

# WELLVITA MOOD BALANCE

## PROPRIETARY NAME AND DOSAGE FORM

WELLVITA® MOOD BALANCE (capsule)

## COMPOSITION

Each capsule contains: Active ingredient: St John's Wort (*Hypericum perforatum* L. herb as a 4:1 extract) 50 mg, 5 HTP (*Griffonia simplicifolia*, seed extract) 50 mg, Rhodiola (*Rhodiola rosea*, root powder) 50 mg, L-Theanine 50 mg and Vitamin B6 12.5 mg.

## PHARMACOLOGICAL CLASSIFICATION

D 33.7 Combination product

Complementary medicine - Western herbal

## INDICATIONS

Wellvita® Mood Balance formula provides the body with mood-enhancing herbals and nutrients traditionally used for mental and emotional wellness.

## CONTRA-INDICATIONS

Do not use this medicine if you are hypersensitive (allergic) to any of the ingredients in the formulation; or if you are pregnant or breastfeeding. Not suitable for use in children, unless under medical supervision.

## WARNINGS AND SPECIAL PRECAUTIONS

If you suffer from any serious ailments or conditions (including diabetes); or if you are taking any prescribed medication (such as warfarin or immunosuppressants), please check with your healthcare provider before taking this medicine.

- Consult a relevant healthcare provider prior to use if you are taking carbidopa or medicines supplements with serotonergic activity. These may include, but are not limited to, tryptophan, S-Adenosylmethionine (SAME), antidepressants, pain killers, over the counter cough and cold medication containing dextromethorphan, anti-nausea medication and anti-migraine medication.
- Stop use and consult a relevant healthcare provider if you show signs of weakness, oral ulcers, abdominal pain accompanied by severe muscle pain or if you experience skin changes.
- Avoid taking with alcohol or products that cause drowsiness.
- This medicine might slow blood clotting and should be used cautiously with any other blood thinning medication. Discontinue use two weeks prior to any scheduled surgery.
- Use cautiously if you have sensitive skin as this medicine can cause photosensitivity. Sunblock should be applied while taking this medicine.
- Do not suddenly stop taking this medicine, the dosage should be decreased over a period of time. Please consult your healthcare provider for further advice.
- Consult a healthcare provider if symptoms worsen or persist.
- This medicine might cause drowsiness and may have an influence on your ability to drive or use machinery. Do not drive or operate machinery until you know how it affects you.
- Porphyria: Safety has not been established.

Nutritional supplementation should not replace a balanced diet. Do not exceed the recommended dose without consulting a healthcare provider.

## PREGNANCY AND LACTATION

If you are pregnant or breastfeeding, do not take this medicine.

## INTERACTIONS

If you are taking other medicines regularly, including complementary or traditional medicines, or start taking any additional medicines while taking this medicine, consult your healthcare provider for advice. This medicine may interfere with the way the body processes certain drugs using the liver's "cytochrome P450" enzyme system. As a result, the levels of these drugs may be altered in the blood, and may cause a decrease in efficacy or potentially serious adverse reactions. Anyone using any other medications (for example warfarin, carbamazepine, phenobarbital, HIV medicine, digoxin, oral contraceptives, SSRI's, Lithium, epilepsy medicine etc.) should check with their healthcare provider about possible interactions before taking this medicine. This medicine may also increase the risk of photosensitivity. Use cautiously in people with sensitive skin or those taking photosensitizing drugs.

## DOSAGE AND DIRECTIONS FOR USE

Adults: Take one to two capsules daily with water. Consult your healthcare provider if symptoms worsen.

## SIDE EFFECTS AND SPECIAL PRECAUTIONS

Side effects may include skin rash, insomnia, vivid dreams, restlessness, anxiety, gastrointestinal discomfort, diarrhoea, fatigue, dry mouth, dizziness, headache and hypoglycemia. Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, discontinue use immediately and consult your doctor, pharmacist or other healthcare provider for advice.

## KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

In case of an overdose, or a suspected overdose, contact your healthcare provider immediately. Treatment is symptomatic and supportive.

## IDENTIFICATION

White capsule.

## PRESENTATION

30 Capsules are packed in a plastic container.

## STORAGE INSTRUCTIONS

Store all medicines out of reach of children. Store in a cool dry place below 25 °C and keep away from direct sunlight. Keep the container tightly closed.

## NAME AND BUSINESS ADDRESS OF THE APPLICANT

Alveta Healthcare (Pty) Ltd, 1 Greenwich Grove, Station Road, Rondebosch, 7700. Company registration number: 2004/021899/07. Pharmacy audit number: Y60123.

## DATE OF PUBLICATION OF THE PACKAGE INSERT

1 October 2022

# WELLVITA MOOD BALANCE

**HANDELSMERKNAAM EN DOSEERVORM**  
WELLVITA® MOOD BALANCE (kapsule)

## **SAMESTELLING**

Elke kapsule bevat: Aktiewe bestanddele: St John's Wort (*Hypericum perforatum L.*, kruie as a 4:1 uittreksel) 50 mg, 5 HTP (*Griffonia simplicifolia*, saaduittreksel) 50 mg, Rhodiola (*Rhodiola rosea*, wortelpoeier) 50 mg, L-Theanine 50 mg en Vitamien B6 12.5 mg.

## **FARMAKOLOGIESE KLASSIFIKASIE**

D 33.7 Kombinasie produk  
Komplementêre medisyne - Westerse kruie.

## **INDIKASIES**

Wellvita® Mood Balance voorsien die liggaam van gemoedsversterkende kruie en voedingstowwe wat tradisioneel gebruik word vir geestelike en emosionele welstand.

## **KONTRA-INDIKASIES**

Vermag as jy hipersensitief (allergies) is vir enige van die bestanddele in die formule; of as jy swanger is of borsvoed. Nie geskik vir gebruik in kinders, behalwe onder die toesig van 'n geneesheer.

## **WAARSKUWINGS EN SPESIALE VOORSORGMATREËLS**

As jy enige voorgeskrewe medisyne (soos warfarien of immuunonderdrukkers) gebruik of aan enige ernstige siektes (insluitend diabetes) of toestande ly, raadpleeg jou geneesheer voordat jy hierdie medisyne begin gebruik.

- Raadpleeg 'n gesondheidsorgverskaffer vir gebruik as jy karbidopa of medisyne/aanvullings met serotonergiese aktiwiteit gebruik. Hierdie kan insluit, maar is nie beperk nie tot, tryptofaan, S-adenosilmetonien (SAME), antidepressante, pynstillers, oor-die-toonbank hoese en verkoue medikasie wat deksametofan bevat asook medikasie vir naargee en migraine.
- Staak gebruik en raadpleeg 'n gesondheidsorgverskaffer as jy tekens toon van swakheid, mondseer, abdominale pyn wat gepaard gaan met erge spierpyn, of as jy vel veranderings opmerk.
- Vermag inname saam met alkohol of produkte wat lomerigheid kan veroorsaak.
- Hierdie medisyne kan moontlik bloedstolling vertraag en moet met sorg gebruik word in pasiënte wat enige ander bloedverduunningsmedikasie gebruik. Staak gebruik ten minste twee weke voor enige beplande sjirurgie.
- Gebruik met sorg in pasiënte wat 'n sensitiewe vel het, omdat hierdie medisyne fotosensitieweit kan veroorsaak. Sonblik moet gebruik word in diegene wat hierdie medisyne gebruik.
- Moenie skielik die gebruik van hierdie medisyne staak nie. Die dosis moet verlaag word oor 'n tydperk. Raadpleeg jou geneesheer vir meer advies.
- Raadpleeg jou geneesheer indien simptome vererger of nie verbeter nie.
- Hierdie medisyne kan lomerigheid veroorsaak en kan 'n invloed hê op bestuur en die gebruik van masjinerie. Moenie bestuur of masjinerie gebruik totdat jy weet hoe die medisyne jou beïnvloed nie.
- Porfirie: Veiligheid is nie vasgestel nie.

Voedingsaanvullings moet nie 'n gebalanseerde dieet vervang nie. Moenie die aanbevole dosis oorskry sonder om 'n geneesheer te raadpleeg nie.

## **SWANGERSKAP EN BORSVOEDING**

Moenie gebruik indien jy swanger is of borsvoed nie.

## **INTERAKSIES**

As jy ander medisyne gereed gebruik, insluitend aanvullende (komplementêre) of tradisionele medisyne, of as jy enige addisionele medisyne begin neem terwyl jy hierdie medisyne gebruik, raadpleeg jou geneesheer vir raad. Hierdie medisyne kan inmeng met die metabolisme van sekere medisyne wat gemetaboliseer word via die lewer se 'sitochroom P450-stelsel'. As gevolg van hierdie interaksie kan die vlakke van sekere middels verander in die bloedstroom wat kan lei tot oneffektiwiteit of potensieel ernstige nuwe-effekte. Indien jy enige ander medikasie (voorbeeld sluit in warfarien, karbamazepine, fenobarbital, HIV medikasie, digoksin, oral kontrasepsie, SSR's, Lithium, epilepsie medikasie ens.) gebruik, raadpleeg jou geneesheer vir raad aangaande enige interaksies voordat jy hierdie medikasie begin gebruik. Hierdie medikasie kan ook fotosensitieweit veroorsaak: Gebruik met sorg in pasiënte met 'n sensitiewe vel of wat ander medisyne gebruik wat dit ook kan veroorsaak.

## **DOSIS EN GEBRUIKSAANWYSINGS**

Volwassenes: Neem een tot twee kapsules daagliks met water. Raadpleeg jou geneesheer indien simptome vererger.

## **NEWE-EFFEKTE**

Neuwe-effekte kan veluislag, slaaploosheid, slaapversteurings (insluitend erge drome), rusteloosheid, angs, gastro-intestinale ongemak, diarree, moegheid, droë mond, duiiselheid, hoofpyn, en lae bloedsuikervlakke insluit. Sommige aangemelde nuwe-effekte is nie in hierdie vouiljet ingesluit nie. Indien jy enige onaangename nuwe-effekte ervaar of voel dat jou algemene gesondheid verswak, hou onmiddellik op om die medisyne te gebruik en kontak jou geneesheer.

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

In geval van oordosering, of indien oordosering vermoed word, raadpleeg jou geneesheer onmiddellik. Behandeling is simptomaties en ondersteunend.

## **IDENTIFIKASIE**

Wit kapsule.

## **AANBIEDING**

30 Kapsules is in 'n plastiekhouer verpak.

## **BERGINGSAAWYSINGS**

Berg alle medisyne buite bereik van kinders. Berg in 'n koel, droë plek onder 25 °C en hou weg van direkte sonlig. Hou die houer dig toe.

## **NAAM EN BESIGHEIDSADRES VAN DIE APPLIKANT**

Alveta Healthcare (Pty) Ltd, Greenwich Grove 1, Station weg, Rondebosch, 7700. Maatskappy registrasie nommer: 2004/021899/07. Apteek oudit nommer: Y60123.

## **DATUM VAN VOUBILJET PUBLIKASIE**

1 Oktober 2022

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