

# PROFESSIONAL INFORMATION

## DOCTOR DAYCARE Calm and Ease

SCHEDULING STATUS: **[S0]**

PROPRIETARY NAME AND DOSAGE FORM:  
DOCTOR DAYCARE Calm and Ease (syrup).

### COMPOSITION:

Each 5 ml syrup contains:

Active Ingredients	Per 5 ml
<i>Valeriana officinalis</i> L. (Valerian root) extract	320 mg
<i>Bacopa monnieri</i> L. Wettst. (Bacopa) extract	72 mg
<i>Melissa officinalis</i> L. (Lemon balm leaf) extract	64 mg

Inactive ingredients: Flavourant (Blueberry), glycerine, maltodextrin, microcrystalline cellulose, sodium carmellose and water.

Preservatives: potassium sorbate 0,035 % m/v; sodium benzoate 0,045 % m/v.

Contains sugar (sorbitol (2,695 g/5 ml)).

Artificial colourant and flavourant free.

Free of Sucrose and Glucose.

Tartrazine free.

Alcohol free.

### CATEGORY AND CLASS:

Category of medicine: D

Class: D 33.6 Western Herbal.

Complementary Medicine.

### PHARMACOLOGICAL ACTION:

Pharmacodynamic properties:

DOCTOR DAYCARE Calm and Ease contains *Valeriana officinalis* L. (valerian root) extract, *Bacopa monnieri* L. Wettst. (bacopa) extract and *Melissa officinalis* L. (lemon balm leaf) extract.

**Valeriana officinalis** L. (Valerian root): An extract made from the *Valeriana officinalis* L. perennial herb. Valerian's anxiolytic, anticonvulsant, and sedative properties may be due to the effects of its constituents on gamma-Aminobutyric acid (GABA), adenosine A1, and serotonin (5HT) receptors. The extract is traditionally used for treating symptoms of mental stress/nervous tension and sleep disorders.

## PATIENT INFORMATION LEAFLET

This leaflet tells you about DOCTOR DAYCARE Calm and Ease.

Complementary Medicine. Western Herbal.

SCHEDULING STATUS: **[S0]**

PROPRIETARY NAME AND DOSAGE FORM:  
DOCTOR DAYCARE Calm and Ease (syrup).

Read all of this leaflet carefully because it contains important information for you. DOCTOR DAYCARE Calm and Ease is available without a doctor's prescription. Nevertheless, you still need to use DOCTOR DAYCARE Calm and Ease carefully to get the best results from it. Keep this leaflet. You may need to read it again. Do not share DOCTOR DAYCARE Calm and Ease with any other person. Ask your pharmacist if you need more information or advice. You must see a doctor if your symptoms worsen or do not improve.

### WHAT DOCTOR DAYCARE Calm and Ease CONTAINS:

Each 5 ml contains:

Active Ingredients	Per 5 ml
<i>Valeriana officinalis</i> L. (Valerian root) extract	320 mg
<i>Bacopa monnieri</i> L. Wettst. (Bacopa) extract	72 mg
<i>Melissa officinalis</i> L. (Lemon balm leaf) extract	64 mg

Inactive ingredients: Flavourant (Blueberry), glycerine, maltodextrin, microcrystalline cellulose, sodium carmellose and water.

Preservatives: potassium sorbate 0,035 % m/v; sodium benzoate 0,045 % m/v.

Contains sugar (sorbitol (2,695 g/5 ml)).

Artificial colourant and flavourant free.

Free of Sucrose and Glucose.

Tartrazine free.

Alcohol free.

### WHAT DOCTOR DAYCARE Calm and Ease IS USED FOR:

DOCTOR DAYCARE Calm and Ease assists with the relief of mental stress and sleep disturbances to support cognitive health and brain function.

### BEFORE YOU TAKE DOCTOR DAYCARE Calm and Ease:

Do NOT take DOCTOR DAYCARE Calm and Ease:

- If you are allergic to any of the ingredients (see "WHAT DOCTOR DAYCARE Calm and Ease CONTAINS").
- If you are pregnant or breastfeeding your baby (see "Pregnancy and breastfeeding").
- For children younger than 6 years old since safety and efficacy has not been established.

### Take special care with DOCTOR DAYCARE Calm and Ease:

There are no known warnings and special precautions associated DOCTOR DAYCARE Calm and Ease.

DOCTOR DAYCARE Calm and Ease does not intend to prevent or cure any form of illness or disease and should not replace any medication. If you suffer from a chronic medical condition, consult your healthcare practitioner before using this product.

### Taking DOCTOR DAYCARE Calm and Ease with food and drink:

There are no known side effects to taking DOCTOR DAYCARE Calm and Ease with food and drink. To minimize gastrointestinal discomfort, DOCTOR DAYCARE Calm and Ease is best taken with food or after a meal (see "DOSAGE AND DIRECTIONS FOR USE").

### Pregnancy and breastfeeding:

Do not use DOCTOR DAYCARE Calm and Ease during pregnancy and/or while you are breastfeeding your baby, as safety and efficacy have not been established.

### Driving and using machinery:

No studies on the effect of DOCTOR DAYCARE Calm and Ease on the ability to drive or operate machinery were performed. However, the concomitant use of DOCTOR DAYCARE Calm and Ease with medications and health supplements with sedative properties might have an additive effect. The use of DOCTOR DAYCARE Calm and Ease while operating or using machinery should be done with caution or avoided.

### Important information about some of the ingredients in DOCTOR DAYCARE Calm and Ease:

DOCTOR DAYCARE Calm and Ease contains sorbitol and may have a laxative effect. If you have been told that you have an intolerance to some sugars, you should not take DOCTOR DAYCARE Calm and Ease.

### Taking other medicines with DOCTOR DAYCARE Calm and Ease:

Always tell your healthcare professional if you are taking other medicines on a regular basis, including complementary or traditional medicines. The use of DOCTOR DAYCARE Calm and Ease with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.

Consult your doctor if you want to take DOCTOR DAYCARE Calm and Ease in combination with medicines such as:

- Anti-epileptic and Anti-Parkinson's disease or medicines for Alzheimer's disease and dementia.

**Bacopa monnieri** L. Wettst. (Bacopa): A herbal extract traditionally used to assist in cognitive health and brain function.

**Melissa officinalis** L. (Lemon balm leaf): A perennial, aromatic herb traditionally used for the relief of mild symptoms of mental stress and sleep disturbances.

### Pharmacokinetic properties:

The active ingredients in this formulation are well known. Pharmacokinetic studies have not been conducted on DOCTOR DAYCARE Calm and Ease.

### INDICATIONS:

DOCTOR DAYCARE Calm and Ease assists with the relief of mental stress and sleep disturbances to support cognitive health and brain function.

### CONTRAINDICATIONS:

- Hypersensitivity to any of the ingredients.
- Children younger than 6 years since safety and efficacy have not been established.

### WARNINGS and SPECIAL PRECAUTIONS:

There are no known warnings or special precautions for DOCTOR DAYCARE Calm and Ease.

The safety and efficacy for pregnant or breastfeeding women using DOCTOR DAYCARE Calm and Ease has not been established (see "PREGNANCY AND LACTATION").

DOCTOR DAYCARE Calm and Ease contains sorbitol and may have a laxative effect.

### Effects on the ability to drive and use machinery:

No studies on the effect of DOCTOR DAYCARE Calm and Ease on the ability to drive or operate machinery were performed. However, the concomitant use of valerian root or lemon balm leaf extract and medications or health products with sedative properties might have an additive effect. The use of DOCTOR DAYCARE Calm and Ease while operating or using machinery should be done with caution or avoided.

### INTERACTIONS:

Adverse effects have not become known with the simultaneous ingestion of DOCTOR DAYCARE Calm and Ease with food and drink.

### HOW TO TAKE DOCTOR DAYCARE Calm and Ease:

Always take DOCTOR DAYCARE Calm and Ease as your doctor has instructed you. You should verify with your doctor or pharmacist if you are unsure.

The usual dose is:

Children from 6 – 12 years: Take 5 ml once or twice daily with meals.

### SHAKE THE BOTTLE WELL BEFORE EACH USE.

Do not take more than the recommended daily dose.

If the symptoms worsen or persist, please consult your healthcare practitioner.

**If you take more DOCTOR DAYCARE Calm and Ease than you should:**

Excessive intake of Valerian root has been reported to cause chest tightness, abdominal cramps and hepatotoxic symptoms.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, immediately seek help at the nearest hospital or poison control centre.

### If you forget to take DOCTOR DAYCARE Calm and Ease:

Always take DOCTOR DAYCARE Calm and Ease as prescribed. 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 (see "HOW TO TAKE DOCTOR DAYCARE Calm and Ease"). Do not take a double dose to make up for forgotten individual doses.

### POSSIBLE SIDE EFFECTS:

There are no known side effects with DOCTOR DAYCARE Calm and Ease.

Not all side effects reported for the ingredients are included in this leaflet. Should your general health worsen while taking DOCTOR DAYCARE Calm and Ease, please consult your doctor, pharmacist or other healthcare professional for advice.

### Side effects associated with bacopa, valerian root or lemon balm extract:

Cardiac disturbances (*Less frequent*).  
Gastrointestinal upset, increased stool frequency, nausea, abdominal cramps and increased appetite (*Frequent*).  
Headache and mental dullness (*Frequent*).  
Excitability and uneasiness (*Frequent*).

Please report/inform your doctor or pharmacist if you notice any side effects not mentioned in this leaflet.

### STORAGE AND DISPOSING OF DOCTOR DAYCARE Calm and Ease:

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

Keep the bottle tightly closed.

Protect from light.

STORE ALL MEDICINE OUT OF REACH OF CHILDREN.

Do not use after the expiry date stated on the label. Return all unused DOCTOR DAYCARE Calm and Ease to your pharmacist.

Do not dispose of unused DOCTOR DAYCARE Calm and Ease in drains or sewerage systems (e.g. toilets).

### PRESENTATION OF DOCTOR DAYCARE Calm and Ease:

DOCTOR DAYCARE Calm and Ease 200 ml is packed in a white PVC 225 ml bottle with a white polypropylene cap. This bottle is sealed with a tamper-evident seal for your safety. Do not use if the seal is broken.

### IDENTIFICATION OF DOCTOR DAYCARE Calm and Ease:

A brown syrup with a blueberry taste.

### REGISTRATION NUMBER:

To be allocated.

DOCTOR DAYCARE Calm and Ease is an unregistered medicine and has not been evaluated by SAHPRA for its quality, safety or intended use.

### NAME AND ADDRESS OF THE REGISTRATION HOLDER:

RELEAF PHARMACEUTICALS (PTY) LTD  
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Dal Josaphat  
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Tel: +27 (21)001 9748  
Email: info@releafpharma.co.za

DATE OF PUBLICATION: June 2019

**DOCTOR DAYCARE Calm and Ease** might interact with the following medicines, herbs or supplements:

Clinical research suggests that bacopa seems to inhibit acetylcholinesterase and might increase acetylcholine levels. Theoretically, concurrent use of bacopa with other acetylcholinesterase (AChE) inhibitors, anticholinergic drugs or with other cholinergic drugs might have additive effects and increase the risk of cholinergic side effects.

Valerian extract and lemon balm extract might have an additive sedative effect when combined with alcohol. Concomitant use with benzodiazepines, barbiturates and anesthetics may cause additive therapeutic and adverse effects.

#### HUMAN REPRODUCTION:

##### Pregnancy and lactation:

Do not use **DOCTOR DAYCARE Calm and Ease** during pregnancy or whilst breastfeeding, as safety and efficacy have not been established.

#### DOSE AND DIRECTIONS FOR USE:

Children from 6 – 12 years: Take 5 ml once or twice daily with a meal.

#### SHAKE THE BOTTLE WELL BEFORE USE.

If the symptoms worsen or persist, please consult your healthcare practitioner.

#### SIDE EFFECTS:

There are no known side effects with **DOCTOR DAYCARE Calm and Ease**.

**Side effects associated with bacopa, valerian root or lemon balm leaf extract:**

##### Cardiovascular disorders:

*Less frequent:* Cardiac disturbances.

##### Gastrointestinal disorders:

*Frequent:* Gastrointestinal upset, increased stool frequency, nausea, abdominal cramps and increased appetite.

##### Neurological disorders:

*Frequent:* Headache and mental dullness.

##### Psychiatric:

*Frequent:* Excitability and uneasiness.

#### KNOWN SYMPTOMS OF OVERDOSE AND PARTICULARS OF ITS TREATMENT:

Excessive intake of valerian root has been reported to cause chest tightness, abdominal cramps and hepatotoxic symptoms.

Treatment of overdosage is symptomatic and supportive.

#### IDENTIFICATION:

A brown syrup with a blueberry taste.

#### PRESENTATION:

200 ml: Container is a white PVC 225 ml bottle and a white polypropylene cap with a tamper evident seal.

#### STORAGE INSTRUCTIONS:

Store in a cool, dry place at or below 25 °C. Keep the bottle tightly closed. Protect from light. Do not use later than the expiry date. Protect from light. KEEP OUT OF REACH OF CHILDREN.

#### REGISTRATION NUMBER:

To be allocated.

**DOCTOR DAYCARE Calm and Ease** is an unregistered medicine and has not been evaluated by the SAHPRA for its quality, safety or intended use. **DOCTOR DAYCARE Calm and Ease** does not intend to prevent or cure any form of illness or disease and should not replace any medication. If you suffer from a chronic medical condition, consult your healthcare practitioner before using this product. Do not exceed the recommended dose.

#### NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE

##### CERTIFICATE OF REGISTRATION:

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## PASİËNTINLIGTINGSBLAD

Inligting oor **Doctor Daycare Calm and Ease**.

Komplementêre Medisyne. Westerse Krui.

SKEDULERINGSSTATUS: S0

#### EIENDOMSNAAM EN DOSEERVORM: DOCTOR DAYCARE Calm and Ease (stroop).

Lees die hele inligtingsblad deeglik, want dit bevat belangrike inligting. **DOCTOR DAYCARE Calm and Ease** is beskikbaar sonder 'n dokter se voorskrif. U moet egter steeds **DOCTOR DAYCARE Calm and Ease** versigtig gebruik om die beste resultate daarmee te verkry. Hou hierdie inligtingsblad. Dit kan nodig wees dat u dit weer lees. Moenie **DOCTOR DAYCARE Calm and Ease** met enige ander persoon deel nie. Indien u verdere inligting of advies verlang, vra asseblief u apteker. U moet 'n dokter raadpleeg indien u simptome vererger.

#### WAT DOCTOR DAYCARE Calm and Ease BEVAT:

##### Elke 5 ml stroop bevat:

Aktiewe bestanddele:	Per 5 ml
<i>Valeriana officinalis</i> L. (Valeriaanwortel) ekstrakt	320 mg
<i>Bacopa monnieri</i> L. Wettst. (Bacopa) ekstrakt	72 mg
<i>Melissa officinalis</i> L. (Suurlemoenbalsemblaar) ekstrakt	64 mg

Onaktiewe bestanddele: Geurmiddel (Bloubessie), gliserien, karmellose natrium, maltodekstrien, mikrokristalliene sellulose en water. Preserverer middels: kaliumsorbaat 0,035 % m/v; natriumbensoaat 0,045 % m/v. Bevat suiker (sorbitol (2,695 g/5 ml)). Vry van kunsmatige kleur- en geurmiddels. Vry van Sukrose en Glukose. Tartrasien vry. Alkohol vry.

**WAARVOOR DOCTOR DAYCARE Calm and Ease GEBRUIK WORD:** **DOCTOR DAYCARE Calm and Ease** stroop ondersteun die verligting van geestelike spanning en slaapersteurings. Dit bevorder ook kognitiewe gesondheid asook breinfunksie.

#### VOORDAT U DOCTOR DAYCARE Calm and Ease NEEM:

##### Moet NIE DOCTOR DAYCARE Calm and Ease neem NIE:

- Indien u allergies is vir enige van die bestanddele (sien "Wat **DOCTOR DAYCARE Calm and Ease** bevat").
- Indien u swanger is of u baba geboersvoed word (sien "Swangerskap en borsvoeding").
- Indien u kind(ers) jonger as 6 jaar is nie, want die veiligheid en toleransie is nog nie bepaal nie.

#### Neem spesiale sorg met DOCTOR DAYCARE Calm and Ease:

Daar is geen bekende waarskuwings of spesiale voorsorgmaatreëls vir **DOCTOR DAYCARE Calm and Ease** nie.

**DOCTOR DAYCARE Calm and Ease** beoog nie om enige ongesteldheid of sieketetoestand te genees nie en moet nie enige medikasie vervang nie. Mensse wat aan 'n chroniese mediese toestand ly moet hulle gesondheidspraktisyn raadpleeg voor hulle hierdie produk gebruik.

#### Die neem van DOCTOR DAYCARE Calm and Ease saam met kos en drinkgoed:

Daar is geen bekende nuwe-effekte met die neem van **DOCTOR DAYCARE Calm and Ease** met kos en drinkgoed nie. **DOCTOR DAYCARE Calm and Ease** moet verkielik saam met voedsel geneem word om maag ongemak te verminder.

#### Swangerskap en borsvoeding:

Moenie **DOCTOR DAYCARE Calm and Ease** gebruik tydens swangerskap of gedurende borsvoeding nie, aangesien die veiligheid hiervan nie bepaal is nie.

#### Bestuur en die gebruik van masjinerie:

Geen navorsingsstudies is uitgevoer op **DOCTOR DAYCARE Calm and Ease** oor die effek op die vermoë om te bestuur of masjinerie te hanteer nie. Die gesamentlike gebruik met medikasie of gesondheidsaanvullings met sederende eienskappe mag 'n toenemende effek hê. Wees egter versigtig tot u seker is u vermoë om hierdie aktiwiteite uit te voer word nie negatief beïnvloed nie.

#### Belangrike inligting oor sommige van die bestanddele in DOCTOR DAYCARE Calm and Ease:

**DOCTOR DAYCARE Calm and Ease** bevat sorbitol en kan 'n lakserende effek hê. Indien u in kennis gestel is dat u 'n intoleransie het vir sommige suikers, moet u nie **DOCTOR DAYCARE Calm and Ease** neem nie.

#### Die neem van ander medisyne saam met DOCTOR DAYCARE Calm and Ease:

Lig altyd u gesondheidspraktisyn in wanneer u medisyne op 'n gereelde grondslag neem, insluitend komplementêre of tradisionele medisyne. Die gebruik van **DOCTOR DAYCARE Calm and Ease** saam met hierdie medisyne mag ongewenste wisselwerkings veroorsaak. Raadpleeg asseblief u dokter, apteker of ander professionele gesondheidsorgwerker.

Raadpleeg u dokter as u **DOCTOR DAYCARE Calm and Ease** in kombinasie met medisyne soos die volgende wil gebruik:

- Medikasie vir epilepsie, Parkinson siekte, Alzheimer siekte of demensie.

#### HOE OM DOCTOR DAYCARE Calm and Ease TE NEEM:

Neem **DOCTOR DAYCARE Calm and Ease** soos wat jou dokter of mediese praktisyn dit aanbeveel. Maak asseblief seker wat die aanbevole dosis is indien u onseker is.

#### Die normale dosis is:

Kinders van 6 – 12 jaar: Neem 5 ml een of twee maal daaglik met 'n maaltyd.

#### SKUD DIE BOTTEL GOED VOOR ELKE GEBRUIK.

Moenie die voorgeskrewe dosis oorskry nie.

Indien die simptome vererger of voortduur, raadpleeg asseblief u mediese praktisyn.

#### Indien u meer DOCTOR DAYCARE Calm and Ease geneem het as wat u moes:

Geen informasie is beskikbaar oor die oordosering van **DOCTOR DAYCARE Calm and Ease** nie. Alhoewel, oormatige inname van valerianawortel ekstrakt mag lei tot 'n benoude bors, abdominale pyn en hepatotoksiese simptome.

In die geval van oordosering, raadpleeg u dokter of apteker. Indien nie een van hulle beskikbaar is nie, soek dadelik hulp by die naaste hospitaal of gifbeheersentrum.

#### Indien u vergeet om DOCTOR DAYCARE Calm and Ease te neem:

Neem altyd **DOCTOR DAYCARE Calm and Ease** soos aangedui. Indien u 'n dosis vergeet het, neem dit so gou as wat u onthou. Indien u egter nie die vergete dosis onthou voordat dit tyd is vir die volgende dosis nie, slaan die vergete dosis oor en keer terug na u gewone doseringskedule (sien "HOE OM DOCTOR DAYCARE Calm and Ease TE NEEM"). Moenie 'n dubbele dosis neem om te vergoed vir die oorgeslane individuele dosisse nie.

#### MOONTLIKE NUWE-EFFEKTE:

Daar is geen bekende nuwe-effekte van **DOCTOR DAYCARE Calm and Ease** nie.

Nie alle nuwe-effekte van die bestanddele, is in hierdie inligtingstuk vervat nie. Indien u algemene gesondheid agteruitgaan terwyl u **DOCTOR DAYCARE Calm and Ease** gebruik, raadpleeg asseblief u dokter, apteker of ander professionele gesondheidsorgwerker.

#### Nuwe-effekte wat gepaard gaan met valerianawortel, bacopa of suurlemoenbalsemblaar:

- Hart versteurings (*Minder dikwels*)
- Gastrointestinale ongemak, vermeerderde ontlasting, naarheid, abdominale pyn en verhoogde eetlus (*Dikwels*).
- Hoofpyn en geestelike dofhed (*Dikwels*).
- Opgewondenheid en onrustigheid (*Dikwels*).

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

#### BERGING EN WEGDOENING VAN DOCTOR DAYCARE Calm and Ease:

Bewaar in 'n koel, droë plek by of benede 25 °C.

Hou die bottel dig toe.

Beskerm teen lig.

HOU ALLE MEDISYNE BUITE BEREIK VAN KINDERS.

Moenie gebruik na die vervaldatum op die etiket nie. Neem alle ongebruikte **DOCTOR DAYCARE Calm and Ease** na u apteker terug. Moenie ongebruikte **DOCTOR DAYCARE Calm and Ease** in afvoerpype of rioolsisteme, byvoorbeeld toilette weggooi nie.

#### AANBIEDING VAN DOCTOR DAYCARE Calm and Ease:

**DOCTOR DAYCARE Calm and Ease** 200 ml is verpak in 'n wit 225 ml bottel met 'n wit polipropileen doppie en 'n peutervrye seël vir u veiligheid. Moenie **DOCTOR DAYCARE Calm and Ease** gebruik as die seël gebreek is nie.

#### IDENTIFIKASIE VAN DOCTOR DAYCARE Calm and Ease:

'n Bruin stroop met 'n bloubessie smaak.

#### REGISTRASIONOMMER:

Sal toegeken word.

**DOCTOR DAYCARE Calm and Ease** is nie geregistreer nie en nie deur die Sahpra geëvalueer vir gehalte, veiligheid of beoogde gebruik nie.

#### NAAM EN SAKEADRES VAN DIE HOUER VAN DIE REGISTRASIE:

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