

## PROFESSIONAL INFORMATION

SCHEDULING STATUS: **S0**

Category D: Complementary medicine.

Discipline: Discipline specific

33.6 Western Herbal Medicine

PROPRIETARY NAME, STRENGTH, PHARMACEUTICAL FORM –

### ESTROVERA®, 30 Tablets

#### COMPOSITION

Each one (1) tablet of ESTROVERA® contain the following actives:

|   |        |
|---|--------|
| Rhapontic Rhubarb (Rheum raphaniticum L.) | 4 mg   |
| [Root Extract (ERr 731®)]                 |        |
| Providing:                                | 2,2 mg |
| Rhaponticin                               |        |
| Desoxy-rhaponticin                        | 1 mg   |

**Inactive Ingredients:** Croscarmellose sodium, enteric coating (ammonium hydroxide, ethyl cellulose, hydroxypropylcellulose, hydroxypropylmethylcellulose, medium-chain triglycerides, oleic acid, sodium alginate, and stearic acid), microcrystalline cellulose, silica and stearic acid (vegetable). This product is non-GMO and Sugar Free.

#### PHARMACOLOGICAL CLASSIFICATION

Complementary Medicine

#### INDICATION & PHARMACOLOGICAL ACTION

ESTROVERA® features a plant-based, non-hormonal extract, which alleviates 12 of the most common menopausal symptoms such as hot flashes, night sweats, joint and body discomfort, vaginal dryness as well as mood concerns such as irritability and anxiety. Estrovera is hormone free and does not affect estrogen levels in the body and is safe for long-term use. A simple once-daily dose offers a convenient solution to menopausal concerns.

| Ingredients       | Uses for ingredient   |
|-------------------|---|
| Rhapontic Rhubarb | An extract from the roots of the Siberian rhubarb, called ERr 731, can help treat menopausal symptoms such as oligomenorrhea and amenorrhea. ERr 731 is a plant-derived polyphenolic compound that acts as a selective estrogen receptor modulator. |

#### CONTRA INDICATIONS:

If you are taking any chronic medication, do not use this product without consulting your healthcare professional. Do not take ESTROVERA® 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.

#### WARNING AND SPECIAL PRECAUTIONS

Should you have any of the following diagnosed conditions, consult with your healthcare professional before use: Gastrointestinal (GI) conditions, Kidney disease, Kidney stones, Liver problems. If you are taking the following medication, please consult with your healthcare professional before taking: Digoxin (Lanoxin), Medications for inflammation (Corticosteroids), Medications that can harm the kidneys (Nephrotoxic drugs), Stimulant laxatives, Anticoagulants (Warfarin (Coumadin)). If any of the following happens, stop using ESTROVERA® 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 ESTROVERA®. 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):

- stomach pain, diarrhea, nausea, vomiting, and cramps.
- These are all very serious effects. If you have them, you may have had a serious reaction to ESTROVERA®. 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.

#### 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**)

#### DOSAGE AND DIRECTIONS FOR USE

**Adults:** Take one (1) tablet with food and a glass of water once daily at the same time of day 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.

#### 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 ESTROVERA® if you notice visible signs of deterioration.

#### IDENTIFICATION

Off-white, speckled, coated round tablet.

#### PRESENTATION

A white 175 ml HDPE bottle with a white cap, induction seal, tampo 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:

Amipro 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.

# PROFESIONELE INLIGTINGSBLAD

SKEDULERINGSSTATUS: 50

Kategorie D: Komplementêre medisyne.

Dissipline: Dissipline spesifiek

33.6 Westerse kruie medisyne

HANDELSNAAM EN DOSEERVORM,

## ESTROVERA®, 30 Tablet

### SAMESTELING

Elke (1) tablet ESTROVERA® bevat die volgende aktiewe stowwe:

|  |        |
|--|--------|
| Rhaptontiese rabarber (Rheum rhaponticum L.) | 4 mg   |
| [Wortel uittreksel (E <sub>HR</sub> 731*)]   |        |
| Voorsiening van:                             | 2,2 mg |
| Rhapon                                       |        |
| Desoksi-rhaptontikien                        | 1 mg   |

**Onaktiewe bestanddele:** Croscarmellose-natrium, enteriese laag (ammoniumhidroksied, etielsellulose, hidroksipropylselulose, hidroksipropylmetelselulose, mediumkettingrigliseriede, oliesuur, natriumalgiinaat en steariensuur), mikrokristallyne selulose, silika en steariensuur (groente). Hierdie produk is nie-GGO en suikervry.

### FARMAKOLOGIESE KLASSIFIKASIE

Komplementêre medisyne

### AANDUIDING EN FARMAKOLOGIESE WERKING

ESTROVERA® beskik oor 'n plantgebaseerde, nie-hormonale uittreksel, wat 12 van die mees algemene menopousale simptome soos warm gloede, nagsweat, gewrigs- en liggaamsongemak, vaginale droogheid sowel as gemoedsprobleme soos prikkelbaarheid en angs verlig. Estrovera is hormoonvry en beïnvloed nie estrogeenvlakke in die liggaam nie en is veilig vir langtermyngebruik. 'n Eenvoudige dosis een keer per dag bied 'n gerieflike oplossing vir menopousale bekommernisse.

| Bestanddele           | Gebruik vir bestanddeel   |
|-----------------------|---|
| Rhaptontiese rabarber | 'n Uittreksel uit die wortels van die Siberiese rabarber, genaamd E <sub>HR</sub> 731, kan help om menopousale simptome soos oligomenorrhea en amenorrhea te behandel. E <sub>HR</sub> 731 is 'n plant-afgeleide polifenoliese verbinding wat optree as 'n selektiewe estrogeen reseptor modulator. |

### KONTRA-INDIKASIES:

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

### WAARSKUWING EN SPESIALE VOORSORGMATREËLS

Indien jy enige van die volgende gedagnoseerde toestande het, raadpleeg jou gesondheidsorgpraktisyn voor gebruik: Gastro-intestinale (GI) toestande, niersiekte, nierstene, lewerprobleme. As jy die volgende medisyne neem, raadpleeg asseblief jou gesondheidspraktisyn voordat jy neem: Digoksien (Lanoxin), medisyne vir inflammasie (Kortikosteroïede), medisyne wat die niere kan benadeel (Nefrotoksiese middels), Stimulerende lakseermiddels, Antikoagulant (Warfarin (Coumadin)). As enige van die volgende gebeur, hou op om ESTROVERA® 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 ESTROVERA® gehad. Jy sal dalk dringende mediese hulp of hospitalisasie nodig hê.

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

- maagpyn, diarree, naarheid, braking en krampe.

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

Raadpleeg 'n gesondheidsorgpraktisyn as u enige mediese toestand het.

Staaik 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.

### INTERAKSIE

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**)

### DOSIS EN AANWYSINGS VIR GEBRUIK

**Volwasse:** Neem een (1) tablet met kos en 'n glas water een keer per dag by dieselfde tyd van die dag of soos voorgeskryf deur jou gesondheidspraktisyn.

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

### NEWE-EFFEKTE

Indien jou algemene gesondheid vererger of as jy enige nadelige

effekte ervaar tydens die gebruik van hierdie aanvulling, 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.

### BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN

Sien nuwe-effekte.

#### Behandeling:

Staaik gebruik en raadpleeg jou dokter, apteker of ander gesondheidsorgpraktisyn vir advies.

### BERGING INSTRUKSIE

Hou dig toegemaak op 'n koel, droë plek, onder 25 °C.

Beskerk 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 ESTROVERA® gebruik as u sigbare tekens van agteruitgang opmerk nie.

### IDENTIFIKASIE

Spienwit, gesigkelde, bedekte ronde tablet.

### AANBIEDING

'n Wit 175 ml HDPE-bottel met 'n wit dop, induksieseël,

peuterkrimpseël, spons en silikagelsakke.

### REGISTRASIE NOMMER

Om by registrasie deur SAHPRA toegeken te word.

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

### NAAM EN BESIGHEIDSAADRES VAN APPLIKANT

Versprei deur:

Amipro Advanced Development Products (Pty) Ltd

Unit 3, Eastgate Business Park, 1 South Road,

Eastgate Extension,

Sandton, 2146,

Tel: 011- 802-8101

### DATUM VAN PUBLIKASIE

Om deur die regulerende owerheid toegeken te word.