

PATIENT INFORMATION LEAFLET

COMPLEMENTARY MEDICINE – HEALTH SUPPLEMENT

This unregistered medicine has not been evaluated by the SAHPRA for its safety, quality or intended use.

SCHEDULING STATUS: S0

MEGAMINO capsules.

Isoleucine, Leucine, Lysine, Methionine, Threonine, Valine, Chromium picolinate, Copper sulphate, Ferrous fumarate, Magnesium oxide, Manganese glycerophosphate, Molybdenum amino acid chelate 0,2%, Selenium amino acid chelate 0,2%, Zinc gluconate, Vitamin A, Vitamin B1, Vitamin B2, Calcium Pantothenate, Vitamin B6, Vitamin B12, Vitamin C, Vitamin D3, Vitamin E, Biotin, Folic acid and Nicotinamide.

Sugar free.

Read all of this leaflet carefully because it contains important information for you.

MEGAMINO is available without a doctor's prescription, for you to maintain your health. Nevertheless, you still need to use MEGAMINO carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share MEGAMINO with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.

What is in this leaflet

1. What MEGAMINO is and what it is used for.
2. What you need to know before you take MEGAMINO.
3. How to take MEGAMINO.
4. Possible side effects.
5. How to store MEGAMINO.
6. Contents of the pack and other information.

1. What MEGAMINO is and what it is used for

A fast and stressful lifestyle as well as an unbalanced diet can deplete and exhaust you physically and mentally. MEGAMINO contains the essential Amino Acids, Minerals and Vitamins to assist in the maintenance of general well being.

2. What you need to know before you take MEGAMINO capsules

Do not take MEGAMINO:

- If you are allergic (hypersensitive) to the active ingredients or any of the other ingredients of MEGAMINO. (see section 6).
- If you have high levels of calcium in your blood (hypercalcaemia) or urine (hypercalciuria).
- If you are suffering from kidney failure, have kidney stones (renal calculi) or have a tendency to form kidney stones.
- If you have high levels of vitamin D in your blood (hypervitaminosis D).

Warnings and precautions

Talk to your doctor or pharmacist before taking MEGAMINO:

- If you suffer from heart disease or narrowing of the arteries.
- If you suffer from sarcoidosis (a multisystem chronic inflammatory condition which can affect your lungs, heart and kidneys), then there is a risk of increased conversion of vitamin D into its active form.
- If you are taking medicines containing vitamin D, or eating foods or drinking milk enriched with vitamin D.

Your doctor may want you to have regular blood tests to check the amount of calcium in your blood.

A varied diet is the most effective and safe way to achieve good nutrition, health, body composition as well as mental and physical performance.

Other medicines and MEGAMINO

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

- The response of zinc may be lessened by taking calcium (milk and milk containing products), iron containing supplements and phosphorous containing preparations at the same time.
- Taking zinc supplements with antibiotics such as penicillin or tetracycline may lessen the effectiveness of those antibiotics.

You must tell your doctor or pharmacist if you are taking any of the following medicines:

- Medicines for epilepsy such as barbiturates or other anti-convulsants (e.g. carbamazepine, phenobarbital, phenytoin, primidone).
- Other vitamin D containing medicines including multi-vitamins.
- Medicines to control the rate of your heart beat (e.g. digoxin, digitoxin).
- Diuretics (water tablets) such as Bendroflumethiazide.
- Calcium supplements.
- Medicines to treat tuberculosis e.g. rifampicin, isoniazid.
- Medicines leading to fat malabsorption e.g. orlistat, cholestyramine, liquid paraffin.
- Medicines to treat fungal infections i.e. ketoconazole, itraconazole.
- Actinomycin (a medicine used to treat some forms of cancer) as it may interfere with the metabolism of vitamin D.
- Glucocorticosteroids (steroid hormones such as hydrocortisone or prednisolone).

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby ask your doctor or pharmacist for advice before taking this medicine. If you require extra vitamin D do not take it without medical supervision because too much vitamin D may harm your baby.

Driving and using machines

MEGAMINO should not affect your driving ability or the ability to use or operate machinery.

3. How to take MEGAMINO

Always take MEGAMINO exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is:

Adults:

One capsule with your main meal. Avoid taking capsule with hot liquids.

If you take more MEGAMINO than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take MEGAMINO

Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

Not all side effects reported for MEGAMINO are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking MEGAMINO, please consult your health care provider for advice.

If any of the following happens, stop taking MEGAMINO and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to MEGAMINO. You may need urgent medical attention or hospitalisation.

Side effects with MEGAMINO may include:

Uncommon side effects, affecting less than 1 in 100 people

- Too much calcium in your blood (hypercalcaemia). You may feel or be sick, lose your appetite, have constipation, stomach ache, feel very thirsty, have muscle weakness, drowsiness or confusion.
- Too much calcium in your urine (hypercalciuria).

Rare side effects, affecting less than 1 in 1000 people

- Skin rash.
- Itching.
- Raised itchy rash (hives).

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the "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 MEGAMINO.

5. How to store MEGAMINO

- Store all medicines out of reach of children.
- Store at or below 25°C.
- Store in the original container.
- Keep the container tightly closed.
- Protect from light and moisture.
- Do not store in a bathroom.
- Do not use after the expiry date stated on the label.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What MEGAMINO contains:

Each capsule contains:

Isoleucine	7 mg
Leucine	8,00 mg
Lysine	12,00 mg
Methionine	12,00 mg
Threonine	6,00 mg
Valine	8,00 mg
Chromium picolinate	45,00 mcg
providing Chromium (elemental)	5,58 mcg
Copper sulphate	1,00 mg
providing Copper (elemental)	0,40 mg
Ferrous fumarate	4,00 mg
providing Iron (elemental)	4,62 mg
Magnesium oxide	100,00 mg
providing Magnesium (elemental)	39,70 mg
Manganese glycerophosphate	1,50 mg
providing Manganese (elemental)	360,00 mcg
Molybdenum amino acid chelate 0,2%	70,00 mcg
providing Molybdenum (elemental)	0,14 mcg
Selenium amino acid chelate 0,2%	70,00 mcg
providing Selenium (elemental)	0,14 mcg
Zinc gluconate	10,00 mg
providing Zinc (elemental)	1,435 mg
Vitamin A	1,40 mg
Vitamin B1 (Thiamine Hydrochloride)	20,00 mg
Vitamin B2 (Riboflavin)	20,00 mg
Calcium Pantothenate	20,00 mg
Vitamin B6 (Pyridoxine Hydrochloride)	20,00 mg
Vitamin B12	20,00 mcg
Vitamin C (Ascorbic Acid)	150,00 mg
Vitamin D3	10,00 mcg
Vitamin E	25,00 mg
Biotin	380,00 mcg
Folic Acid	450,00 mcg
Nicotinamide	18,00 mg
Other ingredients: Magnesium Stearate, Soy Protein Isolate 90%, Talc.	
Sugar free.	

What MEGAMINO looks like and contents of the pack

Royal blue capsules.

30 and 60 capsules in a tabtainer with a white lid.

Holder of the certificate of registration

Crux Pharmaceutical (Pty) Ltd
630 Jacqueline Drive
Garsfontein
Pretoria
0042

Marketed by:

Cedarpharm (Pty) Ltd
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Randpark Ridge
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www.cedarpharm.co.za

This leaflet was last revised in

October 2023.

Registration numbers

To be allocated.

PASIËNTINLIGTINGSPAMFLET

KOMPLEMENTÊRE MEDISYNE – GESONDHEIDSAANVULLING

Hierdie ongeregisteerde medisyne is nie deur die SAHPRA geëvalueer vir sy kwaliteit, veiligheid of aangeduide gebruik nie.

SKEDULERINGSSTATUS: S0

MEGAMINO kapsules.

Isoleucien, Leucien, Lysien, Metionien, Threonine, Valine, Chroompikolinaat, Kopersulfaat, Ysterhoudende fumaraat, Magnesiumoksied, Mangaangliserofosfaat, Molibdeen aminosuur chelaat 0,2%, Selenium aminosuur chelaat 0,2%, Sinkglukonaat, Vitamien A, Vitamien B1, Vitamien B2, Kalsiumpantotenaat, Vitamien B6, Vitamien B12, Vitamien C, Vitamien D3, Vitamien E, Biotien, Foliensuur, Nikotinamied.

Suikervry.

Lees die hele pamflet noukeurig deur, want dit bevat belangrike inligting vir jou.

MEGAMINO is beskikbaar sonder 'n dokter se voorskrif, vir jou om jou gesondheid te handhaaf. Nietemin moet jy MEGAMINO steeds versigtig gebruik om die beste resultate daaruit te kry.

- Bewaar hierdie pamflet. Jy sal dit dalk weer moet lees.
- Moenie MEGAMINO met enige ander persoon deel nie.
- Vra jou gesondheidsorgverskaffer of apteker as jy meer inligting of advies nodig.

Wat is in hierdie pamflet

1. Wat MEGAMINO is en waarvoor dit gebruik word.
2. Wat jy moet weet voordat jy MEGAMINO neem.
3. Hoe om MEGAMINO te neem.
4. Moontlike nuwe-effekte.
5. Hoe om MEGAMINO te stoor.
6. Inhoud van die houër en ander inligting.

1. Wat MEGAMINO is en waarvoor dit gebruik word.

'n Vinnige en stresvolle leefstyl sowel as 'n ongebalanseerde dieet kan jou fisies en geestelik uitput. MEGAMINO bevat die noodsaaklike aminosure, minerale en vitamien om te help met die handhawing van algemene welstand.

2. Wat jy moet weet voordat jy MEGAMINO neem.

Moenie MEGAMINO neem nie:

- as jy allergies (hipersensitief) vir die aktiewe bestanddele of enige van die ander bestanddele van MEGAMINO (sien afdeling 6)
- as jy hoë vlakke van kalsium in jou bloed (hiperkalsemie) of urine (hiperkalsiurie) het.
- as jy aan nierversaking ly, nierstene (nierstene) het of 'n neiging het om nierstene te vorm.
- as jy hoë vlakke van vitamien D in jou bloed het (hipervitaminose D).

Waarskuwings en voorsorgmaatreëls

Praat met jou dokter of apteker voordat jy MEGAMINO neem:

- As jy aan hartsiekte of verouing van die are ly.
 - As jy aan sarkoïdiese ly ('n multisistiese chroniese inflammatoriese toestand wat jou longe, hart en niere kan beïnvloed), dan is daar 'n risiko van verhoogde omskakeling van vitamien D in sy aktiewe vorm.
 - As jy medisyne gebruik wat vitamien D bevat, of kos eet of melk drink wat vitamien D bevat, moet jy dit met jou dokter bespreek.
- Jou dokter wil dalk hê jy moet gereeld bloedtoetse laat doen om die hoeveelheid kalsium in jou bloed te kontroleer. 'n Gevarieerde dieet is die mees doeltreffende en veilige manier om goeie voeding, gesondheid, liggaamsamestelling sowel as geestelike en fisiese prestasie te bereik.

Ander medisyne en MEGAMINO

Vertel altyd jou gesondheidsorgverskaffer as jy enige ander medisyne gebruik. (Dit sluit alle komplementêre of tradisionele medisyne in.)

- Die reaksie van sink kan verminder word deur kalsium (melk en melkbevattende produkte), ysterbevattende aanvullings en fosforbevattende preparate gelyktydig te neem.
- Die neem van sinkaanvullings saam met antibiotika soos penisillien of tetrasiklien kan die doeltreffendheid van daardie antibiotika verminder.

Jy moet jou dokter of apteker vertel as jy enige van die volgende medisyne gebruik:

- Medisyne vir epilepsie soos barbiturate of ander anti-convulsiewe middels (bv. karbamasepien, fenobarbital, fenitoïen, primidoon).
- Ander vitamien D-bevattende medisyne insluitend multi-vitamien.
- Medisyne om die tempo van jou hartklop te beheer (bv. digoksien, digitoksien).
- Diuretika (watertablette) soos Bendroflumethiazide.
- Kalsiumaanvullings.
- Medisyne om tuberkulose te behandel bv. rifampisien, isoniasied.
- Medisyne wat lei tot vetwanabsorpsie bv. orlistat, cholestyramien, moeibare paraffien.
- Medisyne om swaminfeksies te behandel, dws ketokonasool, itrakonasool.
- Aktinomisien ('n medisyne wat gebruik word om sommige vorme van kanker te behandel) aangesien dit die metabolisme van vitamien D kan inmeng.
- Glukokortikosteroïede (steroïedhormone soos hidrokortison of prednisonoel).

Swangerskap, borsvoeding en fertiliteit

As jy swanger is of borsvoed, dink jy is dalk swanger of beplan om 'n baba te hê, vra jou dokter of apteker vir advies voordat jy hierdie medisyne neem. As jy ekstra vitamien D nodig, moenie dit sonder mediese toesig neem nie, want te veel vitamien D kan jou baba benadeel.

Bestuur en gebruik van masjinerie

MEGAMINO behoort nie jou bestuursvermoë of die vermoë om masjinerie te gebruik of te bestuur, beïnvloed nie.

3. Hoe om MEGAMINO te neem

Neem MEGAMINO altyd presies soos beskryf in hierdie pamflet of soos jou dokter of apteker vir jou gesê het. Gaan met jou dokter of apteker as jy nie seker is nie.

Die gewone dosis is:

Volwassenes:

Een kapsule saam met jou hoofmaaltyd. Vermyn die neem van kapsules met warm vloeistowwe.

As u meer MEGAMINO tablette geneem het as wat u moes

In die geval van oordosis, raadpleeg jou dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.

As u vergeet om HYPACE tablette te neem

Moenie 'n dubbeldosis neem om vergeet individuele dosisse in te haal nie.

4. Moontlike nuwe effekte

MEGAMINO kan nuwe-effekte hê.

Nie alle nuwe-effekte wat vir MEGAMINO gemeld is, is ingesluit in hierdie inligtingspamflet.

Indien u algemene gesondheid agteruitgaan terwyl u MEGAMINO gebruik raadpleeg asseblief u dokter, apteker of ander gesondheidsorgwerker vir advies.

Indien enige van die volgende gebeur, moet u die gebruik van MEGAMINO staak en u dokter dadelik in kennis stel of na die naaste ongevalle afdeling van die naaste hospitaal gaan:

- Swelling van die hande, voete, enkels, gesig, lippe en mond of keel, wat probleme kan veroorsaak om te sluk of asem te haal.
- Uitslag of jeuk;
- Floute

Dit is alles baie ernstige nuwe-effekte. As jy hulle het, het jy moontlik 'n ernstige allergiese reaksie op MEGAMINO gehad het. Jy benodig dalk dringende mediese aandag of hospitalisasie.

Nuwe-effekte met MEGAMINO kan die volgende insluit:

Ongewone nuwe-effekte, wat minder as 1 uit 100 mense affekteer

- Te veel kalsium in jou bloed (hiperkalsemie). Jy kan siek voel of wees, jou eetlus verloor, hardlywigheid, maagpyn hê, baie dors voel, spierswakheid, lomerigheid of verwaring hê.
- Te veel kalsium in jou urine (hiperkalsiurie).

Skaars nuwe-effekte, wat minder as 1 uit 100 mense affekteer

- Veluitslag.
- Jeuk.
- Verhoogde jeukerige uitslag (korwe).

Rapportering van vermoedelike ongewenste effekte

Rapportering van vermoedelike ongewenste effekte na die magtiging van die medisyne is belangrik. Dit help met die monitoring van die voordele/risiko balans van die medisyne. Gesondheidsorgkundiges word gevra om enige vermoedelike ongewenste effekte aan SAHPRA te rapporteer via die "6.04 Adverse Drug Reaction Reporting Form", wat aanlyn gevind word onder SAHPRA se publikasies: <https://www.sahpra.org.za/Publications/Index/8>.

5. Hoe om MEGAMINO te stoor

- Stoor alle medisyne buite bereik van kinders.
- Stoor by of benede 25 C.
- Hou in die oorspronklike houër.
- Beskerm teen li gen vog.
- Moenie in die badkamer stoor nie.
- Moenie gebruik na die vervaldatum op die etiket nie.
- Neem alle ongebruikte medisyne terug na u apteker vir vernietiging.
- Moenie ongebruikte medisyne in dreine of rioolstelsels (bv. toilette) weggooi nie.

6. Inhoud van die houër en ander inligting.

Wat MEGAMINO bevat:

Die aktiewe bestanddele per kapsule is:

Isoleucien	7,00 mg
Leucien	8,00 mg
Lysien	12,00 mg
Metionien	12,00 mg
Threonine	6,00 mg
Valine	8,00 mg
Chroompikolinaat	45,00 mcg
verskaffing van Chroom (elementaal)	5,58 mcg
Kopersulfaat	1,00 mg
verskaffing van Koper (elementeel)	0,40 mg
Ysterhoudende fumaraat	14,00 mg
verskaf Yster (elementeel)	4,62 mg
Magnesiumoksied	100,00 mg
verskaffing van Magnesium (elementeel)	39,70 mg
Mangaangliserofosfaat	1,50 mg
verskaffing van Mangaan (elementeel)	360,00 mcg
Molibdeen aminosuur chelaat 0,2%	70,00 mcg
verskaffing van Molibdeen (elementeel)	0,14 mcg
Selenium aminosuur chelaat 0,2%	70,00 mcg
verskaffing van Selenium (elementeel)	0,14 mcg
Sinkglukonaat	10,00 mg
verskaffing van sink (elementeel)	1,435 mg
Vitamien A	1,40 mg
Vitamien B1 (Tiamienhidrochloried)	20,00 mg
Vitamien B2 (riboflavien)	20,00 mg
Kalsiumpantotenaat	20,00 mg
Vitamien B6 (Pyridoxine Hydrochloried)	20,00 mg
Vitamien B12	20,00 mcg
Vitamien C (askorbiensuur)	150,00 mg
Vitamien D3	10,00 mcg
Vitamien E	25,00 mg
Biotien	380,00 mcg
Foliensuur	450,00 mcg
Nikotinamied	18,00 mg

- Die ander bestanddele is magnesiumstearaat, sojaproteïenisoalaat 90%, talk.
- Suikervry.

Hoe MEGAMINO lyk en die inhoud van die houër

Koningsblou kapsules.

30 en 60 kapsules in 'n houër met 'n wit deksel.

Houer van Sertifikaat van Registrasie

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630 Jacqueline Drive
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Hierdie pamflet is laas hersien in

Oktober 2023

Registrasienommer

Om toegeken te word.