

## PROFESSIONAL INFORMATION

SCHEDULING STATUS: **S0**

Category D: Complementary medicine.

Discipline: Discipline Specific

33.7 Combination Product



PROPRIETARY NAME, STRENGTH, PHARMACEUTICAL FORM -

### MYOCALM<sup>®</sup>, 60 Tablets

#### COMPOSITION

Each one (1) tablet of MYOCALM<sup>®</sup> contain the following actives:

Magnesium (as Magnesium citrate)	100 mg
Calcium (as Calcium lactate)	50 mg
Passionflower ( <i>Passiflora incarnata</i> ) [Flower 5,5:1 Extract]	40 mg
Valerian ( <i>Valeriana officinalis</i> ) [Root 5:1 Extract]	20 mg

**Inactive Ingredients:** Cellulose, coating (hypromellose, medium chain triglycerides, and hydroxypropylcellulose), croscarmellose sodium, microcrystalline cellulose, silica, stearic acid (vegetable).

**This product is suitable for Vegetarians, dairy and gluten free and is non-GMO. (Sugar Free)**

#### PHARMACOLOGICAL CLASSIFICATION

Complementary Medicine

#### INDICATION & PHARMACOLOGICAL ACTION

MYOCALM<sup>®</sup> contains bioavailable forms of calcium and magnesium that contributes to the maintenance of normal muscle function.

These minerals are blended with passionflower and valerian for added relaxation support.

Ingredient	Uses for Ingredient
Magnesium (as Magnesium citrate)	Supports muscle relaxation, nerve function, and sleep quality by promoting a calm state.
Calcium (as Calcium lactate)	Contributes to bone health, muscle function, and nerve signalling.
Passionflower ( <i>Passiflora incarnata</i> )	Acts as a natural calming agent to reduce anxiety and improve sleep.
Valerian ( <i>Valeriana officinalis</i> )	Promotes relaxation and helps alleviate insomnia and mild anxiety.

#### CONTRA INDICATIONS:

If you are taking any chronic medication, do not use this product without consulting your healthcare professional. Do not take MYOCALM<sup>®</sup> 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. **SURGERY:** MYOCALM<sup>®</sup> should be discontinued at least 2 weeks prior to reduce bleeding risks. **LABORATORY TESTS:** MYOCALM<sup>®</sup> may influence electrolyte and kidney function tests. Please tell your healthcare practitioner that you are taking MYOCALM<sup>®</sup> before having any laboratory tests. **ANTIBIOTICS:** MYOCALM<sup>®</sup> may bind with antibiotics like tetracyclines and fluoroquinolones, reducing their effectiveness. Administer these supplements 2-4 hours before or after taking antibiotics.

#### 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 two (2) tablets twice daily or as directed by your healthcare practitioner. **Do not take more than the recommended dose.**

#### 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.

#### WARNING AND SPECIAL PRECAUTIONS

Should you have any of the following diagnosed conditions, consult with your healthcare professional before use: Severe kidney impairment or renal failure, Heart block or significant bradycardia, Severe dehydration, Severe hypercalcemia (e.g., hyperparathyroidism, certain cancers), Kidney stones or history of calcium-containing stones, severe kidney disease, Severe liver disease. If you are taking the following medication, please consult with your healthcare professional before taking: May enhance effects of certain muscle relaxants (e.g., neuromuscular blockers), May reduce absorption of antibiotics (e.g., tetracyclines, fluoroquinolones), Reduced effectiveness of bisphosphonates and thyroid medications if taken together, May enhance sedative effects of CNS depressants (e.g., benzodiazepines, opioids, alcohol), May interact with anticoagulants, Possible interaction with anticonvulsants or anaesthetics. If any of the following happens, stop using MYOCALM<sup>®</sup> 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).

These are all very serious effects. If you have them, you may have had a serious reaction to MYOCALM<sup>®</sup>. 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):

- Gastrointestinal issues, dizziness, nausea, stomach cramps.
- These are all very serious effects. If you have them, you may have had a serious reaction to MYOCALM<sup>®</sup>. 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.

#### 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 MYOCALM<sup>®</sup> if you notice visible signs of deterioration.

#### IDENTIFICATION

Tan, speckled, coated, oval tablet.

#### PRESENTATION

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

#### 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.

**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

33.7 Kombinasie produk

HANDELSNAAM EN DOSEERVORM,

## MYOCALM®, 60 Tablette

### SAMESTELING

Elke een (1) tablet van MYOCALM® bevat die volgende aktiewe stowwe:

Magnesium (as magnesiumsitraat)	100 mg
Kalsium (as kalsiumlaktataat)	50 mg
Passieblom ( <i>Passiflora incarnata</i> )	40 mg
[Blom 5,5:1 Uittreksel]	
Valeriaan ( <i>Valeriana officinalis</i> ) [Wortel	20 mg
5:1 Uittreksel]	

**Onaktiewe bestanddele:** Sellulose, laag (hipromellose, mediumketting trigliseriede en hidroksipropylsellulose), kroskarmellose natrium, mikrokristallyne sellulose, silika, steariensuur (groente).

**Hierdie produk is geskik vir vegetariërs, suiwel- en glutenvry en is nie-GGO. (Suikervry)**

### FARMAKOLOGIESE KLASSEERINGSKATEGORIE

Komplementêre medisyne

### AANDUIDING EN FARMAKOLOGIESE WERKING

**MYOCALM®** bevat bioeskbare vorme van kalsium en magnesium

Dit dra by tot die instandhouding van normale spierfunksie.

Hierdie minerale word gemeng met passieblom en valeriaan vir

Bygevoegde ontspanningsondersteuning.

Bestanddeel	Gebruik vir bestanddeel
Magnesium (as magnesiumsitraat)	Ondersteun spierverlapping, senuweefunksie en slaapkwaliteit deur 'n rustige toestand te bevorder.
Kalsium (as kalsiumlaktataat)	Dra by tot beoegesondheid, spierfunksie en senuweesein.
Passieblom ( <i>Passiflora incarnata</i> )	Dien as 'n natuurlike kalmerende middel om angs te verminder en slaap te verbeter.
Valeriaan ( <i>Valeriana officinalis</i> )	Bevorder ontspanning en help om slapeloosheid en ligte angs te verlig.

### KONTRA-INDIKASIE:

As jy enige chroniese medisyne neem, moenie hierdie produk gebruik

sonder om jou gesondheidsorgpraktisyn te raadpleeg nie. Moenie

**MYOCALM®** 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.

**CHIRURGIE:** **MYOCALM®** moet ten minste 2 weke voor die tyd gestaak word

om bloedingrisiko's te verminder. **LABORATORIUMTOETSE:** **MYOCALM®**

kan elektroliet en nierfunksietoets beïnvloed. Vertel asseblief jou

gesondheidsorgpraktisyn dat jy **MYOCALM®** neem voordat enige

laboratoriumtoets ondergaan word. **ANTIBIOTIKA:** **MYOCALM®** kan bind

met antibiotika soos tetrasielene en fluoroquinolone, wat hul

doeltreffendheid verminder. Dien hierdie aanvullings 2-4 ure toe voor of na

die neem van antibiotika.

### 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**)

### DOSES EN AANWYSINGS VIR GEBRUIK

**Volwassenes:** Neem twee (2) tablette twee keer per dag of soos voorgeskryf

deur jou gesondheidspraktisyn.

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

### DATUM VAN PUBLIKASIE

Om deur die regulerende owerheid toegeken te word.

### WAARSKUWING EN SPESIALE VOORSORGMAATREËLS

Indien jy enige van die volgende gediagnoseerde toestande het, raadpleeg jou

gesondheidsorgpraktisyn voor gebruik: Ernstige nierversaking of nierversaking,

Hartblok of beduidende bradikardie, Ernstige dehidrasie, Ernstige hiperkalsemie

(bv. hiperparatiroïdisme, sekere kankers), Nierstene of geskiedenis van

kalsiumbevattende stene, ernstige niersiekte, Ernstige lewersiekte. As jy die

volgende medisyne neem, raadpleeg asseblief jou gesondheidspraktisyn voordat

jy neem: Kan die effekte van sekere spierverlappers verbeter (bv.

neuromuskulêre blokkers), Kan absorpsie van antibiotika verminder (bv.

tetrasielene, fluoroquinolone), Verminderde doeltreffendheid van bisfosfonate

en skildkliermedikasie indien dit saam geneem word, Kan kalmerende effekte

van SSS-depressante verbeter (bv. bensodiasepiene, opioïede, alkohol), Kan

interaksie hê met antikoagulant, Moontlike interaksie met antikonvulsante of

narkose. As enige van die volgende gebeur, hou op om **MYOCALM®** te gebruik

en vertel jou dokter of gaan na die ongevalle-afdeling by jou naaste hospitaal:

• Allergiese reaksie- uitslag, jeuk / swelling (veral van die gesig / tong /

keel);

Dit is alles baie ernstige gevolge. As jy dit het, het jy dalk 'n ernstige reaksie op

**MYOCALM®** gehad. Jy sal dalk dringende mediese hulp of hospitalisasie nodig

hê. Nuwe-effekte wat gewoonlik nie mediese hulp benodig nie (rapporteer aan

jou gesondheidsorgpraktisyn as hulle voortduur):

• Gastro-intensinale probleme, duiseligheid, naarheid, maagkrampe.

Dit is alles baie ernstige gevolge. As u dit het, het u moontlik 'n ernstige reaksie

op **MYOCALM®** gehad. Miskien het u dringende mediese hulp of hospitalisasie

nodig.

Raadpleeg 'n gesondheidsorgpraktisyn as u enige mediese toestand het. Staak

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.

### NEWE-EFFEKTE

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.

### BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE

**BEHANDELING DAARVAN** Sien nuwe-effekte.

**Behandeling:** Staak gebruik en raadpleeg jou dokter, apteker of ander

gesondheidsorgpraktisyn vir advies.

### BERGING INSTRUKSIE

Bêre in 'n koel, donker plek, onder 25 °C.

Beskermt 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 **MYOCALM®** gebruik as u sigbare tekens van agteruitgang opmerk nie.

### IDENTIFIKASIE

Bruin, gespikkelde, bedekte, ovaal tablet.

### AANBIEDING

'n Wit 175 ml HDPE-bottel met 'n wit dop, induksiesêël, peutekrimpseël, spons

en silikagelsakkie.

### 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 BESIGHEIDSADRES 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