

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S0

Category D: Complementary medicine.

Discipline: Health Supplement

33.12 Multiple Substance Formulation

PROPRIETARY NAME, STRENGTH, PHARMACEUTICAL FORM –

METARELAX[®], 60 Tablets

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

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

WHAT IS IN THIS LEAFLET

- What **METARELAX[®]** is and what it is used for.
- What you need to know before you take **METARELAX[®]**.
- How to take **METARELAX[®]**.
- Possible side effects.
- How to store **METARELAX[®]**.
- Contents of the pack and other information.

WHAT METARELAX[®] CONTAINS

Each one (1) tablet of **METARELAX[®]** contains 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.

WHAT METARELAX[®] IS AND WHAT IT IS USED FOR

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.

BEFORE YOU TAKE METARELAX[®]

If you are taking any chronic medication, do not use this product without consulting your healthcare practitioner. 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.

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. 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 **METARELAX[®]** 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 **METARELAX[®]** may affect you.

TAKING OTHER MEDICINES WITH METARELAX[®]

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

HOW TO TAKE METARELAX[®]

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

Directions for use:

Adults: Take two (2) tablets daily or as directed by your healthcare Practitioner.

Do not take more than the recommended dose.

IF YOU TAKE MORE METARELAX[®] THAN YOU SHOULD

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



IF YOU FORGET TO TAKE METARELAX[®]

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

POSSIBLE SIDE EFFECTS

METARELAX[®] may have side effects.

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 left untreated, this could cause permanent nerve damage). If you are taking the following medication, please consult with your healthcare practitioner 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.

Not all side effects and interactions reported for **METARELAX[®]** 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 **METARELAX[®]**.

STORAGE AND DISPOSING OF METARELAX[®]

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 **METARELAX[®]** if you notice visible signs of deterioration.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

PRESENTATION OF METARELAX[®]

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

IDENTIFICATION OF METARELAX[®]

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

19 November 2024

NAME AND ADDRESS OF REGISTRATION HOLDER

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PASIËNT INLIGTINGSBLAD

SKEDULERINGSSTATUS **50**

Kategorie D: Komplementêre medisyne.

Dissipline: Gesondheidsaanvulling

34.12 Meervoudige Bestanddeel Formulasie

HANDELSNAAM EN DOSEERVORM,

METARELAX[®], 60 Tablette

LEES HIERDIE INLIGTINGSBLAD NOUKEURIG, WANT DIT BEVAT

BELANGRIKE INLIGTING VIR U

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

WAT IS IN HIERDIE INLIGTINGSBLAD

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

WATTER METARELAX[®] BEVAT

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

Magnesium (as magnesiumgliseroosfaat)	200 mg
Taurine	150 mg
Vitamiën B6 (as piridoksaal-5-fosfaat)	2 mg
Folaat (as kalsium-L-metielofolaat)	200 µg
Vitamiën B12 (as metielkobalamin)	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 vegetariërs glutenvry, nie-GGO en suikervry.

WAT IS METARELAX[®] KAPSULES EN WAARVOOR WORD DIT GEBRUIK

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

VOORDAT JY METARELAX[®] NEEM

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 voordat jy hierdie aanvulling neem.

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

SWANGERSKAP EN BORSVOEDING

Veiligheid tydens swangerskap en borsvoeding is nie vasgestel nie. 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.

BESTUUR EN GEBRUIK VAN MASJIENE

Dit is nie altyd moontlik om te voorspel in watter mate **METARELAX[®]** 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, bedryfsmasjien/toerusting, totdat hulle bewys is van die mate waartoe **METARELAX[®]** jou beïnvloed.

NEEM VAN ANDER MEDISYNE SAAM MET METARELAX[®]

Wees versigtig wanneer Magnesium saam met hipertensiewe, diuretiese en spierverslapping medisyne geneem word om ongewenste interaksies te vermy. 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.

HOE OM METARELAX[®] TE NEEM

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

Aanwysings vir gebruik:

Volwasse: Neem daaglik twee (2) tablette of soos voorgeskrif deur jou gesondheidsorgpraktisyn.

Moenie meer as die aanbevole dosis neem nie.

AS JY MEER METARELAX[®] 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 VERGET OM METARELAX[®] TE NEEM

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

MOONTLIKE NUWE-EFFEKTE

METARELAX[®] kan nuwe-effekte hê. 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 naarheid / braking wat nie ophou nie, pyn, krampe), hoë kalsium / vitamien D-vlakke (hiperkalsemie / hipervitamiose D), probleme om voeding uit voedsel te absorbeer (wanaborsiesindroom), hart-/bloedvatsiekte, niersiekte (insluitend nierstene), sekere immuunstelselversteuring (sarkoidose), lewersiekte, sekere dermsiektes (Crohn se siekte, Whipple se siekte), min of geen maagsuur (achlorhidrie), lae vlakke van gal, onbehandelde fosfaatwanbalans. As dit nie behandel word nie, kan dit permanente senuweesake veroorsaak). As jy die volgende medisyne neem, raadpleeg asseblief jou gesondheidspraktisyn voordat jy neem: digoksien, natriumpolitiereensulfonaat, tetrasiëne/kinolonantibiotika (soos tetrasiëne, ciprofloxacine). As enige van die volgende gebeur, hou op om **METARELAX[®]** te gebruik en vertel jou dokter of gaan na die ongevalle-afdeling by jou naaste hospitaal:

- Allergiese reaksie-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[®]** gehad. Jy mag dalk dringende mediese hulp of hospitalisasie nodig hê.

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

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

Nie alle nuwe-effekte en interaksies wat vir **METARELAX[®]** 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 nuwe-effekte sien wat nie in hierdie inligtingsblad genoem word nie, stel asseblief jou dokter, apteker of gesondheidsorgpraktisyn in kennis.

AANMELDING VAN NUWE-EFFEKTE

As jy nuwe-effekte ervaar, praat met jou dokter, apteker of ander gesondheidsorgpraktisyn. U kan ook nuwe-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 nuwe-effekte aan te meld, kan u help om meer inligting te verskaf oor die veiligheid van **METARELAX[®]**.

HOE OM METARELAX[®] TE BEREÏ

Hou buite bereik van kinders. Hou dig toegemaak op 'n koel, droë 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 **METARELAX[®]** gebruik as u sigbare tekens van agteruitgang opmerk nie.

Moenie ongebruikte medisyne in dreine of rioolstelsels (bv. toilette) weggooi nie.

AANBIEDING VAN METARELAX[®]

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

IDENTIFIKASIE VAN METARELAX[®]

Tablet.

REGISTRASIONOMMER

Om deur SAHPRA toegeken te word by registrasie.

TOEGANG TOT DIE OOREENSTEMMende PROFESSIONELE INLIGTING

Skandeer QR-kode.

HIERDIE INLIGTINGSBLAD IS LAAS HERSIEN OP

19 November 2024

NAAM EN ADRES VAN REGISTRASIEHOUDER

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