

PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

COMPLEMENTARY MEDICINE
Ayurveda. Discipline-Specific

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

SCHEDULING STATUS S0

1. NAME OF THE MEDICINE

RE: BALANCE FOR HER™ (capsules)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains:

<i>Asparagus racemosus</i> Willd. (Shatavari) [root; 10:1 extract providing 1000 mg dried herb equivalent]	100 mg
<i>Saraca asoca</i> (Roxb.) Willd. (Ashoka) [bark; 10:1 extract providing 1000 mg dried herb equivalent]	100 mg
<i>Vitis vinifera</i> L. (Draksha) [seed; 10:1 extract providing 700 mg dried herb equivalent]	70 mg
<i>Bacopa monnieri</i> (L.) Wettst. (Brahmi) [aerial; 10:1 extract providing 650 mg dried herb equivalent]	65 mg
<i>Symplocos racemosa</i> Roxb. (Lodhra) [bark; 5:1 extract providing 250 mg dried herb equivalent]	50 mg
<i>Trigonella foenum-graecum</i> L. (Methi) [seed; 10:1 extract providing 500 mg dried herb equivalent]	50 mg
<i>Nelumbo nucifera</i> Gaertn. (Kamal) [flower; 10:1 extract providing 150 mg dried herb equivalent]	15 mg

Sugar free.

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Clear, size 00 vegi capsules, filled with brown powder.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

The RE: BALANCE FOR HER™ unique blend of natural herbs promotes hormonal balance in women throughout the menstrual cycle, maintains energy levels, combats stress and anxiousness, and promotes a healthy libido.

4.2 Posology and method of administration

Posology:

Adults over 18 years:

Take 1 capsule twice daily with water or milk.

Special populations:

Elderly population:

No dosage adjustment is required for this population.

Paediatric population:

This product is not indicated in patients younger than 18 years.

Method of administration:

For oral use only.

4.3 Contraindications

RE: BALANCE FOR HER™ should not be used in patients who have a hypersensitivity to the active substances, *Asparagus racemosus* Willd. (Shatavari), *Saraca asoca* (Roxb.) Willd. (Ashoka), *Vitis vinifera* L. (Draksha), *Bacopa monnieri* (L.) Wettst. (Brahmi), *Symplocos racemosa* Roxb. (Lodhra), *Trigonella foenum-graecum* L. (Methi), *Nelumbo nucifera* Gaertn. (Kamal) or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

- Nelumbo nucifera*,¹ *Trigonella foenum-graecum*,² and *Vitis vinifera*³ may theoretically have antiplatelet effects and may increase the risk of bleeding. Use with caution in patients with bleeding disorders.
- Bacopa monnieri* may theoretically worsen bradycardia – use with caution in patients with slow heart rate.⁴
- Use RE: BALANCE FOR HER™ with caution in patients who are allergic to other Fabaceae plants, including soybeans, peanuts, green peas, and other legumes.²
- Nelumbo nucifera* might decrease blood glucose levels – use with caution in patients taking antidiabetic medication.¹
- Bacopa monnieri* may inhibit acetylcholinesterase which may theoretically exacerbate gastrointestinal obstruction, peptic ulcers, pulmonary conditions (asthma and chronic obstructive pulmonary disease) and urogenital tract obstruction.⁴
- Bacopa monnieri* may theoretically exacerbate hyperthyroidism – use with caution in patients with thyroid disorders.⁴
- Discontinue use 2 weeks prior to elective surgical procedures.¹⁻³
- Consult a healthcare practitioner prior to use if you are pregnant or breastfeeding (see 4.6 'Fertility, pregnancy and lactation').

Paediatric population:

RE: BALANCE FOR HER™ is not recommended for use in patients under the age of 18 years.

4.5 Interaction with other medicines and other forms of interaction

No interaction studies have been performed.

Possible interactions with medicines:

- Anticholinergics:** Concomitant use might theoretically decrease the effectiveness of both *Bacopa monnieri* and anticholinergic agents.⁵
- Anticoagulants:** Concomitant use of *Nelumbo nucifera*,¹ *Trigonella foenum-graecum*,² or *Vitis vinifera*³ and anticoagulant medication/herbal supplements may theoretically have additive anticoagulant effects, consequently increasing the risk of bleeding.
- Beta-blockers:** *Trigonella foenum-graecum*² may theoretically have additive blood pressure lowering effects when using concomitantly with the beta-blocker, metoprolol.
- Cholinergics:** Theoretically, the concomitant use of *Bacopa monnieri* with other cholinergic agents might have additive effects (increased acetylcholine levels).⁴
- Cytochrome substrates:** Theoretically, *Bacopa monnieri* may increase the levels and adverse effects of CYP2C19, CYP2C9, CYP3A4 and CYP1A2 substrates.⁴
- Diuretics:** *Asparagus racemosus* root may theoretically increase diuresis and electrolyte loss when using concomitantly with diuretics.⁵
- Hypoglycaemics:** Theoretically, the concomitant use of *Nelumbo nucifera*¹ or *Trigonella foenum-graecum*² and hypoglycaemic medication/herbal supplements may have additive blood glucose lowering effects. Dose adjustments might be necessary.
- Lithium:** *Asparagus racemosus* root may theoretically reduce lithium excretion. Lithium dose adjustments might be necessary.⁵
- Thyroid hormones:** *Bacopa monnieri* may have additive effects (increases thyroxine (T4) levels) when using concomitantly with thyroid hormones.⁴
- Xanthines:** *Trigonella foenum-graecum*² may theoretically reduce the effectiveness of theophylline.

Possible interactions with diseases / conditions:

- Bleeding conditions:** Theoretically, *Nelumbo nucifera*,¹ *Trigonella foenum-graecum*,² and *Vitis vinifera*³ extracts may increase the risk of bleeding and bruising in individuals with bleeding conditions.
- Bradycardia:** *Bacopa monnieri* may inhibit acetylcholinesterase, which may theoretically worsen bradycardia.⁴
- Cross-allergenicity:** Patients who are allergic to other Fabaceae plants, including soybeans, peanuts, green peas, and other legumes, may theoretically be allergic to *Trigonella foenum-graecum*.²
- Diabetes:** *Nelumbo nucifera* might decrease blood glucose levels. Dosing adjustments for insulin or oral hypoglycaemic agents may be necessary.¹
- Gastrointestinal obstruction:** *Bacopa monnieri* may inhibit acetylcholinesterase, which may theoretically exacerbate gastrointestinal obstruction.⁴
- Peptic ulcers:** *Bacopa monnieri* may inhibit acetylcholinesterase, which may theoretically exacerbate peptic ulcer disease.⁴
- Pulmonary conditions:** *Bacopa monnieri* may inhibit acetylcholinesterase, which may theoretically exacerbate pulmonary conditions such as asthma and chronic obstructive pulmonary disease.⁴
- Surgery:** As *Nelumbo nucifera*¹ might decrease blood glucose levels, it may theoretically also interfere with blood glucose control during and after surgical procedures. *Trigonella foenum-graecum*,² *Nelumbo nucifera*,¹ and *Vitis vinifera*³ might have antiplatelet effects, and may cause excessive bleeding if used perioperatively. Discontinue use 2 weeks prior to elective surgical procedures.
- Thyroid disorders:** *Bacopa monnieri* may increase thyroxine levels, which may theoretically exacerbate hyperthyroidism.⁴
- Urogenital tract obstruction:** *Bacopa monnieri* may inhibit acetylcholinesterase, which may theoretically exacerbate urogenital tract obstruction.⁴

4.6 Fertility, pregnancy and lactation

Women of childbearing potential / Contraception in males and females:

No information available.

Pregnancy:

The safety of this product during pregnancy has not been established. In the absence of sufficient data, the use of RE: BALANCE FOR HER™ during pregnancy is not recommended, unless under supervision of and on recommendation of a doctor.

Breastfeeding:

The safety of this product during lactation has not been established. In the absence of sufficient data, the use of RE: BALANCE FOR HER™ during breastfeeding is not recommended, unless under supervision of and on recommendation of a doctor.

Fertility:

Fertility studies have not been performed.

4.7 Effects on ability to drive and use machines

No studies on the effect on the ability to drive and use machines have been performed. RE: BALANCE FOR HER™ may affect the ability to drive or operate machinery, as it may cause dizziness,² drowsiness,² headache,²⁻⁴ or insomnia.⁴

It is not always possible to predict to what extent RE: BALANCE FOR HER™ may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which RE: BALANCE FOR HER™ affects them.

4.8 Undesirable effects

If symptoms of hypersensitivity or allergic reactions (itching, rash, urticaria) occur, discontinue use of product, and contact a healthcare professional immediately.

Summary of adverse reactions:

Frequent:

Gastrointestinal disorders: Abdominal distention/pain,^{2,3} cramps⁴ diarrhoea,²⁻⁴ dry mouth,^{3,4} indigestion,^{2,3} flatulence,² and nausea.²⁻⁴

Less frequent (Rare):

Immunological disorders: Allergic reactions.^{2,3}

Musculoskeletal disorders: Joint pain and back pain.³

Respiratory disorders: Sore throat, cough, allergic rhinitis, and nasopharyngitis.³

Frequency unknown:

Cardiovascular disorders: Heart palpitations.⁴

Musculoskeletal disorders: Muscle fatigue.⁴

Neurological disorders: Dizziness,² drowsiness,² headache,²⁻⁴ and insomnia.⁴

Reporting of suspected adverse reactions:

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are asked to report any suspected adverse reactions to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8>.

4.9 Overdose

Insufficient reliable information. Side effects can be precipitated and/or be of increased severity (see 4.8 'Undesirable effects'). Treatment of overdose should be symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

D33 Ayurveda. Complementary Medicine: Discipline-Specific Traditional Claims.

Mechanism of action:

Asparagus racemosus Ayurvedic medicine used for female health⁶ and considered an aphrodisiac in females.^{6,7} *Asparagus racemosus* has adaptogenic properties, which may reduce stress in women and help to improve sexual performance.⁷

Nelumbo nucifera

The flowers contain flavonoids such as quercetin, luteolin, and kaempferol,¹ acting as antioxidants to help decrease the incidence of oxidative stress.^{2,10} Antioxidants may enhance sexual wellness by stimulating nitric oxide synthesis.¹¹

Trigonella foenum-graecum

A botanical extract rich in steroidal saponins which might induce estrogen-responsive genes.^{2,6} In females, *Trigonella foenum-graecum* extract increases estradiol, luteinizing hormone (LH) and follicle stimulating hormone (FSH) levels⁷ which may increase sexual arousal.

Bacopa monnieri

Pharmacological activity of *Bacopa monnieri* can be attributed to the saponin, bacoside and other saponin constituents.⁴ *Bacopa monnieri* has been found to have anxiolytic,^{4,12} adaptogenic⁴ and antioxidant^{4,12} properties, which may reduce stress, and as an effect, enhance libido.¹³

Vitis vinifera

Vitis vinifera is a source of antioxidants (oligomeric proanthocyanidins (OPCs), proanthocyanidins, flavonols, and polyflavan-3-ols).³ Antioxidants may enhance sexual wellness by stimulating nitric oxide synthesis.¹¹

Saraca asoca

Saraca asoca is traditionally used to support a healthy reproductive system in women.¹⁴ It has been shown to have oxytocic, uterotropic, anti-progestational, anti-estrogenic, anti-inflammatory, and antioxidant properties.¹⁴ Antioxidants may enhance sexual wellness by stimulating nitric oxide synthesis.¹¹ *Saraca asoca* also acts as a demulcent for uterine disorders, regulates menstrual pain and is used for overall uterine problems.¹⁴

Symplocos racemose

Symplocos racemose has been shown to have promising effects in treating female reproductive dysfunctions induced by cold restraint stress, along with increased serum LH and FSH levels.^{4,15}

5.2 Pharmacokinetic properties

No information available.

5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber which are additional to that already included in other sections of the Professional Information.

Asparagus racemosus

Possibly safe when used appropriately in healthy individuals.⁵

Bacopa monnieri

Possibly safe when used appropriately, short-term.⁴

Nelumbo nucifera

Insufficient reliable information available about the safety of medicinal use.¹

Saraca asoca

Unknown.

Symplocos racemose

Unknown.

Trigonella foenum-graecum

Possibly safe when used orally in medicinal amounts.²

Vitis vinifera

Possibly safe when used orally in medicinal amounts.³

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

- Potassium sorbate
- Silicon dioxide (Aerosil®)
- Sodium benzoate
- Starch
- Stearic acid
- Talc

6.2 Incompatibilities

In the absence of compatibility studies, RE: BALANCE FOR HER™ must not be mixed with other medicines.

6.3 Shelf life

24 months

6.4 Special precautions for storage

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

Protect from light / moisture.

Do not use if seal under the cap is broken or missing.

6.5 Nature and contents of container

60 clear, size 00 vegi capsules filled with brown powder. The capsules are packed in a 250 mL black PET bottle, with a black polypropylene plastic cap. The bottle contains a 2.0 g silica gel sachet and wadding on top of the capsules.

6.6 Special precautions for disposal of a used medicine or waste materials derived from such medicine and other handling of the product

No special requirements.

7. THE HOLDER OF THE CERTIFICATE OF REGISTRATION

AR-VEDA (PTY) LTD

767 The Ridge

Ridge Road

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Pretoria

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Email: info@ar-veda.com

8. REGISTRATION NUMBER(S)/REFERENCE NUMBER

To be allocated

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

To be allocated

10. DATE OF REVISION OF TEXT

January 2023



RB-P-v1.0

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S0

RE: BALANCE FOR HER™ (capsules)

Asparagus racemosus Willd. (Shatavari), *Saraca asoca* (Roxb.) Willd. (Ashoka), *Vitis vinifera* L. (Draksha), *Bacopa monnieri* (L.) Wettst. (Brahmi), *Symplocos racemosa* Roxb. (Lodhra), *Trigonella foenum-graecum* L. (Methi), and *Nelumbo nucifera* Gaertn. (Kamal)

Sugar free.

COMPLEMENTARY MEDICINE

Ayurveda. Discipline-Specific

This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use. A varied diet is the most effective and safe way to achieve good nutrition, health, body composition as well as mental and physical performance.

Read all of this leaflet carefully because it contains important information for you RE: BALANCE FOR HER™ is available without a doctor's prescription. Nevertheless, you still need to use RE: BALANCE FOR HER™ carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share RE: BALANCE FOR HER™ with any other person.
- Ask your doctor, pharmacist or other healthcare provider if you need more information or advice.
- If symptoms worsen or do not improve, a doctor, pharmacist or other healthcare provider should be consulted.

What is in this leaflet

- What RE: BALANCE FOR HER™ is and what it is used for.
- What you need to know before you take RE: BALANCE FOR HER™.
- How to take RE: BALANCE FOR HER™.
- Possible side effects.
- How to store RE: BALANCE FOR HER™.
- Contents of the pack and other information.

1. What RE: BALANCE FOR HER™ is and what it is used for

The RE: BALANCE FOR HER™ unique blend of natural herbs promotes hormonal balance in women throughout the menstrual cycle, maintains energy levels, combats stress and anxiousness, and promotes a healthy libido.

2. What you need to know before you take RE: BALANCE FOR HER™

Do not take RE: BALANCE FOR HER™:

- If you are hypersensitive (allergic) to the active substances, *Asparagus racemosus* Willd. (Shatavari), *Saraca asoca* (Roxb.) Willd. (Ashoka), *Vitis vinifera* L. (Draksha), *Bacopa monnieri* (L.) Wettst. (Brahmi), *Symplocos racemosa* Roxb. (Lodhra), *Trigonella foenum-graecum* L. (Methi), *Nelumbo nucifera* Gaertn. (Kamal), or any of the other ingredients (listed in section 6).

Warnings and precautions

Take special care with RE: BALANCE FOR HER™:

- If you have a bleeding disorder or using blood thinners/antiplatelet medicine, as *Nelumbo nucifera*,¹ *Trigonella foenum-graecum*,² and *Vitis vinifera*³ may theoretically have antiplatelet effects and increase the risk of bleeding.
- If you have a slow heart rate, as *Bacopa monnieri* may theoretically worsen this condition.⁴
- If you are allergic to other Fabaceae plants, including soybeans, peanuts, green peas, and other legumes.²
- If you have diabetes and are taking supplements to decrease your blood glucose levels.¹
- If you have an intestinal obstruction, stomach ulcer, asthma, lung condition or a urinary tract obstruction, as *Bacopa monnieri* may theoretically exacerbate these conditions.⁴
- If you have a thyroid disorder, as *Bacopa monnieri* may theoretically exacerbate hyperthyroidism (overactive thyroid).⁴
- Discontinue use 2 weeks prior to elective surgical procedures.¹⁻³
- Consult a healthcare practitioner prior to use if you are pregnant or breastfeeding (see 'Pregnancy, breastfeeding and fertility').

Children and adolescents:

RE: BALANCE FOR HER™ is not recommended for use in patients under the age of 18 years.

Other medicines and RE: BALANCE FOR HER™:

Always tell your healthcare provider if you are taking any other medicine (this includes all complementary or traditional medicines).

Consult your doctor if you want to take RE: BALANCE FOR HER™ in combination with medicines or treatments such as:

- Anticholinergics, as the concomitant use might theoretically decrease the effectiveness of both *Bacopa monnieri* and anticholinergic agents.⁵
- Anticoagulants (blood thinners), as the concomitant use of *Nelumbo nucifera*,¹ *Trigonella foenum-graecum*,² or *Vitis vinifera*³ and anticoagulant medication/herbal supplements may theoretically increase the risk of bleeding.
- Beta-blockers, as *Trigonella foenum-graecum*² may theoretically have additive blood pressure lowering effects when using concomitantly with the beta-blocker, metoprolol.
- Cholinergics, as the concomitant use of *Bacopa monnieri* with other cholinergic agents might theoretically have additive effects (increase acetylcholine levels).⁴
- Cytochrome substrates, as *Bacopa monnieri* may theoretically increase the levels and adverse effects of CYP2C19, CYP2C9, CYP3A4 and CYP1A2 substrates.⁴
- Diuretics, as *Asparagus racemosus* root may theoretically increase diuresis (increased flow of urine) and electrolyte loss when using concomitantly with diuretics.⁵
- Hypoglycaemics (blood glucose lowering agents), as the concomitant use of *Nelumbo nucifera*¹ or *Trigonella foenum-graecum*² and hypoglycaemic medication/herbal supplements may theoretically have additive blood glucose lowering effects. Dose adjustments might be necessary.
- Lithium, as *Asparagus racemosus*

Driving and using machinery:

RE-BALANCE FOR HER™ may affect the ability to drive or operate machinery, as it may cause dizziness,² drowsiness,⁴ headache,² or insomnia.⁴

It is not always possible to predict to what extent RE-BALANCE FOR HER™ may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which RE-BALANCE FOR HER™ affects them.

3. How to take RE-BALANCE FOR HER™

Do not share medicines prescribed for you with any other person.

Always take RE-BALANCE FOR HER™ exactly as described in this leaflet or as your doctor, pharmacist or other healthcare provider have told you. Check with your doctor, pharmacist or other healthcare provider if you are not sure.

The usual dose is:

Adults over 18 years:

Take 1 capsule twice daily with water or milk.

For oral use only.

If you take more RE-BALANCE FOR HER™ than you should:

Insufficient reliable information. Side effects can be precipitated and/or be of increased severity (see 4 'Possible side effects').

In the event of overdose, consult your doctor, pharmacist or other healthcare provider. If none is available, contact the nearest hospital or poison centre.

If you forget to take a dose of RE-BALANCE FOR HER™:

Always take RE-BALANCE FOR HER™ as described in this leaflet. If you miss a dose, take it as soon as you remember. If you do not remember the missed dose until the next dose is due, skip the missed dose and go back to your regular dosing schedule. Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

RE-BALANCE FOR HER™ can have side effects.

Not all side effects reported for RE-BALANCE FOR HER™ are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking RE-BALANCE FOR HER™, please consult your healthcare provider for advice.

If any of the following happens, stop taking RE-BALANCE FOR HER™ and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing;
- rash or itching;
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to RE-BALANCE FOR HER™. You may need urgent medical attention or hospitalisation.

Other possible side effects are:

Frequency:

- Abdominal bloating/pain,^{2,3} cramps,⁴ diarrhoea,²⁻⁴ dry mouth,^{3,4} indigestion,^{2,3} flatulence,² and nausea.²⁻⁴

Less frequent (Rare):

- Allergic reactions.^{2,3}
- Joint pain and back pain.³
- Sore throat, cough, hay fever, and cold.³

Frequency unknown:

- Heart palpitations.⁴
- Muscle fatigue.⁴
- Dizziness,² drowsiness,⁴ headache,²⁻⁴ insomnia.⁴

If you notice any side effects not mentioned in this leaflet, please inform your doctor, pharmacist or other healthcare provider.

Reporting of side effects:

If you get side effects, talk to your doctor, pharmacist or healthcare provider. You can also report side effects to SAHPRA via the "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 RE-BALANCE FOR HER™.

5. How to store RE-BALANCE FOR HER™

- Store all medicines out of reach of children.
- Store at or below 25 °C in a cool, dry place.
- Protect from light / moisture.
- Do not use if seal under the cap is broken or missing.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What RE-BALANCE FOR HER™ contains:

The active substances are:

Asparagus racemosus Willd. (Shatavari) 100 mg

[root; 10:1 extract providing 1000 mg dried herb equivalent]

Saraca asoca (Roxb.) Willd. (Ashoka) 100 mg

[bark; 10:1 extract providing 1000 mg dried herb equivalent]

Vitis vinifera L. (Draksha) 70 mg

[seed; 10:1 extract providing 700 mg dried herb equivalent]

Bacopa monnieri (L.) Wettst. (Brahmi) 65 mg

[aerial; 10:1 extract providing 650 mg dried herb equivalent]

Symplocos racemosa Roxb. (Lodhra) 50 mg

[bark; 5:1 extract providing 250 mg dried herb equivalent]

Trigonella foenum-graecum L. (Methi) 50 mg

[seed; 10:1 extract providing 500 mg dried herb equivalent]

Nelumbo nucifera Gaertn. (Kamal) 15 mg

[flower; 10:1 extract providing 150 mg dried herb equivalent]

The other ingredients are:

Potassium sorbate, silicon dioxide (Aerosil®), sodium benzoate, starch, stearic acid and talc.

What RE-BALANCE FOR HER™ looks like and contents of the pack:

60 clear, size 00 vegi capsules filled with brown powder. The capsules are packed in a 250 mL black PET bottle, with a black polypropylene plastic cap. The bottle contains a 2,0 g silica gel sachet and wadding on top of the capsules.

Holder of Certificate of Registration and Manufacturer:

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This leaflet was last revised in:

January 2023

Registration/reference number:

To be allocated.

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- Antistolmiddels (bloedverdunders), omrede die gesamentlike gebruik van *Nelumbo nucifera*,¹ *Trigonella foenum-graecum*,² of *Vitis vinifera*² en antistolmiddels/kruiëaanvullings teoreties die risiko van bloeding kan verhoog.
- Diëtablokkers, omrede *Trigonella foenum-graecum*² teoreties bykomende bloeddrukverlagende effekte kan hê wanneer dit saam met die betablokker metoprolol gebruik word.
- Cholinergiese middels, omrede die gesamentlike gebruik van *Bacopa monnieri* met ander cholinergiese middels teoreties bykomende effekte kan hê (verhoog asetiëcholinienvlakke).⁴
- Sitochroom substrate, omrede *Bacopa monnieri* teoreties die vlakke en nadelige effekte van CYP2C19, CYP2C9, CYP3A4 en CYP1A2 substrate kan verhoog.⁴
- Diuretika, omrede *Asparagus racemosus* wortel teoreties diuresis (verhoogde vloeï van urine) en elektrolietverlies kan verhoog wanneer dit saam met diuretika gebruik word.⁵
- Hipoglisemiese middels (bloedglukoseverlagende middels), omrede die gesamentlike gebruik van *Nelumbo nucifera*,¹ of *Trigonella foenum-graecum*² en hipoglisemiese medikasie/kruiëaanvullings teoreties bykomende bloedglukoseverlagende effekte kan hê. Dosisaanpassings kan nodig wees.
- Litium, omrede *Asparagus racemosus* wortel teoreties litiumuitskeiding kan verminder. Litium dosisaanpassings mag nodig wees.⁵
- Skildklierhormone, omrede *Bacopa monnieri* bykomende effekte kan hê (verhoog tiroksien (T4) vlakke) wanneer dit saam met tiroïedhormone gebruik word.⁴
- Xantiene, omrede *Trigonella foenum-graecum*² teoreties die doeltreffendheid van teofilien (ontspanning van die spiere in die lugweë van die longe) kan verminder.

RE-BALANCE FOR HER™ kos, drinkgoed en alkohol:

Onbekend.

Swangerskap, borsvoeding en vrugbaarheid:

Die veiligheids van RE-BALANCE FOR HER™ tydens swangerskap en borsvoeding is nie vasgestel nie.

As u swanger is of borsvoed, dink u is dalk swanger of beplan om 'n baba te hê, raadpleeg asseblief u dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat u hierdie medisyne gebruik. Vrugbaarheidstudies is nie uitgevoer nie.

Bestuur en die gebruik van masjinerie:

RE-BALANCE FOR HER™ kan die vermoë om te bestuur of masjinerie te gebruik beïnvloed, omrede dit duiseligheid,² lomerigheid,⁴ hoofpyn,²⁻⁴ en slapeeloosheid⁴ kan veroorsaak.

Dit is nie altyd moontlik om te voorspel tot watter mate RE-BALANCE FOR HER™ die daaglikse aktiwiteite van 'n pasiënt kan beïnvloed nie.

Pasiënte moet seker maak dat hulle nie aan bogenoemde aktiwiteite deelneem totdat hulle nie bewus is van hoe RE-BALANCE FOR HER™ hulle beïnvloed nie.

3. Hoe om RE-BALANCE FOR HER™ te neem

Moenie medisyne wat vir u voorgeskryf is, met enige ander persoon deel nie.

Neem RE-BALANCE FOR HER™ soos voorgeskryf in hierdie vouiljet of soos u dokter, apteker of gesondheidsorgverskaffer aanbeveel het.

Maak seker by u dokter, apteker of gesondheidsorgverskaffer wat die aanbevole dosis is indien u onseker is.

Die gewone dosis is:

Volwassenes ouer as 18 jaar:

Neem 1 kapsule twee keer per dag met water of melk.

Slegs vir orale gebruik.

Indien u meer RE-BALANCE FOR HER™ neem as wat u behoort:

Onvoldoende betroubare inligting. Nieuwe-effekte kan ontstaan en/of die graad daarvan kan toeneem (sien 4 'Moontlike nuwe-effekte').

In die geval van 'n oordosis, raadpleeg u dokter, apteker of ander gesondheidsorgverskaffer. Indien nie een van hulle beskikbaar is nie, kontak die naaste hospitaal of dibzbeheersentrum.

Indien u vergeet om 'n dosis RE-BALANCE FOR HER™ te neem:

Neem RE-BALANCE FOR HER™ altyd soos voorgeskryf in hierdie vouiljet. Indien u 'n dosis vergeet het, neem dit so gou as wat u onthou. Indien u egter nie van die vergeete dosis onthou voordat dit tyd is vir die volgende dosis nie, slaan die vergeete dosis oor en keer terug na u gewone doseringskedule. Moenie 'n dubbele dosis neem om te vergoed vir die oorgeslane individuele dosis nie.

4. Moontlike nuwe-effekte

RE-BALANCE FOR HER™ kan nuwe-effekte hê.

Nie alle nuwe-effekte wat aangemeld is vir RE-BALANCE FOR HER™ is in hierdie vouiljet ingesluit nie. Indien u algemene gesondheid vererger, of as u ongewenste gevolge ervaar tydens die gebruik van RE-BALANCE FOR HER™, raadpleeg u gesondheidsorgverskaffer vir advies.

Indien enige van die volgende gebeur, hou op om RE-BALANCE FOR HER™ te neem en lig u dokter dadelik in of gaan na die ongevallende afdeling by u naaste hospitaal:

- Swelling van die hande, voete, enkels, gesig, lippe, mond of keel, wat probleme kan veroorsaak om te sluk of asem te haal;
- uitslag of jeuk;
- flou val.

Dit is alles baie ernstige nuwe-effekte. Indien u dit het, het u dalk 'n ernstige reaksie op RE-BALANCE FOR HER™ gehad. U benodig hoogs waarskynlik dringende mediese aandag of hospitalisasie.

Ander moontlike nuwe-effekte is:

Algemeen:

Abnormale opgeblasenheid/pyn,^{2,3} krampe,⁴ diarree,²⁻⁴ droë mond,^{3,4} omgekrapte maag,^{2,3} winderigheid,² en naarheid.²⁻⁴

Minder algemeen (Skaars):

Allergiese reaksies.^{2,3}

Gewrigspyn en rugpyn.³

Seer keel, hoes, hooikoors en verkoue.³

Frekwensie onbekend:

Hartkloppings.⁴

Spiermoegheid.⁴

Duiseligheid,² lomerigheid,⁴ hoofpyn,²⁻⁴ slapeeloosheid.⁴

Lig asseblief u dokter, apteker of gesondheidsorgverskaffer in indien u enige nuwe-effekte opmerk wat nie in hierdie vouiljet genoem word nie.

Rapportering van nuwe-effekte:

Praat met u dokter, apteker of gesondheidsorgverskaffer indien u nuwe-effekte ervaar. U kan ook nuwe-effekte by SAHPRA aanmeld via die "6.04 Adverse Drug Reaction Reporting Form", wat aanlyn gevind kan 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 rakende die veiligheid van RE-BALANCE FOR HER™ te verskaf.

5. Hoe om RE-BALANCE FOR HER™ te stoor

- Berg alle medisyne buite bereik van kinders.
- Berg by of onder 25 °C in 'n koel, droë plek.
- Beskerm teen lig / vog.
- Moet nie gebruik as seël onder die doppie gebreek of weg is nie.
- Neem alle ongebruikte medisyne terug na u apteker.
- Moenie ongebruikte medisyne in dreine of rioolstelsels (bv. toilette) weggooi nie.

6. Inhoud van die verpakking en ander inligting

Wat RE-BALANCE FOR HER™ bevat:

Die aktiewe bestanddele is:

Asparagus racemosus Willd. (Shatavari) 100 mg

[wortel; 10:1 ekstrak verskaf 1000 mg gedroogde kruit ekwivalent]

Saraca asoca (Roxb.) Willd. (Ashoka) 100 mg

[bas; 10:1 ekstrak verskaf 1000 mg gedroogde kruit ekwivalent]

Vitis vinifera L. (Draksha) 70 mg

[saad; 10:1 ekstrak verskaf 1000 mg gedroogde kruit ekwivalent]

Bacopa monnieri (L.) Wettst. (Brahmi) 65 mg

[luggedeeltes; 10:1 ekstrak verskaf 650 mg gedroogde kruit ekwivalent]

Symplocos racemosa Roxb. (Lodhra) 50 mg

[bas; 5:1 ekstrak verskaf 250 mg gedroogde kruit ekwivalent]

Trigonella foenum-graecum L. (Methi) 50 mg

[saad; 10:1 ekstrak verskaf 500 mg gedroogde kruit ekwivalent]

Nelumbo nucifera Gaertn. (Kamal) 15 mg

[blom; 10:1 ekstrak verskaf 150 mg gedroogde kruit ekwivalent]

Die ander bestanddele is:

Kaliumsorbaat, natriumbensoaat, silikondioksied (Aerosil®), steariensuur, stysel, en talc.

Hoe RE-BALANCE FOR HER™ lyk en die inhoud van die verpakking:

60 deursynende, grootte 00 vegi kapsules gevul met bruin poeier. Die kapsules is verpak in 'n 250 mL swart PET bottel, met 'n swart polipropileen plastiek doppie. Die bottel bevat 'n 2,0 g silikagel sakkie en 'n watte bo-op die kapsules.

Houer van die Sertifikaat van Registrasie en Vervaardiger:

AR-VEDA (PTY) LTD

767 The Ridge

Ridge Road

Tijger Valley

Pretoria

0081

Epos: info@ar-veda.com

Hierdie vouiljet was laaste hersien in:

Januarie 2023

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PRO-PRINT (PTY) LTD
THE PROFESSIONALS IN PRINT

REPRO

Date: 23 January 2023
Operator: Jacky Pistorius
Customer: Ar-Veda (Pty) Ltd
Product Name: Re:Balance For Her
Product Code: RB-P-v1.0
Dimensions: 210 x 380 mm
Fold Size: 30 x 50
Font Size: 6 point Helvetica
Colours: (1) Black
--
Barcode: --
Pharmacode: --
Stock: 40 gsm
Proof Status: 1st (First)

Proof read by: _____

Reset: Alterations: Disk/Possie:

No alterations - Proceed as soon as possible

Note alterations - Further proof is required

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Although we endeavour to proof accurately, we cannot accept responsibility for errors once proofs are signed and accepted by our clients.

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