

PROFESSIONAL INFORMATION

Category D: human complementary medicine. This medicine has not been evaluated by the SAHPRA. This medicine is not intended to diagnose, treat, cure or prevent any disease.

SCHEDULING STATUS

S0

1. NAME OF THE MEDICINE

Obel CALMAG capsules

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Ingredients per serving (1 capsule): Calcium Carbonate 1122 mg (providing 449 mg elemental Calcium), Magnesium Glycinate 900 mg (providing 127 mg elemental Magnesium), Vitamin K (MK7) 75 mcg, Vitamin D3 1000 IU.

3. PHARMACEUTICAL FORM

Obel CALMAG capsules capsules are hard gel capsules containing off-white powder.

4. CLINICAL PARTICULARS

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4.1. Therapeutic Indications

Obel CALMAG capsules are used for muscle and bone support.

4.2. Posology and method of administration

Posology

Adults:

Standard Adult dose: Take one capsule daily, with food.

Adults over 50 years of age or those with low dietary intake: Take two capsules daily, with food.

Method of administration

Obel CALMAG capsules should be taken orally, with food.

4.3. Contraindications

Avoid if allergic or sensitive to any of the listed ingredients. Do not exceed recommended dosage(s).

4.4. Special warnings and precautions for use

Obel CALMAG capsules must not be used if hypersensitive (allergic) to any ingredients.

4.5. Interaction with other medicines and other forms of interaction

If you are taking prescription medication, consult a healthcare practitioner prior to use. Obel CALMAG capsules are not known to react badly with any types medicines, or food or drink.

4.6. Fertility, pregnancy and lactation

Obel CALMAG capsules should not be used during pregnancy and a healthcare provider should be consulted for advice prior to taking Obel CALMAG capsules when breastfeeding.

4.7. Effects on ability to drive and use machines.

No effects on the ability to drive and use machines has been reported.

4.8. Undesirable effects

None known. Should general health worsen, or if any untoward effects are experienced while using this product, please consult a doctor, pharmacist, or other health care professional for advice.

4.9. Overdose

If you take more Obel CALMAG capsules than you should:

If anyone, especially a child, accidentally takes too much Obel CALMAG capsules contact your doctor or local poison centre immediately. If symptoms persist consult your doctor. If you see a doctor or have to go to hospital for any reason, tell them what medicines you are taking.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

33.6 Western Herbal Medicine. Obel CALMAG capsules contain substances for muscle and bone support.

5.2. Pharmacokinetic properties

There is no pharmacokinetic data available on the active ingredients via the route of administration described.

5.3. Preclinical safety data

There is no preclinical safety data available on the active ingredients via the route of administration described.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Inactive ingredients: Magnesium Stearate, HPMC Capsules.

6.2. Incompatibilities: None

6.3. Shelf life

2 years

6.4. Special precautions for storage

Store below 30 °C in a cool, dry place. Store out of reach of children. Do not use after the expiry date stated on the bottle. The expiry date refers to the last day of the month.

6.5. Nature and contents of container

Obel CALMAG capsules is a clear capsule with light brown powder in a white HDPE tamper-evident container, containing 60 veggie-capsules.

Special precautions for disposal

No special requirements.

7. PROPOSED HOLDER OF CERTIFICATE OF REGISTRATION

Galileo Labs Ltd.

5630 Venice Blvd #1119, LA, CA 90019.

3rd Floor, 14505 Bannister Road SE,

Calgary, AB, T2X 3J3.

Name and Address of Holder of Certificate of Registration

Microbel Laboratories (Pty) Ltd,

86 Gazelle Ave, Corporate Park South,

Midrand, Gauteng, 1685, South Africa.

Email: info@microbel.co.za

+27 11 076 4000

8. REGISTRATION NUMBER(S)

Application Number: TBC by SAHPRA

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

TBA by SAHPRA. Date of Revision: February 2026

PROFESSIONELE INLIGTING

Kategorie D: Menslike komplementêre medisyne. Hierdie medisyne is nog nie deur SAHPRA geëvalueer nie. Die doel van hierdie medisyne is nie om enige siekte te diagnoseer, behandel, genees of te voorkom nie.

SKEDULERINGSTATUS: S0

1. NAAM VAN MEDIKASIE

Obel CALMAG kapsules

2. KWALITATIEWE EN KWANTITATIEWE SAMESTELLING

Aktiewe bestanddele per porsie (1 kapsule): Kalsiumkarbonaat 1122 mg (verskaf 449 mg elementêre kalsium), magnesiumlisinaat 900 mg (verskaf 127 mg elementêre magnesium), Vitamien K (MK7) 75 mcg, Vitamien D3 1000 IE.

3. FARMASEUTIESE DOSEERVORM

Obel CALMAG kapsule is 'n harde gelkapsule wat afwit poeier bevat.

4. KLINIESE BESONDERHEDE

Kategorie D: Menslike komplementêre medisyne. Hierdie medisyne is nog nie deur SAHPRA geëvalueer nie. Die doel van hierdie medisyne is nie om enige siekte te diagnoseer, behandel, genees of te voorkom nie.

4.1 TERAPEUTIESE INDIKASIES

Obel CALMAG kapsules word gebruik vir spier-en been-ondersteuning.

4.2 DOSERING EN METODE VAN TOEDIENING

Dosering

Volwassenes:

Standaard volwasse dosis: Neem 1 kapsule daagliks, saam met kos.

Volwassenes ouer as 50 jaar of dié met lae dieet: Neem twee kapsules daagliks, saam met kos.

Metode van toediening

Obel CALMAG kapsules moet mondelings geneem word, saam met kos.

4.3 Kontra-indikasies

Vermyn as allergies of sensitief vir enige van die genoemde bestanddele. Moenie die aanbevole dosis(se) oorskry nie.

4.4 Waarskuwings en spesiale voorsorgmaatreëls

Obel CALMAG kapsules moet nie gebruik word as u hipersensitief (allergies) is vir enige bestanddele nie.

4.5 Interaksies met ander medisyne en ander tipe interaksies

As jy voorskrifmedikasie neem, raadpleeg 'n gesondheidsorgpraktisyn voor gebruik. Dit is nie bekend dat Obel CALMAG kapsules sleg reageer met enige tipe medisyne, of kos of drank nie.

4.6 Vrugbaarheid, swangerskap en borsvoeding

Obel CALMAG kapsules moet nie tydens swangerskap gebruik word nie en 'n gesondheidsorgverskaffer moet geraadpleeg word vir advies voordat Obel CALMAG kapsules geneem word tydens borsvoeding.

4.7 Effek op die vermoë om te bestuur en masjinerie te gebruik

Geen effekte op die vermoë om te bestuur of om masjinerie te gebruik is aangemeld nie.

4.8 Nuwe-effekte

Geen bekend. Indien u algemene gesondheid versleg, of indien u enige nuwe-effekte ervaar tydens die gebruik van hierdie produk, moet jou dokter, apteker of ander gesondheidsorgverskaffer vir advies geraadpleeg word.

4.9 Oordosering

As hy meer Obel CALMAG kapsules neem as wat jy moet:

As iemand, veral 'n kind per ongeluk te veel Obel CALMAG kapsules neem, kontak jou dokter of plaaslike gifsentrum onmiddelik. As simptome voortduur, raadpleeg jou dokter. As jy 'n dokter sien of om een of ander rede hopsitaal toe moet gaan, vertel hulle watter medisyne jy neem.

5. FARMAKOLOGIESE EIENSKAPPE

5.1 Farmakodinamiese eienskappe

33.6 Westerse Kruie Medisyne. Obel calmag kapsules bevat stowwe vir spier-en beenondersteuning.

5.2 Farmakokinetiese eienskappe

Daar is geen farmakokinetiese data beskikbaar oor die aktiewe bestanddele via die toedieningsroete wat beskryf word nie.

5.3 Pre-kliniese gesondheidsdata

Daar is geen prekliniese veiligheidsdata beskikbaar oor die aktiewe bestanddele via die toedieningsroete wat beskryf word nie.

6. FARMASEUTIESE BESONDERHEDE

6.1 Lys van hulpstowwe

Onaktiewe bestanddele: Magnesiumstearaat, HPMC-kpasures.

6.2 Onverenigbaarhede

Geen.

6.3 Rakleef tyd

2 Jaar.

6.4 Spesiale voorsorgmaatreëls vir bewaring

Bewaar benede 30 °C in 'n koel droë plek. Hou buite bereik van kinders. Moet nie die produk na die vervaldatum aangedui op die houer gebruik nie. Die vervaldatum verwys na die laaste dag van die maand.

6.5 Samestelling en inhoud van die houer

Obel calmag Kapsules is 'n deursigtige kapsule met afwit poeier in 'n wit HDPE-peuter evident houer, wat 60 groentekapsules bevat.

Spesiale voorsorgmaatreëls vir wegdoening

Geen spesiale vereistes nie.

7. VOORGESTELDE HOUER VAN REGISTRASIESERTIFIKAAT

Galileo Labs Ltd.

5630 Venice Blvd #1119, LA, CA 90019.

3rd Floor, 14505 Bannister Road SE,

Calgary, AB, T2X 3J3.

Naam en Adres van Houer van Registrasiesertifikaat

Microbel Laboratories (Pty) Ltd,

86 Gazelle Ave, Corporate Park South,

Midrand, Gauteng, 1685, South Africa.

Email: info@microbel.co.za

+27 11 076 4000

8. REGISTRASIENOMMER(S)

Aansoeknommer: TBC deur SAHPRA

9. DATUM VAN EERSTE GOEDKEURING/HERNUWING VAN GOEDKEURING

TBA deur SAHPRA. Datum van hersiening: Februarie 2026.