

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

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1. NAME OF THE MEDICINE

Obel Probiotic & Prebiotic capsules

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Ingredients per serving (2 capsules): Lactobacillus acidophilus (3.3 billion cfu), Bifidobacterium longum (3.3 billion cfu), Bifidobacterium lactis (3.3 billion cfu), Bifidobacterium bifidum (3.4 billion cfu), Fructo-Oligosaccharides (69 mg), Maltodextrin (552 mg), Turmeric (500 mg).

3. PHARMACEUTICAL FORM

Obel Probiotic & Prebiotic capsules are hard gel capsules containing light yellow to tan powder.

4. CLINICAL PARTICULARS

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4.1. Therapeutic Indications

Obel Probiotic & Prebiotic capsules are used for digestive support.

4.2. Posology and method of administration

Posology

Adults: The usual dose is 2 capsules daily. Do not take within one hour of antibiotics.

Method of administration

Obel Probiotic & Prebiotic capsules should be taken once a day with or without 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 Probiotic & Prebiotic 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 Probiotic & Prebiotic capsules are not known to react badly with any types medicines, or food or drink.

4.6. Fertility, pregnancy and lactation

Obel Probiotic & Prebiotic capsules should not be used during pregnancy and a healthcare provider should be consulted for advice prior to taking Obel Probiotic & Prebiotic 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 Probiotic & Prebiotic Capsules than you should:

If anyone, especially a child, accidentally takes too much Obel Probiotic & Prebiotic 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

34.9 Probiotics. Obel Probiotic & Prebiotic capsules contain substances for digestive 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, Microspheres (Lecithin & Chitosan), Xanthan Gum, 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 Probiotic & Prebiotic Capsules is a clear capsule with light yellow to tan 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: April 2025