

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S0

Category D: Complementary medicine.

Discipline: Discipline specific

33.6 Western Herbal Medicine

PROPRIETARY NAME, STRENGTH, PHARMACEUTICAL FORM –

ESTROVERA® , 30 Tablets

READ ALL OF THIS LEAFLET CAREFULLY BECAUSE IT CONTAINS

IMPORTANT INFORMATION FOR YOU

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

WHAT IS IN THIS LEAFLET

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

WHAT ESTROVERA® CONTAINS

Each one (1) tablet of **ESTROVERA®** contains 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.**

WHAT ESTROVERA® IS AND WHAT IT IS USED FOR

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.

BEFORE YOU TAKE ESTROVERA®

If you are taking any chronic medication, do not use this product without consulting your healthcare practitioner. 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.

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, do not take if you are pregnant or breastfeeding. 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 **ESTROVERA®** 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 **ESTROVERA®** may affect you.

TAKING OTHER MEDICINES WITH ESTROVERA®

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 healthcare practitioner.

HOW TO TAKE ESTROVERA®

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

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.

IF YOU TAKE MORE ESTROVERA® 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 ESTROVERA®

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

POSSIBLE SIDE EFFECTS

ESTROVERA® may have side effects.

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 practitioner 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.

Not all side effects and interactions reported for **ESTROVERA®** 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/8>. By reporting side effects, you can help provide more information on the safety of **ESTROVERA®**.

STORAGE AND DISPOSING OF ESTROVERA®

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

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

PRESENTATION OF ESTROVERA®

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

IDENTIFICATION OF ESTROVERA®

Off-white, speckled, coated round tablet.

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

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Sandton, 2146
Tel: 011-802-8101



PASIËNT INLIGTINGSBLAD

SKEDULERINGSSTATUS 50

Kategorie D: Komplementêre medisyne.

Dissipline: Dissipline spesifiek

33.6 Westerse kruie medisyne

HANDELSNAAM EN DOSEERVORM,

ESTROVERA[®], 30 Tablette

LEES HIERDIE INLIGTINGSBLAD NOUKEURIG, WANT DIT BEVAT

BELANGRIKE INLIGTING VIR U

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

WAT IS IN HIERDIE INLIGTINGSBLAD

- Wat **ESTROVERA[®]** is en waarvoor dit gebruik word.
- Wat jy moet weet voordat jy **ESTROVERA[®]** neem.
- Hoe om **ESTROVERA[®]** te neem.
- Moontlike nuwe-effekte.
- Hoe om **ESTROVERA[®]** te bêre.
- Inhoud van die pak en ander inligting

WATTER ESTROVERA[®] BEVAT

Eke een (1) tablet **ESTROVERA[®]** bevat die volgende aktiewe:

Rhapontiese rabarber (Rheum rhabonticum L.)	4 mg
[Wortel uittreksel (E _{HR} 731*)]	
Voorsiening van:	2,2 mg
Rhapon	
Desoksi-rhapontikien	1 mg

Onaktiewe bestanddele: Croscarmellose-natrium, enteriese laag (ammoniumhidroksied, etielsellulose, hidroksipropylselulose, hidroksipropylmetielcellulose, mediumkettingtriglyseriede, olie suur, natriumalgiinaat en steariensuur), mikro-kristallyne sellulose, silika en steariensuur (groente). **Hierdie produk is nie-GGO en suikervry.**

WAT IS ESTROVERA[®] KAPSULES EN WAARVOOR WORD DIT GEBRUIK

ESTROVERA[®] beskik oor 'n plantegebaseerde, nie-hormonale uittreksel, wat 12 van die mees algemene menopousale simptome soos warm gloede, nagsweet, 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.

VOORDAT JY ESTROVERA[®] NEEM

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 voordat jy hierdie aanvulling neem.

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

SWANGERSKAP EN BORSWOEDING

Veiligheid tydens swangerskap en borsvoeding is nie vasgestel nie, moenie neem as jy swanger is of borsvoed nie. As u swanger is of borsvoed, dink dat u swanger is of beplan om 'n baba te hê, raadpleeg u gesondheidsorgpraktisyn voordat u hierdie aanvulling neem.

BESTUUR EN GEBUIK VAN MASIËNE

Dit is nie altyd moontlik om te voorspel in watter mate **ESTROVERA[®]** 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 **ESTROVERA[®]** jou beïnvloed.

NEEM VAN ANDER MEDISYNE SAAM MET ESTROVERA[®]

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 gesondheidsorgpraktisyn te raadpleeg nie.

HOE OM ESTROVERA[®] TE NEEM

Moenie medisyne wat vir u voorgeskryf is, met enige ander persoon deel nie. Neem altyd **ESTROVERA[®]** presies soos beskryf in hierdie inligtingsblad, of soos u dokter, gesondheidsorgpraktisyn voorgeskryf het. Raadpleeg jou dokter, apteker of gesondheidsorgpraktisyn as jy onseker is.

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.

AS JY MEER ESTROVERA[®] NEEM AS WAT JY MOET

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

AS JY VERGEET OM ESTROVERA[®] TE NEEM

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

MOONTLIKE NUWE-EFFEKTE

ESTROVERA[®] kan nuwe-effekte hê.

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, Antikoagulanse (Warfarin (Coumadin)). As enige van die volgende gebeur, hou op om **ESTROVERA[®]** te gebruik en vertel jou dokter of gaan na die ongevallende 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. U mag dalk dringende mediese hulp of hospitalisasie nodig hê.

Nuwe-effekte wat gewoonlik nie mediese hulp benodig nie (rapporteur aan u gesondheidsorgpraktisyn as dit voortduur):

- maagpyn, diarree, naarheid, braking en krampe.

Nie alle nuwe-effekte en interaksies wat vir **ESTROVERA[®]** 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 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.

AANMELDING VAN NUWE-EFFEKTE

As jy nuwe-effekte ervaar, praat met jou dokter, apteker of ander gesondheidsorgpraktisyn. 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 **ESTROVERA[®]**.

HOE OM ESTROVERA[®] TE BÊRE

Hou buite bereik van kinders.

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

Beskermt 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 **ESTROVERA[®]** gebruik as u sigbare tekens van agteruitgang opmerk nie.

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

AANBIEDING VAN ESTROVERA[®]

'n Wit 175 ml HDPE-bottel met 'n wit dop, induksiesêel, peuterkrimpsêel, spons en slikaagsakkie.

IDENTIFIKASIE VAN ESTROVERA[®]

Spiervit, gespikkelde, bedekte ronde tablet.

REGISTRASIONOMMER

Om deur SAHPRA toegeken te word by registrasie.

TOEGANG TOT DIE OOREENSTEMMende PROFESSIONELE

INLIGTING

Skandeer QR-kode.

HIERDIE INLIGTINGSBLAD IS LAAS HERSIEN OP

19 November 2024

NAAM EN ADRES VAN REGISTRASIEHOUER

Versprei deur:

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