

# The Real Thing Pro-Probiotic Capsules

**SCHEDULING STATUS:** S0

**THE REAL THING PRO-PROBIOTIC CAPSULES** contain 20 billion cfu per capsule: *Lactobacillus acidophilus*, *bifidobacterium bifidum*, *bifidobacterium longum*, *lactobacillus plantarum*, *bifidobacterium lactis*, *lactobacillus casei*, *lactobacillus fermentum*, *lactobacillus paracasei*, *lactobacillus rhamnosus*, *saccharomyces boulardii* (yeast). The capsules are sugar-free.

Complementary Medicine. Health Supplement.

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

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

THE REAL THING PRO-PROBIOTIC CAPSULES is available without a doctor's prescription, for you to maintain your health. Nevertheless, you still need to use THE REAL THING PRO-PROBIOTIC CAPSULES carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share THE REAL THING PRO-PROBIOTIC CAPSULES with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after one month.

## **What is in this leaflet**

1. What THE REAL THING PRO-PROBIOTIC CAPSULES is and what it is used for.
2. What you need to know before you take THE REAL THING PRO-PROBIOTIC CAPSULES.
3. How to take THE REAL THING PRO-PROBIOTIC CAPSULES.
4. Possible side effects.
5. How to store THE REAL THING PRO-PROBIOTIC CAPSULES.
6. Contents of the pack and other information.

## **1. What THE REAL THING PRO-PROBIOTIC CAPSULES is and what it is used for**

THE REAL THING PRO-PROBIOTIC CAPSULES is a health supplement. It is a combination of 10 probiotics, one of which is also a yeast. It offers the following health benefits for adults –

- Probiotics improve 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;
- In the gastrointestinal tract probiotics help metabolize food and maintain intestinal health.

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

## **2. What you need to know before you take THE REAL THING PRO-PROBIOTIC CAPSULES**

### **Do not take THE REAL THING PRO-PROBIOTIC CAPSULES**

- If you are allergic or hypersensitive to any of the ingredients listed in section 6.
- If you have an immune compromised condition such as AIDS, lymphoma, or you are undergoing long term corticosteroid treatment.

## **Warnings and precautions**

Take special care with THE REAL THING PRO-PROBIOTIC CAPSULES:

- If your symptoms worsen.
- If you have a fever.
- If you are vomiting.
- If you have bloody diarrhoea.
- If you have severe abdominal pain (stomach pain).
- If you have symptoms of digestive upset, such as diarrhoea, if it worsens and/or persists for longer than 3 days, stop use and consult your healthcare practitioner.
- If you are elderly, because of occasional reports of sepsis (when your body responds badly to an infection).

## **Children and adolescents**

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 provider.

## **Other medicines and THE REAL THING PRO-PROBIOTIC CAPSULES**

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

Theoretically, antibiotics and antifungals might decrease the effectiveness of probiotics. Therefore, take these medicines at least two hours apart from THE REAL THING PRO-PROBIOTIC CAPSULES.

## **Pregnancy and breastfeeding**

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before using this medicine.

## **Driving and using machines**

THE REAL THING PRO-PROBIOTIC CAPSULES may have a minor influence on these abilities.

It is not always possible to predict to what extent THE REAL THING PRO-PROBIOTIC CAPSULES may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which THE REAL THING PRO-PROBIOTIC CAPSULES affects them.

## **3. How to take THE REAL THING PRO-PROBIOTIC CAPSULES**

Do not share medicines prescribed for you with any other person.

Always take THE REAL THING PRO-PROBIOTIC CAPSULES exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose for adults 18 years and older is:

- Take one capsule orally once a day with a glass of water.
- Take at least 2 to 3 hours before or after antibiotic and antifungal medications so as not to decrease the effectiveness of the probiotics.
- For continued effect take probiotics regularly.
- Probiotics are generally taken for one month.
- Consult your healthcare practitioner if you wish to take probiotics for longer than one month.

**If you take more THE REAL THING PRO-PROBIOTIC CAPSULES than you should**

More severe side effects may occur if you have taken too much THE REAL THING PRO-PROBIOTIC CAPSULES. Stop taking the supplement. If you are not feeling well, stop taking the supplement and consult your doctor. Treat the symptoms that may occur.

In the event of overdose, consult your doctor or pharmacist. If neither is available, seek help at your nearest hospital or poison centre. Take this leaflet and the product container with you for identification.

**If you forget to take THE REAL THING PRO-PROBIOTIC CAPSULES**

Do not take a double dose to make up for forgotten individual doses. If you forget to take it for a day or two, just start again at the regular daily dose.

**If you stop taking THE REAL THING PRO-PROBIOTIC CAPSULES**

You may not achieve optimal benefit if you do not take it regularly.

**4. Possible side effects**

THE REAL THING PRO-PROBIOTIC CAPSULES can have side effects.

Not all side effects reported for it are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking THE REAL THING PRO-PROBIOTIC CAPSULES, please consult your healthcare provider for advice.

If any of the following happens, stop taking THE REAL THING PRO-PROBIOTIC CAPSULES and tell your doctor immediately or go to the casualty department at your nearest hospital. Take this information leaflet with you.

- Infection (less frequent)
- Bacteraemia (bacteria in the blood) (less frequent)
- Sepsis (infection in the body) (less frequent)
- Splenic abscess (fever and upper body sensitivity due to bacteraemia) (less frequent)
- Endocarditis (infection of inner lining of the heart) (less frequent)
- Necrotizing fasciitis (bacterial infection that destroys tissue under the skin) (less frequent)
- Pancreatic necrosis (part of the pancreas dies) (less frequent)
- Meningoencephalitis (very serious neurological condition resembling both meningitis and encephalitis) (less frequent)
- Fungaemia (fungi or yeast in the blood) (less frequent)
- Rash (less frequent)
- Itching of the skin (less frequent)

These are all very serious side effects. If you have them, you may have had a serious reaction to THE REAL THING PRO-PROBIOTIC CAPSULES. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Less frequent side effects:

- Diarrhoea
- Loose stool
- Dyspepsia (indigestion)
- Abdominal (stomach) pain
- Cramping in the stomach
- Epigastric discomfort (discomfort below the ribs)
- Nausea
- Vomiting
- Bloating (belly feels tight and full, usually due to gas)
- Belching (burping)

- Flatulence (gas)
- Stomach rumbling

Frequencies not known:

- Decreased appetite (not feeling hungry)
- Taste disturbance (altered sense of taste)

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

### 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 THE REAL THING PRO-PROBIOTIC CAPSULES.

Alternatively, side effects may be reported directly to The Real Thing Food Supplements (Pty) Ltd at telephone (021) 701-0244 or email [adr@therealthing.co.za](mailto:adr@therealthing.co.za).

### 5. How to store THE REAL THING PRO-PROBIOTIC CAPSULES

Store all medicines out of reach of children.

- Store in the fridge at 2 to 8 °C.
- Store in a well closed container.
- Do not use after the expiry date as stated on the label or container.

Do not use THE REAL THING PRO-PROBIOTIC CAPSULES if you notice the capsules appear slimy or have discoloured from date of opening.

Return any unused or expired medicine to your pharmacist for proper disposal. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

### 6. Contents of the pack and other information

#### What THE REAL THING PRO-PROBIOTIC CAPSULES contains

- The active substances are:

	<b>Per capsule</b>
<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 other ingredients are inulin, dicalcium phosphate, magnesium stearate (vegetable origin) and a vegetable (hypromellose) capsule shell.

#### What THE REAL THING PRO-PROBIOTIC CAPSULES looks like and contents of the pack

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

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.

**Holder of Certificate of Registration**

THE REAL THING FOOD SUPPLEMENTS (PTY) LTD

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**Registration number**

(To be allocated)

**Access to the corresponding Professional Information**

The Professional Information is located at <https://www.therealthing.co.za/index.php/the-range/immune-boosters/13-the-real-thing/the-range/52-pro-probiotic-capsules>

Or obtain the Professional Information directly from THE REAL THING FOOD SUPPLEMENTS (PTY) LTD using the contact details listed under Holder of Certificate of Registration.

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