# PATIENT INFORMATION LEAFLET

**SCHEDULING STATUS:** S0.
Category D: Complementary medicine.
Discipline: Discipline Specific
33.7 Combination Product

PROPRIETARY NAME, STRENGTH, PHARMACEUTICAL FORM –

## MYOCALM® PLUS, 60 Tablets

**READ ALL OF THIS LEAFLET CAREFULLY BECAUSE IT CONTAINS IMPORTANT INFORMATION FOR YOU**

- **MYOCALM® PLUS** is available without a doctor's prescription.
- Nevertheless, you still need to use **MYOCALM® PLUS** carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Do not share **MYOCALM® PLUS** with any other person.
- Ask your pharmacist or healthcare professional if you need more information or advice.

**WHAT IS IN THIS LEAFLET**



**WHAT MYOCALM® PLUS CONTAINS**

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

| | |
|---|---|
| Lemon Balm (*Melissa officinalis*) [Leaf 4:1 Extract] | 150 mg |
| Magnesium (as magnesium citrate) | 150 mg |
| Calcium (as calcium lactate) | 75 mg |
| Hops (*Humulus lupulus*) [Cone 7,5:1 Extract] | 60 mg |
| Passionflower (*Passiflora incarnata*) [Flower 5,5:1 Extract] | 60 mg |
| Valerian (*Valeriana officinalis*) [Root 5:1 Extract] | 30 mg |

**Inactive Ingredients**: Cellulose, coating (hypromellose, mediumchain 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)**

**WHAT MYOCALM® PLUS IS AND WHAT IT IS USED FOR**

**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.

**BEFORE YOU TAKE MYOCALM® PLUS**

If you are taking any chronic medication, do not use this product without consulting your healthcare provider. 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.
This medicine has not been evaluated by the SAHPRA for quality, safety, or intended use.

**PREGNANCY AND BREASTFEEDING**

Safety during pregnancy and breastfeeding has not been established, consult with your healthcare professional before use. If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult with your healthcare professional before taking this supplement.

**DRIVING AND USING MACHINES**

It is not always possible to predict to what extent **MYOCALM® PLUS** may interfere with the daily activities of a patient. Patients should ensure that they do not engage in activities relating to requiring mental alertness, judgement and/or sound co-ordination and vision e.g. driving, riding, flying, sailing, operating machines/equipment, until they are aware of the measure to which **MYOCALM® PLUS** may affect you.

**TAKING OTHER MEDICINES WITH MYOCALM® PLUS**

Complementary medicine products contain ingredients which may interact with some medication. If you are taking any chronic medication, do not use this product without consulting your medical practitioner.

**Directions for use:**
**Adults:** Take three (3) tablets once daily or as directed by your healthcare practitioner. **Do no take more than the recommended dose.**

**IF YOU TAKE MORE MYOCALM® PLUS THAN YOU SHOULD**

In the event of overdosage, consult your doctor, pharmacist. Should none of these be available, contact the nearest hospital or poison control centre.

**IF YOU FORGET TO TAKE MYOCALM® PLUS**

Do not take a double dose to make up for a missed dose.

**HOW TO TAKE MYOCALM® PLUS**

Do not share medicines prescribed for you with any other person. Always take **MYOCALM® PLUS** exactly as described in this leaflet, or as your doctor, healthcare provider has instructed you. You should check with your doctor, pharmacist or healthcare provider if you are unsure.

**POSSIBLE SIDE EFFECTS**

**MYOCALM® PLUS** may have side effects.
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 practitioner 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.

Not all side effects and interactions reported for **MYOCALM® PLUS** are included in this leaflet.
Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice. If you notice any side effects not mentioned in this leaflet, please inform your doctor, pharmacist or healthcare professional.

**REPORTING OF SIDE EFFECTS**

If you experience side effects, talk to your doctor, pharmacist or other healthcare professional. You can also report side effects to SAHPRA via "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 **MYOCALM® PLUS.**

**STORAGE AND DISPOSING OF MYOCALM® PLUS**

Store all medicines out of the reach of children.
Store in a cool, dark place, below 25 °C.
Protect from direct sunlight and heat.
Store in the original packaging.
Do not use after the expiry date stated on the bottle.
Do not use **MYOCALM® PLUS** if you notice visible signs of deterioration.
Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

**PRESENTATION OF MYOCALM® PLUS**

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

**IDENTIFICATION OF MYOCALM® PLUS**

Grey/Tan speckled, oval coated tablet.

**REGISTRATION NUMBER**

To be allocated by SAHPRA upon registration.

**ACCESS TO THE CORRESPONDING PROFESSIONAL INFORMATION**

Scan QR code.

**THIS LEAFLET WAS LAST REVISED ON**

10 January 2025

**NAME AND ADDRESS OF REGISTRATION HOLDER**
**Distributed by:**
Amipro Advanced Development Products (Pty) Ltd
Unit 3, Eastgate Business Park, 1 South Road, Eastgate Extension, Sandton, 2146
Tel: 011-802-8101

# PASIËNT INLIGTINGSBLAD

**SKEDULERINGSTATUS:** S0
Kategorie D: Komplementêre medisyne.
Dissipline: Dissipline Spesifiek
33.7 Kombinasie produk

HANDELSNAAM EN DOSEERVORM**,**

# MYOCALM® PLUS, 60 Tablette

**LEES HIERDIE INLIGTINGSBLAD NOUKEURIG, WANT DIT BEVAT BELANGRIKE INLIGTING VIR U**

- **MYOCALM® PLUS** is beskikbaar sonder doktersvoorskrif**.**
- U moet steeds **MYOCALM® PLUS** versigtig gebruik om die beste resultate daaruit te kry.
- Hou hierdie inligtingsblad. Miskien moet u dit weer lees.
- Moenie **MYOCALM® PLUS** met enige ander persoon deel nie**.**
- Vra jou apteker of gesondheidsorgpraktisyn of jy meer inligting of advies benodig.

**WAT IS IN HIERDIE INLIGTINGSBLAD**

- Wat **MYOCALM® PLUS** is en waarvoor dit gebruik word.
- Wat jy moet weet voordat jy **MYOCALM® PLUS** neem**.**
- Hoe om **MYOCALM® PLUS** te neem.
- Moontlike newe-effekte.
- Hoe om **MYOCALM® PLUS** te bêre.
- Inhoud van die pak en ander inligting

**WATTER MYOCALM® PLUS BEVAT**

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

| | |
|---|---|
| Suurlemoenbalsem (*Melissa officinalis*) [Blaar 4: 1 Uittreksel] | 150 mg |
| Magnesium (as magnesiumsitraat) | 150 mg |
| Kalsium (as kalsiumlaktaat) | 75 mg |
| Hop (*Humulus lupulus*) [Keël 7,5:1 Uittreksel] | 60 mg |
| Passieblom (*Passiflora incarnata*) [Blom 5,5:1 Uittreksel] | 60 mg |
| Valeriaan (*Valeriana officinalis*) [Wortel 5:1 Uittreksel] | 30 mg |

**Onaktiewe bestanddele**: Sellulose, laag (hipromellose, mediumketting trigliseriede en hidroksipropylsellulose), kroskarmellose, kroskarmellose natrium, mikrokristallyne sellulose, silika, steariensuur (groente).
**Hierdie produk is geskik vir vegetariërs, suiwel- en glutenvry en is nie-GGO. (Suikervry)**

**WAT IS MYOCALM® PLUS KAPSULES EN WAARVOOR WORD DIT GEBRUIK**

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

**VOORDAT JY MYOCALM® PLUS NEEM**

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 **CHIRURGIE: MYOCALM® PLUS** moet ten minste 2 weke voor die vermindering van bloedingsrisiko's gestaak word. **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 tetrasikliene en fluorokinolone, wat hul doeltreffendheid verminder. Dien hierdie aanvullings 2-4 ure toe voor of na die neem van antibiotika.

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

**BESTUUR EN GEBRUIK VAN MASJIENE**

Dit is nie altyd moontlik om te voorspel in watter mate **MYOCALM® PLUS** die daaglikse aktiwiteite van 'n pasiënt kan belemmer nie. Pasiënte moet seker maak dat hulle nie betrokke raak by aktiwiteite wat verband hou met die vereiste van verstandelike waaksaamheid, oordeel en/of gesonde koördinasie en visie nie, byvoorbeeld bestuur, ry, vlieg, seil, bedryfsmasjiene/toerusting, totdat hulle bewus is van die mate waartoe **MYOCALM® PLUS** jou beïnvloed.

**NEEM VAN ANDER MEDISYNE SAAM MET MYOCALM® PLUS**

Komplementêre medisyne produkte bevat bestanddele wat met sommige medisyne 'n interaksie kan hê. As jy enige chroniese medisyne gebruik, moenie hierdie produk gebruik sonder om jou gesondheidsorgpraktisyn te raadpleeg nie.

**SWANGERSKAP EN BORSVOEDING**

Veiligheid tydens swangerskap en borsvoeding is nie vasgestel nie, raadpleeg u gesondheidsorgpraktisyn voor gebruik. As u swanger is of borsvoed, dink dat u swanger is of beplan om 'n baba te hê, raadpleeg u gesondheidsorgpraktisyn voordat u hierdie aanvulling neem.

**HOE OM MYOCALM® PLUS TE NEEM**

Moenie medisyne wat vir u voorgeskryf is, met enige ander persoon deel nie. Neem altyd **MYOCALM® PLUS** presies soos beskryf in hierdie inligtingsblad, of soos u dokter, gesondheidsorgpraktisyn voorgeskryf het. Raadpleeg jou dokter, apteker of gesondheidsorgpraktisyn as jy onseker is.

**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.**

**AS JY MEER MYOCALM® PLUS NEEM AS WAT JY MOET**

In die geval van oordosering, raadpleeg u dokter of apteker. Indien nie een hiervan beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.

**AS JY VERGEET OM MYOCALM® PLUS TE NEEM**

Moenie 'n dubbele dosis neem om op te maak vir 'n dosis wat oorgeslaan is nie.

**MOONTLIKE NEWE-EFFEKTE**

**MYOCALM® PLUS** kan newe-effekte hê.

Indien jy enige van die volgende gediagnoseerde toestande het, raadpleeg jou gesondheidsorgpraktisyn voor gebruik: Hipotireose (kan tiroïedhormoonvlakke inhibeer), Ernstige niersiekte (risiko van magnesiumtoksisiteit), Hartblok of ernstige bradikardie, Hiperkalsemie of hiperparatiroïedisme, Depressie (kan simptome vererger), Estrogeen-sensitiewe toestande (bv. borskanker) as gevolg van fitoestrogeniese effekte, Bradikardie of hipotensie (kan hierdie toestande vererger), Ernstige lewersiekte (potensiële hepatotoksisiteit 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 inmeng met bisfosfonate. Kan antikoagulante 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 ongevalle-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 mag dalk dringende mediese hulp of hospitalisasie nodig hê.

Newe-effekte wat gewoonlik nie mediese hulp benodig nie (rapporteer aan u gesondheidsorgpraktisyn as dit voortduur):

- Slaperigheid, naarheid, hoofpyn, omgekrapte maag.

Nie alle newe-effekte en interaksies wat vir **MYOCALM® PLUS** gerapporteer word, is by hierdie inligtingsblad ingesluit nie. 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 newe-effekte sien wat nie in hierdie inligtingsblad genoem word nie, stel asseblief jou dokter, apteker of gesondheidsorgpraktisyn in kennis.

**AANMELDING VAN NEWE-EFFEKTE**

As jy newe-effekte ervaar, praat met jou dokter, apteker of ander gesondheidsorgpraktisyn. U kan ook newe-effekte aan SAHPRA rapporteer via "6.04 Adverse Drug Reaction Reporting Form", wat aanlyn gevind word onder SAHPRA se publikasies: https://www.sahpra.org.za/Publications/Index/8. Deur newe-effekte aan te meld, kan u help om meer inligting te verskaf oor die veiligheid van **MYOCALM® PLUS.**

**HOE OM MYOCALM® PLUS TE BERÊ**

Bêre alle medisyne buite bereik van kinders.
Bêre in 'n koel, donker plek, onder 25 °C.
Beskerm teen direkte sonlig en hitte.
Bêre in die oorspronklike verpakking.
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.
Moenie ongebruikte medisyne in dreine of rioolstelsels (bv. toilette) weggooi nie.

**AANBIEDING VAN MYOCALM® PLUS**

'n Wit 175 ml HDPE-bottel met 'n wit dop, induksieseël, peuterkrimpseël, spons en silikagelsakkie.

**IDENTIFIKASIE VAN MYOCALM® PLUS**

Grys/bruin gespikkelde, ovaalbedekte tablet.

**REGISTRATION NOMMER**

Om deur SAHPRA toegeken te word by registrasie.

T**OEGANG TOT DIE OOREENSTEMMENDE PROFESSIONELE INLIGTING**

Skandeer QR-kode.

**HIERDIE INLIGTINGSBLAD IS LAAS HERSIEN OP**

10 Januarie 2025

**NAAM EN ADRES VAN REGISTRASIEHOUER**

**Versprei deur:**

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