

PROFESSIONAL INFORMATION

SCHEDULING STATUS: **S0**

Category D: Complementary medicine.

Discipline: Health Supplement

33.12 Multiple Substance Formulation

PROPRIETARY NAME, STRENGTH, PHARMACEUTICAL FORM –

METARELAX® FAST, 15 & 30 Chewable Tablets

COMPOSITION

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

Active Ingredient	Quantity per tablet
Gamma-aminobutyric acid (GABA)	250 mg
Magnesium glycerophosphate	56 mg
– providing elemental magnesium	7 mg
– providing phosphorus	8,9 mg
Magnesium bisglycinate	50,725 mg
– providing elemental magnesium	7 mg
– providing glycine	43,725 mg
Folate (as calcium L-5-methyltetrahydrofolate)	30 µg

Inactive Ingredients: Microcrystalline cellulose, Hydroxypropyl cellulose, Stearic acid, Citric acid, Silicon dioxide, Magnesium salts of fatty acids, Magnesium carbonate, Red beet powder (Beta vulgaris L.), **Contains sweeteners:** Mannitol, Sucralose, Steviol glycosides (from Stevia rebaudiana), Strawberry flavour, Vanilla flavour.

This product is suitable for Vegans, gluten free, non-GMO and Dairy free.

PHARMACOLOGICAL CLASSIFICATION

Complementary Medicine

INDICATION & PHARMACOLOGICAL ACTION

METARELAX® FAST is a convenient, fast-acting, chewable tablet designed to support a sense of calm and emotional balance. It's rapid disintegration allows the active ingredients to become available quickly, helping it take effect in as little as 30 minutes.

Ingredients	Uses for ingredient
Gamma-aminobutyric acid (GABA)	Supports relaxation and helps maintain normal nervous system function.
Magnesium glycerophosphate	Contributes to normal muscle and nerve function and supports electrolyte balance.
Magnesium bisglycinate	Provides a bioavailable source of magnesium to support muscle function and energy metabolism.
Folate (as calcium L-5-methyltetrahydrofolate)	Supports normal red blood cell formation and contributes to healthy cell division.

CONTRA INDICATIONS:

If you are taking any chronic medication, do not use this product without consulting your healthcare professional. Do not take **METARELAX® FAST** 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. This product contains mannitol, which may have a laxative effect when consumed in excessive quantities.

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® FAST** 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® FAST**. 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® FAST**. 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) to two (2) tablets up to four (4) times per day 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® FAST** if you notice visible signs of deterioration.

IDENTIFICATION

Tablet.

PRESENTATION

Branded carton, with blister strips which contain 15 tablets per strip.

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
17 Galaxy Park, Unit 5B
Galaxy Avenue, LINbro Park
Sandton, 2090, 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® FAST, 15 & 30 Koubare Tablette

SAMESTELING

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

Aktiewe Bestanddeel	Hoeveelheid per tablet
Gamma-aminobotersuur (GABA)	250 mg
Magnesiumlisieroffaat	56 mg
– om elementêre magnesium te verskaf	7 mg
– die verskaffing van fosfor	8,9 mg
Magnesiumbisglisinaat	50,725 mg
– om elementêre magnesium te verskaf	7 mg
– die verskaffing van glisien	43,725 mg
Folaat (as kalsium L-5-metietiltrahidrofolaat)	30 µg

Onaktiewe bestanddele: Mikrokristallyne sellulose, hidrokispropielsellulose, steariensuur, sitroensuur, silikondikسيد, magnesiumsoute van vetsure, magnesiumkarbonaat, rooi beetpoer (Beta vulgaris L.), bevat versoeters: mannitol, sukkrose, stevioglikosiede (van Stevia rebaudiana), arbeigeur, vanieljegeruk.

Hierdie produk is geskik vir veganiste, glutenvry, nie-GMO en suiwelvry FARMAKOLOGIESE KLASSIFIKASIE
Komplementêre medisyne

AANDUIDING EN FARMAKOLOGIESE WERKING

METARELAX® FAST is 'n gerieflike, vinnigwerkende, koubare tablet wat ontwerp is om 'n gevoel van kalmte en emosionele balans te ondersteun. Die winnige ontbinding daarvan laat die aktiewe bestanddele vinnig beskikbaar wees, wat help dat dit binne so min as 30 minute werk.

Bestanddele	Gebruik vir bestanddeel
Gamma-aminobotersuur (GABA)	Ondersteun ontspanning en help om normale senuweestelsel funksie te handhaaf.
Magnesiumlisieroffaat	Dra by tot normale spier- en senuweefunksie en ondersteun elektrolietbalans.
Magnesiumbisglisinaat	Verskaf 'n bio-beskikbare bron van magnesium om spierfunksie en energiemetabolisme te ondersteun.
Folaat (as kalsium L-5-metietiltrahidrofolaat)	Ondersteun normale rooibloedsewering en dra by tot gesonde selding.

KONTRA-INDIKASIES:

As jy enige chroniese medisyne neem, moenie hierdie produk gebruik sonder om jou gesondheidsorgpraktisyn te raadpleeg nie. Moenie METARELAX® FAST 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. Hierdie produk bevat mannitol, wat 'n lakseermiddel kan hê wanneer dit in oormatige hoeveelhede gebruik word.

WAARSKUWING EN SPESIALE VOORSORGMATREËLS

Indien jy enige van die volgende gediagnoseerde toestande het, raadpleeg jou gesondheidsorgpraktisyn voor gebruik : rektale bloeding, dermprobleme (soos verstopping, ulseratiewe kolitis, aambeie), hartsiektes (soos onreëlmatige hartklop), niersiekte, huidige maag / abdominale simptome (soos naardheid / 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 immunstelselversteuring (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 digoksin, natriumpolistireensulfonaat, tetraskilien/kinolonantibiotika (soos tetraskilien, ciprofloksaïn). As enige van die volgende gebeur, hou op om METARELAX® FAST 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® FAST gehad. Jy sal dalk dringende mediese hulp of hospitalisasie nodig hê.

Neue-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® FAST 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) tot twee (2) tablette tot vier (4) keer per dag of soos voorgeskryf deur jou gesondheidsorgpraktisyn.

Moenie meer as die aanbevole dosis neem nie.

NEUE-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 neue-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 neue-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® FAST gebruik as u sigbare tekens van agteruitgang opmerk nie.

IDENTIFIKASIE

Tablet.

AANBIEDING

Gebrande karton, met blaastroke wat 15 tablette per strokê bevat.

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 BESIGHEIDSDADRES VAN APPLIKANT

Versprei deur:

Amipro Advanced Development Products (Pty) Ltd

17Galaxy Park, Unit 5B

Galaxy Avenue, Linbro Park

Sandton, 2090, Tel: 011- 802-8101

DATUM VAN PUBLIKASIE

Om deur die regulerende owerheid toegeken te word.