

PROFESSIONAL INFORMATION

SCHEDULING STATUS: S0

Category D: Complementary medicine.

Discipline: Discipline Specific

33.7 Combination Product



PROPRIETARY NAME, STRENGTH, PHARMACEUTICAL FORM -

MYOCALM® PLUS, 60 Tablets

COMPOSITION

Each one (1) tablet of MYOCALM® PLUS contain the following actives:

Lemon Balm (<i>Melissa officinalis</i>) [Leaf 4:1 Extract]	150 mg
Magnesium (as magnesium citrate)	150 mg
Calcium (as calcium lactate)	75 mg
Hops (<i>Humulus lupulus</i>) [Cone 7.5:1 Extract]	60 mg
Passionflower (<i>Passiflora incarnata</i>) [Flower 5.5:1 Extract]	60 mg
Valerian (<i>Valeriana officinalis</i>) [Root 5:1 Extract]	30 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® PLUS contains bioavailable forms of calcium and magnesium that contributes to the maintenance of normal muscle function. It combines essential minerals and herbal extracts that may support overall muscle relaxation and a sense of calm.

Ingredients	Use for Ingredients
Lemon Balm (<i>Melissa officinalis</i>)	Known for its calming effects, used to reduce stress, anxiety, and promote better sleep.
Magnesium (as magnesium citrate)	Supports muscle function, bone health, and helps manage fatigue, cramps, and migraines.
Calcium (as calcium lactate)	Essential for maintaining strong bones and teeth, and supports cardiovascular and muscular health.
Hops (<i>Humulus lupulus</i>)	Used for its sedative properties to aid in sleep disorders, anxiety reduction, and digestive support.
Passionflower (<i>Passiflora incarnata</i>)	Promotes relaxation, reduces anxiety, and helps with sleep disturbances.
Valerian (<i>Valeriana officinalis</i>)	Known for its calming and sedative effects, commonly used for insomnia and anxiety relief.

CONTRA INDICATIONS:

If you are taking any chronic medication, do not use this product without consulting your healthcare professional. Do not take MYOCALM® PLUS 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® PLUS should be discontinued at least 2 weeks prior to reduce bleeding risks. **LABORATORY TESTS:**

MYOCALM® PLUS may influence electrolyte and kidney function tests. Please tell your healthcare practitioner that you are taking MYOCALM® PLUS before having any laboratory tests. **ANTIBIOTICS:** MYOCALM® PLUS 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**)

DOSE AND DIRECTIONS FOR USE

Adults: Take three (3) tablets once 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: Hypothyroidism (may inhibit thyroid hormone levels), Severe kidney disease (risk of magnesium toxicity), Heart block or severe bradycardia, Hypercalcemia or hyperparathyroidism, Depression (may worsen symptoms), Oestrogen-sensitive conditions (e.g., breast cancer) due to phytoestrogenic effects, Bradycardia or hypotension (may exacerbate these conditions), Severe liver disease (potential hepatotoxicity with long-term use). If you are taking the following medication, please consult with your healthcare professional before taking: Additive sedation with CNS depressants (e.g., benzodiazepines, barbiturates), May reduce thyroid medication efficacy, enhances effects of muscle relaxants, May interfere with bisphosphonates. May enhance anticoagulant effects of blood thinners (e.g., warfarin), May increase effects of certain anaesthetics.

If any of the following happens, stop using MYOCALM® PLUS 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® PLUS. 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):

- Drowsiness, nausea, headache, upset stomach.
- These are all very serious effects. If you have them, you may have had a serious reaction to MYOCALM® PLUS. 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® PLUS if you notice visible signs of deterioration.

IDENTIFICATION

Grey/Tan speckled, oval coated 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.

Document reference: MCP60T.PI.V1 01-25

PROFESIONELE INLIGTINGSBLAD

SKEDULERINGSSTATUS: **S0**

Kategorie D: Komplementêre medisyne.

Dissipline: Dissipline Spesifiek

33.7 Kombinasie produk

HANDELSNAAM EN DOSEERVORM,

MYOCALM® PLUS, 60 Tablette

SAMESTELING

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

stowwe:

Suurleumoebalsem (<i>Melissa officinalis</i>) [Blaar 4: 1 Uttreksel]	150 mg
Magnesium (as magnesiumsitraat)	150 mg
Kalsium (as kalsiumlaktat)	75 mg
Hop (<i>Humulus lupulus</i>) [Keël 7,5:1 Uttreksel]	60 mg
Passieblom (<i>Passiflora incarnata</i>) [Blom 5,5:1 Uttreksel]	60 mg
Valeriaan (<i>Valeriana officinalis</i>) [Wortel 5:1 Uttreksel]	30 mg

Onaktiewe bestanddele: Sellulose, laag (hipromellose, mediumketting triglyseriede en hidrosipropylsellulose), kroskarmellose natrium, mikrokristallyne sellulose, silika, steariensuur (groente).

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

FARMAKOLOGIESE KLASIFIKASIE

Komplementêre medisyne

AANDUIDING EN FARMAKOLOGIESE WERKING

MYOCALM® PLUS bevat bio beskikbare vorme van kalsium en magnesium wat bydra tot die instandhouding van normale spierfunksie. Dit kombineer noodsaaklike minerale en kruie-ekstrakte wat algehele spiersverlapping en 'n gevoel van kalmte kan ondersteun.

Bestanddele	Gebruik vir bestanddele
Suurleumoebalsem (<i>Melissa officinalis</i>)	Bekend vir sy kalmerende effekte, wat gebruik word om stres, angs te verminder en beter slaap te bevorder.
Magnesium (as magnesiumsitraat)	Ondersteun spierfunksie, beegesondheid en help om moegheid, krampe en migraine te bestuur.
Kalsium (as kalsiumlaktat)	Noodsaaklik vir die handhawing van sterk bene en tande, en ondersteun kardiovaskulêre en spiergesondheid.
Hop (<i>Humulus lupulus</i>)	Word gebruik vir sy kalmerende eienskappe om te help met slaapstoornisse, angsvermindering en spysverteringsondersteuning.
Passieblom (<i>Passiflora incarnata</i>)	Verbeter ontspanning, verminder angs en help met slaapstoornisse.
Valeriaan (<i>Valeriana officinalis</i>)	Bekend vir sy kalmerende en kalmerende effekte, wat algemeen gebruik word vir slapeloosheid en angsverligting.

KONTRA-INDIKASIES:

As jy enige chroniese medisyne neem, moenie hierdie produk gebruik sonder om jou gesondheidsorgpraktisyn te raadpleeg nie. Moenie **MYOCALM® PLUS** 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® PLUS** moet ten minste 2 weke voor die tyd gestaak word om bloedingsrisiko's te verminder. **LABORATORIUMTOETSE:** **MYOCALM® PLUS** kan elektroliet en nierfunksietoetse beïnvloed. Vertel asseblief jou gesondheidsorgpraktisyn dat jy **MYOCALM® PLUS** neem voordat enige laboratoriumtoetse ondergaan word. **ANTIBIOTIKA:** **MYOCALM® PLUS** kan bind met antibiotika soos tetrasiklene en fluorokinolone, wat hul doeltreffendheid verminder. Dien hierdie aanvullings 2-4 ure toe voor of na die neem van antibiotika.

INTERAKSIES

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**)

DOSIS EN AANWYSINGS VIR GEBRUIK

Volwassenes: Neem drie (3) tablette een 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 te geteken te word.

WAARSKUWING EN SPESIALE VOORSORGMAATREËLS

Indien jy enige van die volgende gediagnoseerde toestande het, raadpleeg jou gesondheidsorgpraktisyn voor gebruik: Hipotireose (kan trioidhormoonvlakke inhibeer), Ernstige niersiekte (risiko van magnesiumtoksisiteit), Hartblik of ernstige bradikardie, Hiperkalsemie of hiperparatiroïdisme, Depressie (kan simptome vererger), Estrogeen-sensitiewe toestande (bv. borskanker) as gevolg van fitoestrogeniese effekte, Bradikardie of hipotensie (kan hierdie toestande vererger), Ernstige lewersiekte (potensiële hepatotoksiteit met langtermyngebruik). As jy die volgende medisyne neem, raadpleeg asseblief jou gesondheidspraktisyn voordat jy neem: Additiewe sedasie met SSS-depressante (bv. bensodiasepiene, barbiturate), Kan die doeltreffendheid van skildkliermedikasie verminder, verhoog die effekte van spierverslappers, Kan innemend met bisfosonate. Kan antikoagulant effekte van bloedverdunner (bv. warfarin) verbeter, kan die effekte van sekere narkose verhoog. As enige van die volgende gebeur, hou op om **MYOCALM® PLUS** 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);

Dit is alles baie ernstige gevolge. As jy dit het, het jy dalk 'n ernstige reaksie op **MYOCALM® PLUS** gehad. Jy sal dalk dringende mediese hulp of hospitalisasie nodig hê. Nieuwe-effekte wat gewoonlik nie mediese hulp benodig nie (rapporteur aan jou gesondheidsorgpraktisyn as hulle voortduur):

- Slaperigheid, naarheid, hoofyn, omgekrapte maag.
- Dit is alles baie ernstige gevolge. As u dit het, het u moontlik 'n ernstige reaksie op **MYOCALM® PLUS** 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.

Beskerem 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® PLUS** gebruik as u sigbare tekens van agteruitgang opmerk nie.

IDENTIFIKASIE

Grys/bruin gespikkelde, ovaalbedekte tablet.

AANBIEDING

'n Wit 175 ml HDPE-bottel met 'n wit dop, induksiesêl, peuterkrimpesêl, 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:

Amipiro Advanced Development Products (Pty) Ltd
Unit 3, Eastgate Business Park, 1 South Road,
Eastgate Extension, Sandton, 2146, Tel: 011-802-8101

