

PROFESSIONAL INFORMATION

SCHEDULING STATUS:^[50]
Category D: Complementary medicine.
Discipline specific Traditional Claims
33.7 Combination Product

PROPRIETARY NAME, STRENGTH, PHARMACEUTICAL FORM –

METARELAX® NIGHT, 30 Tablets

COMPOSITION

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

Magnesium glycerophosphate	268 mg
providing elemental magnesium 30 mg and phosphate 42,6 mg	
Magnesium bisglycinate 13,8% providing elemental magnesium 30 mg and glycine 187 mg	217 mg
Passion flower (Passiflora incarnata L.) [Aerial part PE 3,5% Vitexin]	60 mg
Vitamin C (as L-ascorbic acid)	40 mg
Zinc bisglycinate 28,2% providing elemental zinc 10 mg and glycine 25,5 mg	35,5 mg
Saffron (Crocus sativus L.) [Stigmas, Water extract]	28 mg
Vitamin B6 (as pyridoxal-5-phosphate)	1 mg
Folate (as calcium-L-methylfolate)	140 µg
Vitamin B12 (as methylcobalamin)	25 µg

Inactive Ingredients: Dicalcium phosphate, magnesium bisglycinate, magnesium carbonate, magnesium glycerophosphate, magnesium salts of fatty acids, microcrystalline cellulose, silicon dioxide and stearic acid.
This product is suitable for Vegetarians gluten free, non-GMO and Sugar Free.

PHARMACOLOGICAL CLASSIFICATION

Complementary Medicine

INDICATION & PHARMACOLOGICAL ACTION

METARELAX® NIGHT is designed to help support general well-being during times of stress. Magnesium works to promote muscular relaxation, while folate and vitamin B6 may contribute to maintaining normal psychological function. Passion Flower and Saffron also aids in relaxation and better sleep. This comprehensive formula aims to improve sleep, energy levels and overall health.

Ingredient	Uses for Ingredients
Magnesium glycerophosphate	Supports energy production, muscle function, and bone health; phosphate aids cellular energy.
Magnesium bisglycinate	Helps reduce fatigue, supports nerve and muscle function, and promotes relaxation.
Passion flower (Passiflora incarnata L.)	Traditionally used to promote calmness and support restful sleep.
Vitamin C (as L-ascorbic acid)	Supports immune function, collagen formation, and antioxidant protection.
Zinc bisglycinate	Contributes to immune health, wound healing, and maintenance of skin and vision.
Saffron (Crocus sativus L.)	Traditionally used to support mood balance and emotional well-being.
Vitamin B6 (as pyridoxal-5-phosphate)	Supports neurotransmitter synthesis, energy metabolism, and hormonal regulation.
Folate (as calcium-L-methylfolate)	Essential for DNA synthesis, red blood cell formation, and prenatal health.
Vitamin B12 (as methylcobalamin)	Supports energy production, nerve health, and red blood cell formation.

CONTRA INDICATIONS:

If you are taking any chronic medication, do not use this product without consulting your healthcare professional. Do not take **METARELAX® NIGHT** 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.

Caution is advised when taking Magnesium with hypertensive, diuretic and muscle relaxant medicines in order to avoid unwanted interactions.

WARNING AND SPECIAL PRECAUTIONS

Should you have any of the following diagnosed conditions, consult with your healthcare professional before use: rectal bleeding, bowel problems (such as blockage, ulcerative colitis, hemorrhoids), heart disease (such as irregular heartbeat), kidney disease, current stomach/abdominal symptoms (such as nausea/vomiting that doesn't stop, pain, cramping), high calcium/vitamin D levels (hypercalcemia/hypervitaminosis D), difficulty absorbing nutrition from food (malabsorption syndrome), heart/blood vessel disease, kidney disease (including kidney stones), certain immune system disorder (sarcoidosis), liver disease, certain bowel diseases (Crohn's disease, Whipple's disease), little or no stomach acid (achlorhydria), low levels of bile, untreated phosphate imbalance. If you are taking the following medication, please consult with your healthcare professional before taking: digoxin, sodium polystyrene sulfonate, tetracycline/quinolone antibiotics (such as tetracycline, ciprofloxacin). If any of the following happens, stop using **METARELAX® NIGHT** 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), severe dizziness, trouble breathing;



These are all very serious effects. If you have them, you may have had a serious reaction to **METARELAX® NIGHT**. 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):

- nausea/vomiting, constipation, loss of appetite, mental/mood changes, unusual tiredness.

These are all very serious effects. If you have them, you may have had a serious reaction to **METARELAX® NIGHT**. 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.

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 one (1) tablet daily at night or as directed by your healthcare Practitioner.

Do not take more than the recommended dose.

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.

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.

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 **METARELAX® NIGHT** if you notice visible signs of deterioration.

IDENTIFICATION

Tablet.

PRESENTATION

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

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
Galaxy Park, Unit 5B
Galaxy Avenue, Limbro Park
Sandton, 2090, Tel: 011-802-8101

DATE OF PUBLICATION

To be allocated by the regulatory authority.

PROFESIONELE INLIGTINGSBLAD

SEKEDULERINGSSTATUS: 50

Kategorie D: Komplementêre medisyne.
Dissipline: Gesondheidsaanvulling
34.12 Meervoudige Bestanddeel Formulase

HANDELSNAAM EN DOSEERVORM,

METARELAX® NIGHT, 30 Tablette

SAMESTELING

Elke (1) tablet METARELAX® NIGHT bevat die volgende aktiewe stowwe:

Magnesium gliserofosfaat	268 mg
die verskaffing van elementêre magnesium 30 mg en fosfaat 42,6 mg	
Magnesiumbisglycinaat 13,8% wat elementêre magnesium 30 mg en glisien 187 mg verskaf	217 mg
Passieblom (Passiflora incarnata L.) [Lugdeel PE 3,5% Vitexin]	60 mg
Vitamiën C (as L-askorbiensuur)	40 mg
Sinkbisglycinaat 28,2% wat elementêre sink 10 mg en glisien 25,5 mg verskaf	35,5 mg
Saffraan (Crocus sativus L.) [Stigmas, Water uittreksel]	28 mg
Vitamiën B6 (as piridoksaal-5-fosfaat)	1 mg
Folaat (as kalsium-L-metiefolaat)	140 µg
Vitamiën B12 (as metielkobalamien)	25 µg

Onaktiewe bestanddele: Dikalsiumfosfaat, magnesiumbisglycinaat, magnesiumkarbonaat, magnesiumgliserofosfaat, magnesiumsoute van vetsure, mikrokristallyne sellulose, silikondioksied en steariensuur.
Hierdie produk is geskik vir vegetariërs glutenvry, nie-GGO en suikervry.

FARMAKOLOGIESE KLASSIFIKASIE

Komplementêre medisyne

AANDUIDING EN FARMAKOLOGIESE WERKING

METARELAX® NIGHT is ontwerp om algemene welstand te ondersteun tydens tye van stres. Magnesium werk om spierontspanning te bevorder, terwyl folaat en vitamien B6 kan bydra tot die handhawing van normaal skuldige funksie. Passieblom en saffraan help ook met ontspanning en beter slaap. Hierdie omvattende formule het ten doel om verbeterde slaap, energievakke en algemene gesondheid.

Bestanddeel	Gebruik vir bestanddele
Magnesium gliserofosfaat	Ondersteun energieproduksie, spierfunksie en beengesondheid; Fosfaat help <u>selulêre energie</u> .
Magnesium bisglycinaat	Help om moegheid te verminder, ondersteun senuwee- en spierfunksie en bevorder ontspanning.
Passieblom (Passiflora incarnata L.)	Tradisioneel gebruik om kalmte te bevorder en rustige slaap te ondersteun.
Vitamiën C (as L-askorbiensuur)	Ondersteun immuunfunksie, kollageenvorming en antioksidantbeskerming.
Sinkbisglycinaat	Dra by tot immuungesondheid, wondgeneesing en instandhouding van vel en visie.
Saffraan (Crocus sativus L.)	Tradisioneel gebruik om gemoedsbalans en emosionele welstand te ondersteun.
Vitamiën B6 (as piridoksaal-5-fosfaat)	Ondersteun neurotransmittersintese, energiemetabolisme en hormonale regulering.
Folaat (as kalsium-L-metiefolaat)	Noodsaaklik vir DNA-sintese, rooibloedselvorming en <u>voorgeboortelike gesondheid</u> .
Vitamiën B12 (as metielkobalamien)	Ondersteun energieproduksie, senuweegesondheid en rooibloedselvorming.

KONTRA-INDIKASIES:

As jy enige chroniese medisyne neem, moenie hierdie produk gebruik sonder om jou gesondheidsorgpraktisyn te raadpleeg nie. Moenie **METARELAX® NIGHT** neem as jy hipersensitief (allergies) is vir enige van die bestanddele nie. As jy allergieë het, maak seker dat jy met jou gesondheidsorgpraktisyn gaan praat voordat jy hierdie aanvulling neem. Wees versigtig wanneer Magnesium saam met hipertensiewe, diuretiese en spiersverslappende medisyne geneem word om ongewenste interaksies te vermy.

WAARSKUWING EN SPESIALE VOORSORGMATREËLS

Indien jy enige van die volgende diagnoseerde toestande het, raadpleeg jou gesondheidsorgpraktisyn vir gebruik : rektale bloeding, dermprobleme (soos verstopping, ulseratiewe kolitis, aambeie), hartsiektes (soos onreëlmatige hartklop), niersiekte, huidige maag / abdominale simptome (soos naarheid / braking wat nie ophou nie, pyn, krampe), hoë kalsium / vitamien D-vlakke (hiperkalsemie / hipervitaminose D), probleme om voeding uit voedsel te absorbeer (wanabsorpsiesindroom), hart-/bloedvatsiekte, niersiekte (insluitend nierstene), sekere immuunselferversterking (sarkidose), lewersiekte, sekere dermsiektes (Crohn se siekte, Whipple se siekte), min of geen maagsuur (achlorhidrie), lae vlakke van gal, onbehandelde fosfaatwanbalans. As jy die volgende medisyne neem, raadpleeg asseblief jou gesondheidspraktisyn voordat jy neem digoksin, natriumpolistiirensulfonaat, tetrasiiklien /kinolonantibiotika (soos tetrasiiklien, ciprofloksacin).

As enige van die volgende gebeur, hou op om METARELAX® NIGHT 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), erge duiseligheid, probleme met asemhaling.;

Dit is alles baie ernstige gevolge. As jy dit het, het jy dalk 'n ernstige reaksie op **METARELAX® NIGHT** gehad. Jy sal dalk dringende mediese hulp of hospitalisasie nodig hê.

Neuwe-effekte wat gewoonlik nie mediese hulp benodig nie (rapporteur aan jou gesondheidsorgpraktisyn as hulle voortduur):

- naarheid / braking, hardlywigheid, verlies aan eetlus, geestelike / gemoedsveranderinge, ongewone moegheid.

Dit is alles baie ernstige gevolge. As u dit het, het u moontlik 'n ernstige reaksie op **METARELAX® NIGHT** 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.

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 voorsorgmatreëls**)

DOSIS EN AANWYSINGS VIR GEBRUIK

Volwasse Neem een (1) tablet daaglik in die aand of soos voorgeskryf deur jou gesondheidsorgpraktisyn.

Moenie meer as die aanbevole dosis neem nie.

NEWE-EFFEKTE

Indien jou algemene gesondheid vererger of as jy enige nadelige effekte ervaar tydens die gebruik van hierdie aanvulling, 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.

BEKEUDE 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

Hou dig toegemaak op 'n koel, droë plek, onder 25 °C. Beskerm 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 **METARELAX® NIGHT** gebruik as u sigbare tekens van agteruitgang opmerk nie.

IDENTIFIKASIE

Tablet.

AANBIEDING

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

REGISTRASIE NOMMER

Om by registrasie deur SAHRA toegeken te word. Hierdie medisyne is nie deur SAHRA geëvalueer vir kwaliteit, veiligheid of beoogde gebruik nie.

NAAM EN BESIGHEIDSADRES VAN APPLIKANT

Versprei deur:

Amipro Advanced Development Products (Pty) Ltd
Galaxy Park, Unit 5B
Galaxy Avenue, Limbro Park
Sandton, 2090, Tel: 011- 802-8101

DATUM VAN PUBLIKASIE

Om deur die regulerende owerheid toegeken te word.