

## PATIENT INFORMATION LEAFLET

### SCHEDULING STATUS: S0

Category D: Complementary medicine.

Discipline: Discipline Specific

33.7 Combination Product

PROPRIETARY NAME, STRENGTH, PHARMACEUTICAL FORM –

## ESTROFACTORS<sup>®</sup>, 60 Capsules

### READ ALL OF THIS LEAFLET CAREFULLY BECAUSE IT CONTAINS IMPORTANT INFORMATION FOR YOU

- **ESTROFACTORS<sup>®</sup>** is available without a doctor's prescription.
- Nevertheless, you still need to use **ESTROFACTORS<sup>®</sup>** carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Do not share **ESTROFACTORS<sup>®</sup>** with any other person.
- Ask your pharmacist or healthcare professional if you need more information or advice.

### WHAT IS IN THIS LEAFLET

- What **ESTROFACTORS<sup>®</sup>** is and what it is used for.
- What you need to know before you take **ESTROFACTORS<sup>®</sup>**.
- How to take **ESTROFACTORS<sup>®</sup>**.
- Possible side effects.
- How to store **ESTROFACTORS<sup>®</sup>**.
- Contents of the pack and other information.

### WHAT ESTROFACTORS<sup>®</sup> CONTAINS

Each one (1) capsules of **ESTROFACTORS<sup>®</sup>** contains the following actives:

Mixed Carotenoids (including beta-carotene, alpha-carotene, cryptoxanthin, zeaxanthin and lutein)	1.8 mg
Providing: Vitamin A - 750 mcg	
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<sup>®</sup>

††† As BioResponse DIM<sup>®</sup> (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)**

**WHAT ESTROFACTORS<sup>®</sup> IS AND WHAT IT IS USED FOR**  
**ESTROFACTORS<sup>®</sup>** is a unique formula featuring phytonutrients that provide targeted support for healthy estrogen metabolism. Offering highly bioavailable BioResponse DIM<sup>®</sup> 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.

### BEFORE YOU TAKE ESTROFACTORS<sup>®</sup>

If you are taking any chronic medication, do not use this product without consulting your healthcare provider. Do not take **ESTROFACTORS<sup>®</sup>** 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<sup>®</sup>** might increase the risk of bleeding during and after surgery. Stop using **ESTROFACTORS<sup>®</sup>** at least 2 weeks before a scheduled surgery.

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

### PREGNANCY AND BREASTFEEDING

Safety during pregnancy and breastfeeding has not been established, consult with your healthcare professional before use. If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult with your healthcare professional before taking this supplement.

### DRIVING AND USING MACHINES

It is not always possible to predict to what extent **ESTROFACTORS<sup>®</sup>** may interfere with the daily activities of a patient. Patients should ensure that they do not engage in activities relating to requiring mental alertness, judgement and/or sound co-ordination and vision e.g. driving, riding, flying, sailing, operating machines/equipment, until they are aware of the measure to which **ESTROFACTORS<sup>®</sup>** may affect you.

### TAKING OTHER MEDICINES WITH ESTROFACTORS<sup>®</sup>

Complementary medicine products contain ingredients which may interact with some medication. If you are taking any chronic medication, do not use this product without consulting your medical practitioner.



### HOW TO TAKE ESTROFACTORS<sup>®</sup>

Do not share medicines prescribed for you with any other person. Always take **ESTROFACTORS<sup>®</sup>** exactly as described in this leaflet, or as your doctor, healthcare provider has instructed you. You should check with your doctor, pharmacist or healthcare provider if you are unsure.

### Directions for use:

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

### IF YOU TAKE MORE ESTROFACTORS<sup>®</sup> THAN YOU SHOULD

In the event of overdose, consult your doctor, pharmacist. Should none of these be available, contact the nearest hospital or poison control centre.

### IF YOU FORGET TO TAKE ESTROFACTORS<sup>®</sup>

Do not take a double dose to make up for a missed dose.

### POSSIBLE SIDE EFFECTS

**ESTROFACTORS<sup>®</sup>** may have side effects.

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 practitioner 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<sup>®</sup>** and tell your doctor or go to the casualty department at your nearest hospital:

- The 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<sup>®</sup>**. 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.

Not all side effects and interactions reported for **ESTROFACTORS<sup>®</sup>** are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice. If you notice any side effects not mentioned in this leaflet, please inform your doctor, pharmacist or healthcare professional.

### REPORTING OF SIDE EFFECTS

If you experience side effects, talk to your doctor, pharmacist or other healthcare professional. You can also report side effects to SAHPRA via "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/index/B>. By reporting side effects, you can help provide more information on the safety of **ESTROFACTORS<sup>®</sup>**.

### STORAGE AND DISPOSING OF ESTROFACTORS<sup>®</sup>

Store all medicines out of the reach of children.

Store in a cool, dark place, below 25 °C.

Protect from direct sunlight and heat.

Store in the original packaging.

Do not use after the expiry date stated on the bottle.

Do not use **ESTROFACTORS<sup>®</sup>** if you notice visible signs of deterioration.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

### PRESENTATION OF ESTROFACTORS<sup>®</sup>

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

### IDENTIFICATION OF ESTROFACTORS<sup>®</sup>

Dark green, vegetable capsule

### REGISTRATION NUMBER –

To be allocated by SAHPRA upon registration.

### ACCESS TO THE CORRESPONDING PROFESSIONAL INFORMATION

Scan QR code.

### THIS LEAFLET WAS LAST REVISED ON

19 November 2024

### NAME AND ADDRESS OF REGISTRATION HOLDER

Distributed by:

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# PASIËNT INLIGTINGSBLAD

## SKEDULERINGSSTATUS <sup>50</sup>

Kategorie D: Komplementêre medisyne.

Dissipline: Dissiplinespesifiek

33.7 Kombinasie produk

HANDELSNAAM EN DOSEERVORM,

## ESTROFACTORS<sup>®</sup>, 60 Kapsules

### LEES HIERDIE INLIGTINGSBLAD NOUKEURIG, WANT DIT BEVAT

#### BELANGRIKE INLIGTING VIR U

- **ESTROFACTORS<sup>®</sup>** is beskikbaar sonder doktersvoorskrif.
- U moet steeds **ESTROFACTORS<sup>®</sup>** versigtig gebruik om die beste resultate daaruit te kry.
- Hou hierdie inligtingsblad. Miskien moet u dit weer lees.
- Moenie **ESTROFACTORS<sup>®</sup>** met enige ander persoon deel nie.
- Vra jou apteker of gesondheidsorgpraktisy van jy meer inligting of advies benodig.

#### WAT IS IN HIERDIE INLIGTINGSBLAD

- Wat **ESTROFACTORS<sup>®</sup>** is en waarvoor dit gebruik word.
- Wat jy moet weet voordat jy **ESTROFACTORS<sup>®</sup>** neem.
- Hoe om **ESTROFACTORS<sup>®</sup>** te neem.
- Moontlike nuwe-effekte.
- Hoe om **ESTROFACTORS<sup>®</sup>** te bêre.
- Inhoud van die pak en ander inligting

#### WAT IS ESTROFACTORS<sup>®</sup> KAPSULES EN WAARVOOR WORD DIT GEBRUIK

**ESTROFACTORS<sup>®</sup>** bevat 'n hoësterkte vitamien D3, die mees bioaktiewe vorm van vitamien D. Vitamien D is belangrik vir die instandhouding van gesonde beensterkte en immuunfunksie.

#### BELANGRIKE INLIGTING OOR SOMMIGE VAN DIE BESTANDELE VAN

##### ESTROFACTORS<sup>®</sup>

**ESTROFACTORS<sup>®</sup>** is 'n unieke formule met fitonutriënte wat doelgerig ondersteuning bied vir gesonde estrogenmetabolisme. Bied hoogs bio-aktiewe BioResponse DIM<sup>®</sup> 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.

#### VOORDAT JY ESTROFACTORS<sup>®</sup> NEEM

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

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

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

#### BESTUUR EN GEBRUIK VAN MASJINE

Dit is nie altyd moontlik om te voorspel in watter mate **ESTROFACTORS<sup>®</sup>** die daaglikse aktiwiteite van 'n pasiënt kan belemmer nie. Pasiënte moet seker maak dat hulle nie betrokke raak by aktiwiteite wat verband hou met die vereiste van verstandelike waaksaamheid, oordeel en/of gesonde koördinasie en visie nie, byvoorbeeld bestuur, ry, vlieg, seil, bedryfsmasjien/toerusting, totdat hulle bewus is van die mate waartoe **ESTROFACTORS<sup>®</sup>** jou beïnvloed.

#### WAT ER ESTROFACTORS<sup>®</sup> BEVAT

Elke een (1) kapsule **ESTROFACTORS<sup>®</sup>** bevat die volgende aktiewe:

Gemengde karotenoliede (insluitend beta-karoteen, alfa-karoteen, kriptoksantien, zeaxantien en luteien)	1,8 mg
Voorsien: Vitamien A - 750 mcg	
Vitamien E (as d-alfa-tokoferylsuksinaat en d-alfa-tokoferylpoliëteenglikol 1000 suksinaat††)	36.2 mg
Riboflavin	1 mg
Vitamien B6 (as piridoksin HCl)	50 mg
Folaat (as kalsium L-5-metietietetrahydrofolaat)	340 mcg
	DFE
Vitamien B12 (as metielkobalamien)	30 mcg
Rysproteïenmatriks en polifenole uit hoo (Humulus lupulus L.) Keël uitreksel (gestandaardiseer tot 2.5% xanthohumol)	250 mg
Diindolylmethane (DIM) Kompleks††† [stysel, diindolylmethane, d-alfa-tokoferyl poliëteenglikol 1000 suksinaat, fosfatidieticholien (van sonneblom) en silika] wat 37.5 mg DIM verskaf	150 mg
Kafeïenrye groen tee (Camellia sinensis)	100 mg
blaarekstrak [gestandaardiseer tot 60% (60 mg) katekiene en 40% (40 mg) epigallocatechin gallate (EGCG)]	
L-sisteïen (as N-asetiel-L-sisteïen)	50 mg
7-Hydroxymatairesinol (HMR) Kaliumasetaat	50 mg
Kompleks	
Eie mengsel van Curcumin [van Curcuma longa L. risoom uitreksel gestandaardiseer tot 40% (20 mg) curcuminoliede] en Fragniek Galactomannans (van Trigonella foenum-graecum saad uitreksel)	50 mg

†Vegetariese kapsule

††Van BioResponse DIM<sup>®</sup>

††† As BioResponse DIM<sup>®</sup> ('n eie, verbeterde bio-aktiewe kompleks wat Diindolylmethane bevat wat geïsoleer is van BioResponse, LLC, Boulder, Colorado.)

**Onaktiewe bestanddele:** Kapsule [hidroksipropylmetielcellulose en natriumkoperchlorid (kleur)], mikrokrystaliese sellulose, magnesiumstearaat (groente) en silikondioxide.

**Hierdie produk is geskik vir nie-GMO, glutenvry (suikervry)**

#### NEEM VAN ANDER MEDISYNE SAAM MET ESTROFACTORS<sup>®</sup>

Komplementêre medisyne produkte bevat bestanddele wat met sommige medisyne 'n interaksie kan hê. As jy enige chroniese medisyne gebruik, moenie hierdie produk gebruik sonder om jou gesondheidsorgpraktisy te raadpleeg nie.

#### SWANGERSKAP EN BORSVOEDING

Alhoewel veiligheid tydens swangerskap en borsvoeding vasgestel is, raadpleeg jou gesondheidsorgpraktisy vir gebruik. As u swanger is of borsvoed, dink dat u swanger is of blye om 'n baba te hê, raadpleeg u gesondheidsorgpraktisy voordat u hierdie aanvulling neem.

#### HOE OM ESTROFACTORS<sup>®</sup> TE NEEM

Moenie medisyne wat vir u voorskryf is, met enige ander persoon deel nie. Neem altyd **ESTROFACTORS<sup>®</sup>** presies soos beskryf in hierdie inligtingsblad, of soos u dokter, gesondheidsorgpraktisy voorskryf het. Raadpleeg jou dokter, apteker of gesondheidsorgpraktisy as jy onseker is.

#### Aanwysings vir gebruik:

**Volwasse:** Neem daaglik twee (2) kapsules of soos voorgeskryf deur jou gesondheidsorgpraktisy.

**Moenie meer as die aanbevole dosis neem nie.**

#### AS JY MEER ESTROFACTORS<sup>®</sup> NEEM AS WAT JY MOET

In die geval van oordosering, raadpleeg u dokter of apteker. Indien nie om hiervan beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.

#### AS JY VERGEET OM ESTROFACTORS<sup>®</sup> TE NEEM

Moenie 'n dubbele dosis neem om op te maak vir 'n dosis wat oorgeslaan is nie.

#### MOONTLIKE NUWE-EFFEKTE

**ESTROFACTORS<sup>®</sup>** kan nuwe-effekte hê.

Indien jy enige van die volgende diagnoseerbare toestande het, raadpleeg jou gesondheidsorgpraktisy vir gebruik: Geskiedenis van blootstelling aan asbes, bloedingsversteurings, hartsielste, diabetes, kop- en nekkanke, swak en bros bene (osteoporose), prostaatkanker, 'n oorerlike oogtoestand wat swak nagsig en verlies aan visie (retinitis pigmentosa) veroorsaak, beroerte, lewersiekte, post-chirurgiese stentplasing, Gewigsverlieschirurgie, prosedures om veroude are (angioplastie) te verbreed, beslagleggingsversteuring. As jy die volgende medisyne neem, raadpleeg asseblief jou gesondheidsorgpraktisy voordat jy neem: , medisyne vir kanker (Chemoterapie), bloeddolling (Antikoagulant / Antiplatelet-middels), Warfarin (Coumadin), Antibiotika vir Kanker (Antitumor Antibiotika), Antibiotika (Tetrasielike antibiotika), Amiodaron (Cordaron), 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<sup>®</sup>** te gebruik en vertel jou dokter of gaan na die ongevalle-afdeling by jou naaste hospitaal:

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

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

Nuwe-effekte wat gewoenlik nie mediese hulp benodig nie (rapporteer aan u gesondheidsorgpraktisy as dit voortduur):

- naarheid / braking.

#### Nie alle nuwe-effekte en interaksies wat vir **ESTROFACTORS<sup>®</sup>**

gerapporteer word, is by hierdie inligtingsblad ingesluit nie. 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 gesondheidsorgpraktisy vir raad. As jy enige nuwe-effekte sien wat nie in hierdie inligtingsblad genoem word nie, stel asseblief jou dokter, apteker of gesondheidsorgpraktisy in kennis.

#### AANMELDING VAN NUWE-EFFEKTE

As jy nuwe-effekte ervaar, praat met jou dokter, apteker of ander gesondheidsorgpraktisy. U kan ook nuwe-effekte aan SAHPRA rapporteer via "6.04 Adverse Drug Reaction Reporting Form", wat aanlyn gevind word onder SAHPRA se publikasies:

<https://www.sahpra.org.za/Publications/Index/8>. Deur nuwe-effekte aan te meld, kan u help om meer inligting te verskaf oor die veiligheid van **ESTROFACTORS<sup>®</sup>**.

#### HOE OM ESTROFACTORS<sup>®</sup> TE BÊRÊ

Bêre alle medisyne buite bereik van kinders.

Bêre in 'n koel, donker plek, onder 25 °C.

Beskerm teen direkte sonlig en hitte.

Bêre in die oorspronklike verpakking.

Moet nie gebruik word na die vervaldatum wat op die bottel aangedui word nie.

Moenie **ESTROFACTORS<sup>®</sup>** gebruik as u sigbare tekens van agteruitgang opmerk nie.

Moenie ongebruikte medisyne in dreine of rioolstelsels (bv. toilette) weggooi nie.

#### AANBIEDING VAN ESTROFACTORS<sup>®</sup>

'n Wit 175 ml HDPE-bottel met 'n wit dop, induksiesel, peuterkrimpesel, spons en silikagelsakke.

#### IDENTIFIKASIE VAN ESTROFACTORS<sup>®</sup>

Donkergroen, groente kapsule

#### REGISTRASIE NUMMER

Om deur SAHPRA toegeken te word by registrasie.

#### TOEGANG TOT DIE OOREENSTEMMEDE PROFESSIONELE INLIGTING

Skander QR-kode.

#### HIERDIE INLIGTINGSBLAD IS LAAS HERSIEN OP

19 November 2024

#### NAAM EN ADRES VAN REGISTRASIEHOUER

Versprei deur:

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