PATIENT INFORMATION LEAFLET

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

PROPRIETARY NAME, STRENGTH, PHARMACEUTICAL FORM –

MYOCALM®, 60 Tablets

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

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

WHAT IS IN THIS LEAFLET

WHAT MYOCALM® CONTAINS

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

Magnesium (as Magnesium citrate)	100 mg
Calcium (as Calcium lactate)	50 mg
Passionflower (*Passiflora incarnata*) [Flower 5,5:1 Extract]	40 mg
Valerian (*Valeriana officinalis*) [Root 5:1 Extract]	20 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® IS AND WHAT IT IS USED FOR

MYOCALM® 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.

BEFORE YOU TAKE MYOCALM®

If you are taking any chronic medication, do not use this product without consulting your healthcare provider. Do not take **MYOCALM®** 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®** should be discontinued at least 2 weeks prior to reduce bleeding risks. **LABORATORY TESTS: MYOCALM®** may influence electrolyte and kidney function tests**.** Please tell your healthcare practitioner that you are taking **MYOCALM®** before having any laboratory tests. **ANTIBIOTICS**: **MYOCALM®** 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®** 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®** may affect you.

TAKING OTHER MEDICINES WITH MYOCALM®

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 two (2) tablets twice daily or as directed by your healthcare practitioner. **Do no take more than the recommended dose.**

IF YOU TAKE MORE MYOCALM® 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®

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

HOW TO TAKE MYOCALM®

Do not share medicines prescribed for you with any other person. Always take **MYOCALM®** 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® may have side effects.
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 practitioner 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®** 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®**. 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):

- Gastrointesinal issues, dizziness, nausea, stomach cramps.

Not all side effects and interactions reported for **MYOCALM®** 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®.**

STORAGE AND DISPOSING OF MYOCALM®

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®** if you notice visible signs of deterioration.
Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

PRESENTATION OF MYOCALM®

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

IDENTIFICATION OF MYOCALM®

Tan, speckled, coated, oval 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

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PASIËNT INLIGTINGSBLAD

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

HANDELSNAAM EN DOSEERVORM**,**

MYOCALM®, 60 Tablette

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

- **MYOCALM®** is beskikbaar sonder doktersvoorskrif**.**
- U moet steeds **MYOCALM®** versigtig gebruik om die beste resultate daaruit te kry.
- Hou hierdie inligtingsblad. Miskien moet u dit weer lees.
- Moenie **MYOCALM®** 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®** is en waarvoor dit gebruik word.
- Wat jy moet weet voordat jy **MYOCALM®** neem**.**
- Hoe om **MYOCALM®** te neem.
- Moontlike newe-effekte.
- Hoe om **MYOCALM®** te bêre.
- Inhoud van die pak en ander inligting

WATTER MYOCALM® BEVAT

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

Magnesium (as magnesiumsitraat)	100 mg
Kalsium (as kalsiumlaktaat)	50 mg
Passieblom (*Passiflora incarnata*) [Blom 5,5:1 Uittreksel]	40 mg
Valeriaan (*Valeriana officinalis*) [Wortel 5:1 Uittreksel]	20 mg

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

WAT IS MYOCALM® KAPSULES EN WAARVOOR WORD DIT GEBRUIK

MYOCALM® bevat biobeskikbare 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.

VOORDAT JY MYOCALM® NEEM

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 **CHIRURGIE: MYOCALM®** moet ten minste 2 weke voor die vermindering van bloedingsrisiko's gestaak word. **LABORATORIUMTOETSE: MYOCALM®** kan elektroliet en nierfunksietoetse beïnvloed**.** Vertel asseblief jou gesondheidsorgpraktisyn dat jy **MYOCALM®** neem voordat enige laboratoriumtoetse ondergaan word. **ANTIBIOTIKA**: **MYOCALM®** 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®** 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®** jou beïnvloed.

NEEM VAN ANDER MEDISYNE SAAM MET MYOCALM®

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® TE NEEM

Moenie medisyne wat vir u voorgeskryf is, met enige ander persoon deel nie. Neem altyd **MYOCALM®** 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 twee (2) tablette twee keer per dag, of soos voorgeskryf deur jou gesondheidspraktisyn.

Moenie meer as die aanbevole dosis neem nie.

AS JY MEER MYOCALM® 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® TE NEEM

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

MOONTLIKE NEWE-EFFEKTE

MYOCALM® kan newe-effekte hê.

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. hiperparatiroïedisme, 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 spierverslappers verbeter (bv. neuromuskulêre blokkers), Kan absorpsie van antibiotika verminder (bv. tetrasikliene, fluorokinolone), 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 antikoagulante, 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 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®** 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):

- Gastro-intesinale probleme, duiseligheid, naarheid, maagkrampe.

Nie alle newe-effekte en interaksies wat vir **MYOCALM®** 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®.**

HOE OM MYOCALM® 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®** gebruik as u sigbare tekens van agteruitgang opmerk nie.
Moenie ongebruikte medisyne in dreine of rioolstelsels (bv. toilette) weggooi nie.

AANBIEDING VAN MYOCALM®

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

IDENTIFIKASIE VAN MYOCALM®

Bruin, gespikkelde, bedekte, ovaal 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:

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