

PROFESSIONAL INFORMATION

SCHEDULING STATUS: **S0**

Category D: Complementary medicine.

Discipline: Health Supplement

33.12 Multiple Substance Formulation

PROPRIETARY NAME, STRENGTH, PHARMACEUTICAL FORM –

METARELAX[®], 60 Tablets

COMPOSITION

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

Magnesium (as magnesium glycerophosphate)	200 mg
Taurine	150 mg
Vitamin B6 (as pyridoxal-5-phosphate)	2 mg
Folate (as calcium-L-methylfolate)	200 µg
Vitamin B12 (as methylcobalamin)	25 µg
Vitamin D (as cholecalciferol)	25 µg (1 000 I.U.)

Inactive Ingredients: Cross-linked sodium carboxymethyl cellulose, dicalcium phosphate, hydroxypropyl cellulose, maltodextrin, magnesium carbonate, magnesium stearate and silicon dioxide

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

PHARMACOLOGICAL CLASSIFICATION

Complementary Medicine

INDICATION & PHARMACOLOGICAL ACTION

METARELAX[®] features a blend of magnesium, vitamins B6, B12, D3, folate, and taurine designed to help support general well-being during times of stress. Magnesium and vitamin D work together to promote muscular relaxation, while folate and vitamin B6 may contribute to maintaining normal psychological function. This comprehensive formula aims to support energy levels and overall health.

Ingredients	Uses for ingredient
Magnesium (as magnesium glycerophosphate)	Magnesium glycerophosphate is the ideal form of magnesium to help boost sleep quality. It helps the body and brain relax by activating the parasympathetic nervous system.
Taurine	Taurine may help control the nervous system. It's been used to treat anxiety and seizure issues.
Vitamin B6 (as pyridoxal-5-phosphate)	Vitamin B6 (as pyridoxal-5-phosphate)
Folate (as calcium-L-methylfolate)	It provides the methyl groups needed for the production of neurotransmitters like serotonin, dopamine, and norepinephrine. This helps regulate mood and cognitive function.
Vitamin B12 (as methylcobalamin)	Vitamin B12 is involved in the creation of neurotransmitters like serotonin and dopamine, which are essential for controlling mood.
Vitamin D (as cholecalciferol)	Vitamin D acts as a neuro-steroid and plays a role in protecting against depression and anxiety disorders

CONTRA INDICATIONS:

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

- Do not share medication with any other person.
 - Keep this leaflet. You may need to read it again.
 - 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 or as directed by your healthcare Practitioner.

Do no 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[®] 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
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: **S0**

Kategorie D: Komplementêre medisyne.

Dissipline: Gesondheidsaanvulling

34.12 Meervoudige Bestanddeel Formulasie

HANDELSNAAM EN DOSEERVORM,

METARELAX[®], 120 Tablette

SAMESTELING

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

Magnesium (as magnesiumgliserosfaaf)	200 mg
Taurine	150 mg
Vitamiën B6 (as piridoksaal-5-fosfaat)	2 mg
Folaat (as kalsium-L-metiefolaat)	200 µg
Vitamiën B12 (as metielkobalamien)	25 µg
Vitamiën D (as cholecalciferol)	25 µg
	(1 000 I.U.)

Onaktiewe bestanddele: Kruisgekoppelde natriumkarboksimetielcellulose, dikalsiumfosfaat, hidroksiopropylselulose, maltodekstrien, magnesiumkarbonaat, magnesiumstearaat en silikondioksied

Hierdie produk is geskik vir vegetêriërs glutenvry, nie-GGO en suikervry.

FARMAKOLOGIESE KLASIFIKASIE

Komplementêre medisyne

AANDUIDING EN FARMAKOLOGIESE WERKING

METARELAX[®] bevat 'n mengsel van magnesium, vitamien B6, B12, D3, folaat en taurine wat ontwerp is om algemene welstand te help ondersteun tydens tye van stres. Magnesium en vitamien D werk saam om spierverslapping te bevorder, terwyl folaat en vitamien B6 kan bydra tot die handhawing van normale sielkundige funksie. Hierdie omvattende formule het ten doel om energievakke en algemene gesondheid te ondersteun.

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

Neuwe-effekte wat gewoonlik nie mediese hulp benodig nie (rapporteer 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[®] 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 gewys word.

• Jy moet nie hierdie produk aanvaar as seëls gebreek word nie.

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**)

DOSIS EN AANWYSINGS VIR GEBRUIK

Volwasse Neem een (1) tablet daaglik 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.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN

DE 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.

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 METARELAX[®] 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 silikagessakke.

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 BESIGHEIDSAODRES 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

DATUM VAN PUBLIKASIE

Om deur die regulerende owerheid toegeken te word.

Bestanddele	Gebruik vir bestanddeel
Magnesium (as magnesiumgliserosfaaf)	Magnesiumgliserosfaaf is die ideale vorm van magnesium om slaapkwaliteit te help verhoog. Dit help die liggaam en brein om te ontspan deur die parasimpatiese senuweestelsel te aktiveer.
Taurine	Taurine kan help om die senuweestelsel te beheer. Dit is gebruik om angs en beslagleggingskwessies te behandel.
Vitamiën B6 (as piridoksaal-5-fosfaat)	Vitamiën B6 (as piridoksaal-5-fosfaat)
Folaat (as kalsium-L-metiefolaat)	Dit verskaf die metielgroepe wat nodig is vir die produksie van neurotransmitters soos serotonien, dopamiën en norepinefrien. Dit help om bui en kognitiewe funksie te reguleer.
Vitamiën B12 (as metielkobalamien)	Vitamiën B12 is betrokke by die skepping van neurotransmitters soos serotonien en dopamiën, wat noodsaaklik is vir die beheer van bui.
Vitamiën D (as cholecalciferol)	Vitamiën D dien as 'n neuro-steroïed en speel 'n rol in die beskerming teen depressie en angsversteurings

KONTRA-INDIKASIE:

As jy enige chroniese medisyne neem, moenie hierdie produk gebruik sonder om jou gesondheidsorgpraktisyn te raadpleeg nie. Moenie METARELAX[®] 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 spierverslappende medisyne geneem word om ongewenste interaksies te vermy.

WAARSKUWING EN SPESIALE VOORSORGMAATREËLS

Indien jy enige van die volgende gediagnoseerde toestande het, raadpleeg jou gesondheidsorgpraktisyn voor gebruik : rektale bloeding, dermprobleme (soos verstopping, ulseratiewe kolitis,ambeie), hartsiektes (soos onreëlmatige hartklop), niërsiekte, 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, niërsiekte (insluitend nierstene), sekere immuunselversteuring (sarkoidose), 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 digoksien, natriumdiostreïensulfonaat, tetrasielklien/kinolonantibiotika (soos tetrasielklien, ciprofloksacin). As enige van die volgende gebeur, hou op om METARELAX[®] te gebruik en vertel jou dokter of gaan na die ongevallen-afdeling by jou naaste hospitaal:

- Allergiese reaksies- uitslag, jeuk / swelling (veral van die gesig / tong / keel), erge duiseligheid, probleme met asemhaling,;