Kliëntediens: 0860 103 359 | www.femolene.co.za

DATUM VAN PUBLIKASIE VAN VOUBILJET:

Maart 2017

VRYWARING:

Hierdie medisyne is nie deur die Medisynebeheerraad geëvalueer nie. Hierdie medisyne is nie bedoel om enige siekte te diagnoseer, behandel, genes of voorkom nie.