

PROFESSIONAL INFORMATION

SCHEDULING STATUS: **S0**

Category D: Complementary medicine.

Discipline: Discipline Specific

33.7 Combination Product



PROPRIETARY NAME, STRENGTH, PHARMACEUTICAL

FORM - ESTROFACTORS[®], 60 Capsules

COMPOSITION

Each one (1) capsule of ESTROFACTORS[®] contains the following actives:

Mixed Carotenoids (including beta-carotene, alpha-carotene, cryptoxanthin, zeaxanthin and lutein) Providing: Vitamin A - 750 mcg	1.8 mg
Vitamin E (as d-alpha tocopheryl succinate and d-alpha tocopheryl polyethylene glycol 1000 succinate†††)	36.2 mg
Riboflavin	1 mg
Vitamin B6 (as pyridoxine HCl)	50 mg
Folate (as calcium L-5-methyltetrahydrofolate)	340 mcg
	DFE
Vitamin B12 (as methylcobalamin)	30 mcg
Rice Protein Matrix and Polyphenols from Hops (Humulus lupulus L.) Cone Extract (standardized to 2.5% xanthohumol)	250 mg
Diindolylmethane (DIM) Complex††† [starch, diindolylmethane, d-alpha tocopheryl polyethylene glycol 1000 succinate, phosphatidylcholine (from sunflower), and silica] providing 37.5 mg DIM	150 mg
Decaffeinated Green Tea (Camellia sinensis) Leaf Extract [standardized to 60% (60 mg) catechins and 40% (40 mg) epigallocatechin gallate (EGCG)]	100 mg
L-Cysteine (as N-acetyl-L-cysteine)	50 mg
7-Hydroxymatairesinol (HMR) Potassium Acetate Complex	50 mg
Proprietary Mix of Curcumin [from Curcuma longa L. rhizome extract standardized to 40% (20 mg) curcuminoids] and Fenugreek Galactomannans (from Trigonella foenum-graecum seed extract)	50 mg

†Vegetarian capsule

††From BioResponse DIM[®]

††† As BioResponse DIM[®] (A proprietary, enhanced bioavailability complex containing Diindolylmethane licensed from BioResponse, L.L.C., Boulder, Colorado.)

Inactive Ingredients : Capsule [hydroxypropylmethylcellulose and sodium copper chlorophyllin (color)], microcrystalline cellulose, magnesium stearate (vegetable), and silicon dioxide.

This product is suitable for non-GMO, gluten free (Sugar Free)

PHARMACOLOGICAL CLASSIFICATION - Complementary Medicine

INDICATION & PHARMACOLOGICAL ACTION

ESTROFACTORS[®] is a unique formula featuring phytonutrients that provide targeted support for healthy estrogen metabolism. Offering highly bioavailable BioResponse DIM[®] which may promote the 2-hydroxy estrone pathway. HMR lignans are also featured to increase the production of enterolactone, which has been associated with reduced aromatase activity.

Ingredients	Uses for ingredient
Mixed Carotenoids Providing: Vitamin A - 750 mcg	Provitamin A carotenoids can be converted into vitamin A, which is essential for growth, immune system function, and eye health.
Vitamin E	Your body uses vitamin E for multiple purposes, including protecting you from oxidative stress and supporting your immune system.
Riboflavin	Antioxidants, such as riboflavin, can fight free radicals and may reduce or help prevent some of the damage they cause. Riboflavin is also needed to help the body change vitamin B6 and folate into forms it can use. It is also important for growth and red blood cell production.
Vitamin B6 (as pyridoxine HCl)	Vitamin B6 helps the body make several neurotransmitters, chemicals that carry signals from one nerve cell to another.
Folate (as calcium L-5-methyltetrahydrofolate)	Folic acid is crucial for proper brain function and plays an important role in mental and emotional health. It aids in the production of DNA and RNA, the body's genetic material.
Vitamin B12 (as methylcobalamin)	Methylcobalamin improves their nerve condition and promotes regeneration of the damaged nerves.

CONTRA INDICATIONS:

If you are taking any chronic medication, do not use this product without consulting your healthcare professional. Do not take **ESTROFACTORS[®]** if you are hypersensitive (allergic) to any of the ingredients. If you have allergies, be sure to check with your healthcare professional before taking this supplement. **Surgery:** **ESTROFACTORS[®]** might increase the risk of bleeding during and after surgery. Stop using **ESTROFACTORS[®]** at least 2 weeks before a scheduled surgery.

INTERACTIONS

Always tell your healthcare professional if you are taking any other medicine. It is possible that exposure of certain supplement ingredients may interfere with certain medications. (See Warnings & Special precautions)

DOSEAGE AND DIRECTIONS FOR USE

Adults: Take two (2) capsules daily or as directed by your healthcare practitioner. Do not take more than the recommended dose.

SIDE EFFECTS

Should your general health worsen, or if you experience any untoward effects while being exposed to this product, please consult your doctor, pharmacist or other healthcare professional for advice.

KNOWN SYMPTOMS OF OVER DOSAGE AND PARTICULARS OF ITS TREATMENT

See side-effects.

Treatment: Discontinue use and consult your doctor, pharmacist or other healthcare professional for advice.

WARNING AND SPECIAL PRECAUTIONS

Should you have any of the following diagnosed conditions, consult with your healthcare professional before use: : History of asbestos exposure, Bleeding disorders, Heart disease, Diabetes, Head and neck cancer, Weak and brittle bones (osteoporosis), Prostate cancer, An inherited eye condition that causes poor night vision and loss of side vision (retinitis pigmentosa), Stroke, Liver disease, Post-surgical stent placement, Weight loss surgery, Procedures to widen narrowed arteries (angioplasty), Seizure disorder. If you are taking the following medication, please consult with your healthcare professional before taking: Medications changed by the liver, Medications for cancer (Chemotherapy), blood clotting (Anticoagulant / Antiplatelet drugs), Warfarin (Coumadin), Antibiotics for Cancer (Antitumor Antibiotics), Antibiotics (Tetracycline antibiotics), Amiodarone (Cordarone), Phenobarbital (Luminal), Medications for high blood pressure (antihypertensive drugs), 5-Fluorouracil, Medications for diabetes (Antidiabetes drugs). If any of the following happens, stop using **ESTROFACTORS[®]** and tell your doctor or go to the casualty department at your nearest hospital:

- Allergic reactions – rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing; These are all very serious effects. If you have them, you may have had a serious reaction to **ESTROFACTORS[®]**. You may need urgent medical attention or hospitalisation.

Side effects that usually do not require medical attention (report to your healthcare professional if they continue):

- nausea/vomiting.

These are all very serious effects. If you have them, you may have had a serious reaction to **ESTROFACTORS[®]**. You may need urgent medical attention or hospitalisation.

Seek advice from a healthcare professional if you have any medical condition.

Discontinue use immediately should any adverse reaction occur.

Read this leaflet carefully because it contains important information for you.

This product is available without a doctor's prescription.

- Keep this leaflet. You may need to read it again.
 - Do not share medication with any other person.
 - Ask your pharmacist if you need more information or advice.
 - You must consult a doctor should your condition worsen or does not improve.
- DO NOT USE THIS PRODUCT:
- If you are hypersensitive (allergic) to any of the ingredients listed.
 - Do not accept this package if seals are broken.

Ingredients	Uses for ingredient
Rice Protein Matrix and Polyphenols from Hops (Humulus lupulus L.) Cone Extract	It may have antioxidant properties.
Diindolylmethane (DIM) Complex†††	Supports healthy hormone balance by regulating oestrogen levels, in men and women.
Decaffeinated Green Tea (Camellia sinensis)	This species is rich in polyphenolic compounds and catechins. Catechin derivatives have shown pronounced antiviral activity, observed for derivatives carrying moderate chain length.
L-Cysteine (as N-acetyl-L-cysteine)	NAC may stimulate the synthesis of glutathione, a compound that helps fight free radicals, unstable atoms that can cause inflammation and damage.
7-Hydroxymatairesinol (HMR) Potassium Acetate Complex	Lignans are plant polyphenols which may possess anticancer, antioxidant, antimicrobial, anti-inflammatory and immunomodulatory activities.
Proprietary Mix of Curcumin [from Curcuma longa L. rhizome Fenugreek Galactomannans (from Trigonella foenum-graecum seed extract)	The main role of fenugreek soluble fibre in combination with curcumin is to increase plasma and tissue concentrations of curcumin by slowing down its digestion and elimination

STORAGE INSTRUCTION

Store in a cool, dark place, below 25 °C. Protect from direct sunlight and heat.

Store in the original bottle. Keep the bottle tightly closed.

Replace the protective cap after each use. Do not use after the expiry date stated on the bottle. Do not use **ESTROFACTORS[®]** if you notice visible signs of deterioration.

IDENTIFICATION - Dark green, vegetable capsule.

PRESENTATION - A white 175 ml HDPE bottle with a white cap, induction seal, tamper shrink seal, wadding and silica gel sachet.

REGISTRATION NUMBER - To be allocated by SAHPRA upon registration.

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

NAME AND BUSINESS ADDRESS OF APPLICANT

Distributed by: Ampiro Advanced Development Products (Pty) Ltd
Unit 3, Eastgate Business Park, 1 South Road, Eastgate Extension, Sandton, 2146

Tel: 011-802-8101

DATE OF PUBLICATION

To be allocated by the regulatory authority.

Document reference: EST.PI.V1 11-24

PROFESIONELE INLIGTINGSBLAD

SKEDULERINGSSTATUS: S0

Kategorie D: Komplementêre medisyne.

Dissipline: Dissiplinespesifiek

33.7 Kombinasie produk

HANDELSNAAM EN DOSEERVORM,

ESTROFACTORS® , 60 Kapsules

SAMESTELING

Elke (1) kapsule ESTROFACTORS® bevat die volgende aktiewe stowwe:

Gemengde karotenolede (insluitend beta-karoteen, alfa-karoteen, kriptoksantien, zeaxantien en luteien) Voorsien: Vitamien A - 750 mcg	1,8 mg
Vitamien E (as d-alfa-tokoferylsuksinaat en d-alfa-tokoferylpoliëteenglikol 1000 suksinaat††)	36,2 mg
Riboflavin	1 mg
Vitamien B6 (as piridoksien HCl)	50 mg
Folaat (as kalsium L-5-metiltetrahidrofolaat)	340 mcg
	DFE
Vitamien B12 (as metielkobalamien)	30 mcg
Rysproteïenmatriks en polifenole uit hop (Humulus lupulus L.) Keël uittreksel (gestandaardiseer tot 2.5% xanthohumol)	250 mg
Diindolylmethane (DIM) Kompleks††† [stysel, diindolylmethane, d-alfa-tokoferyl poliëteenglikol 1000 suksinaat, fosfatidietilcholine (van sonneblom en silika) wat 37.5 mg DIM verskaaf	150 mg
Kafeïenvrye groen tee (Camellia sinensis) blaarekstrak [gestandaardiseer tot 60% (60 mg) katekiene en 40% (40 mg) epigallocatechin gallate (EGCG)]	100 mg
L-sisteien (as N-asetiel-L-sisteien)	50 mg
7-Hydroxymatairesinol (HMR) Kaliumasetaat Kompleks	50 mg
Eie mengsel van Curcumin [van Curcuma longa L. risoom uittreksel gestandaardiseer tot 40% (20 mg) curcuminoïede] en Fenegriek Galactomannans (van Trigonella foenum-graecum saad uittreksel)	50 mg

† Vegetariese kapsule

†† Van BioResponse DIM®

††† As BioResponse DIM® ("n eie, verbeterde bio beskikbaarheidskompleks wat Diindolylmethane bevat wat genseïeër is van BioResponse, LLC, Boulder, Colorado.)

Onaktiewe bestanddele: : Kapsule [hidroksipropylmetielcellulose en natriumpiperchlorofillien (kleur)], mikrokristalliese cellulose, magnesiumstearaat (groente) en silikondioksied.

Hierdie produk is geskik vir nie-GGO, glutenvry (suiker) FARMAKOLOGIESE KLASSIFIKASIE - Komplementêre medisyne

AANDUIDING EN FARMAKOLOGIESE WERKING

ESTROFACTORS® is 'n unieke formule met fitonutriënte wat doelgerigte ondersteuning bied vir gesonde estrogenmetabolisme. Bied hoogs bio beskikbare BioResponse DIM® wat die 2-hidroksi-estronweg kan bevorder. HMR-lignane word ook vertoon om die produksie van enterolaktoon te verhoog, wat geassosieer word met verminderde aromatase-aktiwiteit.

Bestanddele	Gebruik vir bestanddeel
Gemengde karotenolede verskaaf: Vitamien A - 750 mcg	Provitamien A-karotenolede kan omgeskakel word in vitamien A, wat noodsaaklik is vir groei, immuunselfunksie en ooggesondheid.
Vitamien E	Jou liggaam gebruik vitamien E vir verskeie doeleindes, insluitend om jou teen oksidatiewe stres te beskerm en jou immuunselfunksie te ondersteun.
Riboflavin	Antioksidante, soos riboflavin, kan vrye radikale beveg en kan sommige van die skade wat hulle veroorsaak verminder of help voorkom. Riboflavin is ook nodig om die liggaam te help om vitamien B6 en folaat te verander in vorms wat dit kan gebruik. Dit is ook belangrik vir groei en rooibloedse produksie.
Vitamien B6 (as piridoksien HCl)	Vitamien B6 help die liggaam om verskeie neurotransmitters te maak, chemikalieë wat seine van een senuweesel na 'n ander dra.
Folaat (as kalsium L-5-metiltetrahidrofolaat)	Folienruis is van kardinale belang vir behoorlike breinfunksie en speel 'n belangrike rol in geestelike en emosionele gesondheid. Dit help met die produksie van DNA en RNA, die liggaam se genetiese materiaal.
Vitamien B12 (as metielkobalamien)	Metielkobalamien verbeter hul senuweetoestand en bevorder wedergeboorte van die beskadigde senuwees.

KONTRA-INDIKASIES:

As jy enige chroniese medisyne neem, moenie hierdie produk gebruik sonder om jou gesondheidsorgpraktisyn te raadpleeg nie. Moenie **ESTROFACTORS®** neem as jy hipersensitief (allergies) is vir enige van die bestanddele nie. As jy allergieë het, maak seker dat jy met jou gesondheidsorgpraktisyn gaan voordat jy hierdie aanvulling neem.

Chirurgie: ESTROFACTORS® kan die risiko van bloeding tydens en na die operasie verhoog. Hou op om **ESTROFACTORS®** ten minste 2 weke voor 'n geskeduleerde operasie te gebruik.

DATUM VAN PUBLIKASIE

Om deur die regulerende owerheid toegeken te word.

INTERAKSIES

Vertel altyd jou gesondheidsorgpraktisyn as jy enige ander medisyne gebruik. Dit is moontlik dat blootstelling van sekere aanvullingsbestanddele met sekere medisyne 'n interaksie mag hê. (Sien **Waarskuwings en Spesiale voorsorgmaatreëls**)

DOSES EN AANWYSINGS VIR GEBRUIK

Volwassenes: Neem daaglik twee (2) kapsules of soos voorgeskryf deur jou gesondheidsorgpraktisyn.

Moenie meer as die aanbevole dosis neem nie.

WAARSKUIWING EN SPESIALE VOORSORGMAATREËLS

Indien jy enige van die volgende gedignoseerde toestande het, raadpleeg jou gesondheidsorgpraktisyn voor gebruik: Geskiedenis van blootstelling aan asbes, bloedingsversteurings, hartaëkties, diabetes, kop- en nekkanke, swak en bros bene (osteoporese), prostaatkanker, 'n oorgeërfde oogtoestand wat swak nagsig en verlies aan syvisie (retinitis pigmentosa) veroorsaak, beroerte, lewersiekte, post-chirurgiese stentplasing, Gewigsverlieschirurgie, prosedures om verouerde are (angioplastie) te verbreed, beslagleggingsversteuring. As jy die volgende medisyne neem, raadpleeg asseblief jou gesondheidsorgpraktisyn voordat jy neem: medisyne vir kanker (Chemoterapie), bloedstolling (Antikoagulant / Antiplaatjie-middels), Warfarin (Coumadin), Antibiotika vir Kanker (Antitumor Antibiotika), Antibiotika (Tetrasielien antibiotika), Amiodarone (Cardarone), Fenobarbital (Luminal), medisyne vir hoë bloeddruk (antihypertensiewe middels), 5-Fluorouracil, medisyne vir diabetes (Antidiabetes dwelms). As enige van die volgende gebeur, hou op om **ESTROFACTORS®** te gebruik en vertel jou dokter of gaan na die ongevulle-afdeling by jou naaste hospitaal:

- Allergiese reaksies- uitslag, jeuk / swelling (veral van die gesig / tong / keel), erge duiseligheid, probleme met asemaling;

Dit is alles baie ernstige gevolge. As jy dit het, het jy dalk 'n ernstige reaksie op **ESTROFACTORS®** gehad. Jy sal dalk dringende mediese hulp of hospitalisasie nodig hê.

Nuwe-effekte wat gewoonlik nie mediese hulp benodig nie (rapporteer aan jou gesondheidsorgpraktisyn as hulle voortduur):

- naerheid / braking,

Dit is alles baie ernstige gevolge. As u dit het, het u moontlik 'n ernstige reaksie op **ESTROFACTORS®** gehad. Miskien het u dringende mediese hulp of hospitalisasie nodig.

Raadpleeg 'n gesondheidsorgpraktisyn as u enige mediese toestand het. Staak gebruik onmiddellik indien enige nadelige reaksie plaasvind. Lees hierdie inligtingsblad aandagtig deur, want dit bevat belangrike inligting vir u. Hierdie produk is beskikbaar sonder doktersvoorskrif.

- Hou hierdie inligtingsblad. Miskien moet u dit weer lees.

- Moenie medisyne met enige ander persoon deel nie.

- Vra jou apteker of jy meer inligting of advies benodig.

- Jy moet 'n dokter raadpleeg indien jou toestand vererger of nie verbeter nie.

MOENIE HIERDIE PRODUK GEBRUIK NIE:

- As jy hipersensitief (allergies) is vir enige van die bestanddele wat gelys word.

- Jy moet nie hierdie produk aanvaar as seëls gebreek word nie.

NEWE-EFFEKTE

Indien jou algemene gesondheid vererger of as jy enige nadelige effekte ervaar tydens die gebruik van hierdie medisyne, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgpraktisyn vir raad. As jy enige nuwe-effekte sien wat nie in hierdie inligtingsblad genoem word nie, stel asseblief jou dokter, apteker of gesondheidsorgpraktisyn in kennis.

BEKEUDE SIMPTOME VAN OORDOSEERING EN BESONDERHEDE VAN DIE

BEHANDELING DAARVAN

Sien nuwe-effekte.
Behandeling: Staak gebruik en raadpleeg jou dokter, apteker of ander gesondheidsorgpraktisyn vir advies.

Bestanddele	Gebruik vir bestanddeel
Rysproteïenmatriks en polifenole uit hop (Humulus lupulus L.) Keël uittreksel	Dit kan antioksidante eienskappe hê.
Diindolylmethane (DIM) kompleks†††	Ondersteun gesonde hormoonbalans deur die regulering van estrogenvlakke, by mans en vroue.
Kafeïenvrye groen tee (Camellia sinensis)	Hierdie spesie is ryk aan polifenoliese verbindings en katekiene. Katekienderivate het uitgesproke antivirale aktiwiteit getoon, waargeneem vir afgeleides met matige kettinglengte.
L-sisteien (as N-asetiel-L-sisteien)	NAC kan die sintese van glutathion stimuleer, 'n verbinding wat help om vrye radikale te beveg, onstabiele atome wat inflammasie en skade kan veroorsaak.
7-Hydroxymatairesinol (HMR) Kaliumasetaat Kompleks	Lignane is plantpolifenole wat antikanker-, antioksidant-, antimikrobiese, anti-inflammatoriese en immunomodulerende aktiwiteite kan best.
Eie mengsel van curcumin [van Curcuma longa L. risoom Fenegriek Galactomannans (van Trigonella foenum-graecum saad uittreksel)]	Die hoofrol van fenegriekoplosbare vesel in kombinasie met curcumin is om plasma- en weefselkonsentrasies van curcumin te verhoog deur die vertering en eliminasië daarvan te vertraag.

BERGING INSTRUKSIE

Bêre in 'n koel, donker plek, onder 25 °C. Beskerm teen direkte sonlig en hitte.

Bêre n die oorspronklike bottel. Hou die bottel styf toe. Vervang die

beskermende dop na elke gebruik. Moet nie gebruik word na die vervaldatum

wat op die bottel aangedui word nie. Moenie **ESTROFACTORS®** gebruik as u

siggare telkens van aëtering af merk nie.

IDENTIFIKASIE - Donkergroen, groentekapsule.

AANBIEDING - 'n Wit 175 ml HDPE-bottel met 'n wit dop, induksieseël, peuterkrimpseël, spons en silikagelsakkie.

REGISTRASIE NOMMER

Om by registrasie deur SAHPRA toegeken te word.

Hierdie medisyne is nie deur SAHPRA getoelueer vir kwaliteit, veiligheid of beoogde gebruik nie.

NAAM EN BESIGHEIDSADES VAN APLIKANT

Versprei deur: Amipro Advanced Development Products (Pty) Ltd

Unit 3, Eastgate Business Park, 1 South Road,

Eastgate Extension, Sandton, 2146,

Tel: 011-802-8101

