

# The Real Thing Pro-Probiotic Capsules

Complementary Medicine. Health Supplement.

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

**SCHEDULING STATUS:** S0

## 1 NAME OF THE MEDICINE

THE REAL THING PRO-PROBIOTIC CAPSULES contain 20 billion cfu per capsule.

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

THE REAL THING PRO-PROBIOTIC CAPSULES contain:

|  | Per capsule   |
|--|---------------|
| <i>Lactobacillus acidophilus</i>                 | 6 billion cfu |
| <i>Bifidobacterium bifidum</i>                   | 3 billion cfu |
| <i>Bifidobacterium longum</i>                    | 3 billion cfu |
| <i>Lactobacillus plantarum</i>                   | 2 billion cfu |
| <i>Bifidobacterium lactis</i>                    | 1 billion cfu |
| <i>Lactobacillus casei</i>                       | 1 billion cfu |
| <i>Lactobacillus fermentum</i>                   | 1 billion cfu |
| <i>Lactobacillus paracasei</i>                   | 1 billion cfu |
| <i>Lactobacillus rhamnosus</i>                   | 1 billion cfu |
| <i>Saccharomyces boulardii</i> (probiotic yeast) | 1 billion cfu |

Cfu = colony-forming units.

The inactive ingredients include inulin, dicalcium phosphate, magnesium stearate (vegetable origin) and vegetable (hypromellose) capsule shell. The capsules are sugar free. For full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

THE REAL THING PRO-PROBIOTIC CAPSULES is a clear, hard vegetable capsule shell, size 0, containing a yellow to cream coloured powder.

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic indications

THE REAL THING PRO-PROBIOTIC CAPSULES is a health supplement that:

- Improves the functioning of the digestive tract/gut when ingested on a regular basis, as probiotics should improve, normalise or replenish/recolonize the microbial balance in the human intestines.
- Help metabolize food in the gastrointestinal tract and maintain intestinal health.

Supplementation should not replace a healthy, balanced and varied diet.

### 4.2 Posology and method of administration

Adults 18 years and older: Take one capsule orally daily with a glass of water to ease swallowing. Take at least 2 to 3 hours before or after antibiotic and antifungal medications so as not to decrease the effectiveness of the probiotics. Probiotics are generally taken for a period of one month. Advise patient to consult a healthcare practitioner for prolonged use.

### **Paediatric population**

THE REAL THING PRO-PROBIOTIC CAPSULES is not indicated in paediatrics. It is not suitable for use in children, unless under the care of a healthcare practitioner.

### **4.3 Contraindications**

Do not use this product if:

- Hypersensitive to any of the ingredients.
- Patients have an immune-compromised condition (e.g. AIDS, lymphoma, patients undergoing long term corticosteroid treatment).

### **4.4 Special warnings and precautions for use**

Advise patient to consult a healthcare practitioner if symptoms worsen.

Patients should consult a healthcare practitioner prior to use if they have fever, vomiting, bloody diarrhoea or severe abdominal pain.

Patients should stop use and consult a healthcare practitioner if symptoms of digestive upset (eg diarrhoea) occur, worsen and/or persist beyond 3 days.

Use probiotics cautiously in the elderly because of occasional reports of sepsis that have rarely occurred in previously healthy patients.

### **4.5 Interaction with other medicines and other forms of interaction**

Other medicines affecting THE REAL THING PRO-PROBIOTIC CAPSULES:

Theoretically, antibiotics and antifungals might decrease the effectiveness of probiotics. Therefore, take these medicines at least two hours apart from probiotics.

### **4.6 Fertility, pregnancy and lactation**

#### **Pregnancy and lactation**

Advise patient to consult a healthcare practitioner prior to use if she is pregnant or breastfeeding. No fertility data is available.

### **4.7 Effects on ability to drive and use machines**

THE REAL THING PRO-PROBIOTIC CAPSULES may have a minor influence on the ability to drive and use machines due to possible undesirable effects.

### **4.8 Undesirable effects**

#### **a) Summary of the safety profile**

Gastrointestinal effects appear to be the most commonly reported undesirable effects for these active ingredients.

#### **b) Tabulated summary of adverse reactions**

##### *Immune system disorders*

Possibility of pathogenic infection in some patients (rare). Bacteraemia (rare) and sepsis (rare) have been reported in patients with indwelling or central venous catheters or patients who are severely ill and/or immunocompromised.

Lactobacillus species have also been isolated in some cases of bacteraemia, sepsis, splenic abscess (rare), endocarditis (rare), necrotizing fasciitis (rare), pancreatic necrosis (rare) and meningoencephalitis (rare). It is possibly due to translocation of bacteria from other locations in the body in which they occur naturally, such as the oral cavity and gastrointestinal tract.

*Saccharomyces boulardii* has been associated with fungaemia (rare) in both immunocompromised and immunocompetent patients. Numerous cases of *Saccharomyces* fungaemia have been reported in critically ill ICU patients, particularly those with indwelling or central venous catheters, those receiving enteral feeding, or those receiving broad spectrum antibiotics.

#### *Gastrointestinal disorders*

Diarrhoea (rare), loose stools (rare), dyspepsia (rare), abdominal pain (rare), abdominal cramps (rare), stomach pain (rare), epigastric discomfort (rare), nausea (rare), vomiting (rare), bloating (rare), belching (rare), burping (rare), flatulence (rare), rumbling (rare), decreased appetite, and taste disturbance.

#### *Skin and subcutaneous tissue disorders*

Rash (rare), dermatitis (rare).

#### *Reporting of suspected adverse reactions*

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are asked to report any suspected adverse reactions to SAHPRA via the “**6.04 Adverse Drug Reactions Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>

Alternatively, suspected adverse reactions may be reported directly to the Holder of the Certificate of Registration, The Real Thing Food Supplements (Pty) Ltd at telephone (021) 701-0244 or e-mail [adr@therealthing.co.za](mailto:adr@therealthing.co.za)

### **4.9 Overdose**

With an overdose, side effects can be precipitated and/or be of increased severity. Insufficient reliable information is available. In the event of overdosage, advise the patient to stop taking the supplement. Treatment is symptomatic and supportive.

## **5 PHARMACOLOGICAL PROPERTIES**

### **5.1 Pharmacodynamic properties**

THE REAL THING PRO-PROBIOTIC CAPSULES belongs to category D Complementary Medicines, Health Supplements, class 34.12 Multiple Substance Formulation.

Probiotics are non-pathogenic, living microbes that are thought to provide a therapeutic benefit to the host. THE REAL THING PRO-PROBIOTIC CAPSULES contains a broad-spectrum of 9 different viable strains of beneficial bacteria and 1 yeast that colonize the intestine to attain ideal intestinal ecology.

Probiotics have antibacterial effects. The probiotics pass through the gut and attach to the intestinal wall where they can persist for at least a week, thereby blocking pathogenic bacteria from finding a spot to attach to the intestinal wall. Some probiotics produce bacteriocins (bactericidal proteins), hydrogen peroxide, lactic acid or acetic acid; these substances can block colonization by pathogenic organisms.

Probiotics also appear to have immunomodulating effects. Some probiotics appear to modulate non-specific cellular and humoral immunity, possibly by stimulating lymphocyte and macrophage activity, and modulating cytokine production by mononuclear cells. In people with immune system hypersensitivity, probiotics seem to down-regulate the immune function. In people without immune system hypersensitivity, probiotics seem to stimulate the immune system. Due to these immunomodulating effects, probiotics fight intestinal and urogenital pathogens.

*Saccharomyces boulardii* is a non-pathogenic species of yeast, commonly used in probiotic supplements.

### **5.2 Pharmacokinetic properties**

Probiotics, when taken orally, are not absorbed in the gastrointestinal tract. They colonize the large bowel. For continued effect they must be taken regularly.

*Saccharomyces boulardii*, which is a yeast, typically reaches a maximum steady state in 3 days when taken orally. It does not multiply in the gut. Normally it is not absorbed. Less than 1 % is found in the stool.

### **Paediatric population**

No information is available.

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

The inactive ingredients include –

- inulin
- dicalcium phosphate
- magnesium stearate (vegetable origin)
- vegetable (hypromellose) capsule shell

### **6.2 Incompatibilities**

Not applicable.

### **6.3 Shelf life**

THE REAL THING PRO-PROBIOTIC CAPSULES has a shelf life of 2 years when stored in the fridge (at 2 to 8 °C).

### **6.4 Special precautions for storage**

Store in the fridge (2 to 8 °C). Keep container tightly closed.

### **6.5 Nature and contents of container**

THE REAL THING PRO-PROBIOTIC CAPSULES is packed in a 75 ml amber glass bottle with a child resistant 38 mm polypropylene black or white screw cap fitted with an aluminium foil heat-induction or pressure tamper-evident seal. A silica gel sachet is included in the bottle. The bottle contains 30 capsules. The bottle is packed in a round core carton fitted with a white insert lid. Alternatively, it may be packed with a non-child resistant cap fitted with a plastic tamper-evident shrink sleeve.

THE REAL THING PRO-PROBIOTIC CAPSULES is packed in a labelled container fitted with a metal base, and an AluPeel top with snap-on clear plastic lid. The container is lined with a clear plastic bag with 5 silica gel sachets included, and the bag is sealed. The container contains 600 capsules.

### **6.6 Special precautions for disposal**

No special requirements.

## **7 HOLDER OF CERTIFICATE OF REGISTRATION**

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## **8 REGISTRATION NUMBER**

(To be allocated)

## **9 DATE OF FIRST AUTHORISATION**

(To be allocated)

## **10 DATE OF REVISION OF THE TEXT**

This is the first edition.