



Read all of this leaflet carefully before you start using TRUBIOTIC, because it contains important information for you.

This product is available without a doctor's prescription. Nevertheless you still need to use TRUBIOTIC carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- You must see a doctor if you experience any unfamiliar symptoms, or if symptoms worsen or do not improve.
- Do not share TRUBIOTIC with any other person.
- This supplement has not been evaluated by the Medicines Control Council. This supplement is not intended to diagnose, treat, cure or prevent any disease.

#### **SCHEDULING STATUS:**

Not scheduled.

#### **PROPRIETARY NAME (AND DOSAGE FORM):**

TRUBIOTIC (Enteric coated vegetable capsules).

#### **WHAT TRUBIOTIC CONTAINS:**

Each TRUBIOTIC capsule contains:

A minimum of  $1 \times 10^8$  viable CFU in total of *Bifidobacterium longum* BB536, *Lactobacillus acidophilus* LA-14 and *Lactobacillus rhamnosus* PB01 at the end of shelf life (24 months\*).

CFU (Colony Forming Units)

\* Meet the 24 months end-of-shelf-life specification, provided that the product is stored at maximum 25°C.

Other inactive ingredients include alginate acid, hypromellose, locust bean gum, magnesium stearate, maize starch, maize starch pregelatinised, oligofructose (FOS), olive oil, shellac, titanium dioxide, triethyl citrate.

TRUBIOTIC contains an enteric coating (ProTarget®) which protects the live microorganisms from gastric acids and increases the intestinal delivery of viable live microorganisms.

TRUBIOTIC contains oligofructose as a prebiotic. Oligofructose, a fructo-oligosaccharide (FOS), is a dietary fibre.

#### **WHAT TRUBIOTIC IS USED FOR:**

TRUBIOTIC is a supplement used to assist in the protection and maintenance of intestinal flora in adults and children over the age of 12 years.

*Lactobacilli*, including *Lactobacillus acidophilus* and *Lactobacillus rhamnosus*, and *Bifidobacteria*, including *Bifidobacterium longum*, are live microorganisms and considered "friendly" bacteria, that are used for the purpose of re-colonising areas of the body where they would normally occur.

Antibiotics, not only destroy disease-causing bacteria, but also eliminate the "friendly" bacteria in our normal intestinal flora. This causes a disturbance in the normal flora, and an increased risk of disease-causing bacteria to colonise causing symptoms such as diarrhoea and cramping.

#### **BEFORE YOU TAKE TRUBIOTIC:**

Do NOT take TRUBIOTIC:

- If you are allergic (hypersensitive) to any of the active or inactive ingredients in the formulation.

- If you are pregnant or breastfeeding your baby (see "Pregnancy and breastfeeding").

#### **Take special care with TRUBIOTIC:**

- If you are immuno-compromised or elderly. The live microorganisms included in TRUBIOTIC may increase the risk of infection. It should be noted that this rarely occurs in healthy individuals and is more likely in severely immuno-compromised individuals.
- If you have short bowel syndrome, as this may increase the risk of an infection from *Lactobacilli*. TRUBIOTIC should be used with caution in this condition.
- TRUBIOTIC contains olive oil, which may have a laxative effect (see "Important information about some of the ingredients of TRUBIOTIC").

Consult your doctor prior to using TRUBIOTIC if any of the above precautions are applicable to you.

TRUBIOTIC should not be used to replace any medicines prescribed by your doctor.

Consult your doctor if you are taking prescription medicines (see "Taking TRUBIOTIC with other medicines").

DO NOT TAKE any other nutritional or herbal supplements without first discussing their combined use with TRUBIOTIC with your doctor or pharmacist (see "Taking TRUBIOTIC with other medicines").

Ensure that you stay within the recommended dosage guidelines.

#### **Use in children:**

TRUBIOTIC should not be taken by or given to children under the age of 12 years, unless under supervision of your doctor.

#### **Taking TRUBIOTIC with food and drink:**

TRUBIOTIC can be taken with or without food. TRUBIOTIC should be taken 2 – 3 hours before or after antibiotic intake (see "Taking TRUBIOTIC with other medicines").

#### **Pregnancy and breastfeeding:**

Do NOT take TRUBIOTIC while you are pregnant or breastfeeding your baby (see "Do NOT take TRUBIOTIC").

The safety of live microorganism use, during pregnancy and breastfeeding, has not been established.

If you are pregnant or breastfeeding your baby while taking TRUBIOTIC, please consult your doctor or pharmacist or other healthcare professional for advice. Avoid the use of TRUBIOTIC during pregnancy and breastfeeding.

#### **Driving or using machinery:**

It is unlikely that TRUBIOTIC will affect your ability to drive or operate machinery.

#### **Important information about some of the ingredients of TRUBIOTIC:**

- Oligofructose, an inactive ingredient, is a dietary fibre and may cause gastrointestinal side-effects (see "POSSIBLE SIDE-EFFECTS").
- Olive oil, an inactive ingredient, may have a laxative effect and cause diarrhoea.

## Taking TRUBIOTIC with other medicines:

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of TRUBIOTIC with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.

Please discuss the use of the following medicines or substances in combination with TRUBIOTIC with your doctor or pharmacist:

- Antibiotics, due to the possibility that concurrent administration of an antibiotic may decrease the effectiveness of *Lactobacilli* and *Bifidobacteria*, by reducing a significant number of the live microorganisms. Antibiotics and TRUBIOTIC must be taken at least 2 - 3 hours apart.
- Immunosuppressant medication, because *Lactobacilli* may cause an infection in patients taking medication that suppresses the immune system. These include azathioprine, cyclosporine, tacrolimus, and cancer chemotherapeutic agents like cyclophosphamide and cisplatin.

## HOW TO TAKE TRUBIOTIC:

### During antibiotic treatment:

Take two capsules daily (1 in the morning and 1 in the evening) during antibiotic treatment, followed by one capsule a day for one week after completion of the antibiotic course.

Capsules should be taken 2 - 3 hours before or after antibiotic intake.

### Daily supplement:

Take one capsule daily, as a daily supplement to protect and maintain intestinal flora, or as prescribed by a healthcare professional.

## DO NOT EXCEED THE RECOMMENDED DAILY DOSAGE.

If you have the impression that the effect of TRUBIOTIC is too strong or too weak, please speak to your doctor or pharmacist.

### If you take more TRUBIOTIC than you should:

If you take more TRUBIOTIC than you should, you may experience an increase in the side-effects listed below (see "POSSIBLE SIDE-EFFECTS").

In the event of overdosage, consult your doctor or pharmacist. If neither is available, immediately seek help at the nearest hospital or poison control centre.

### If you forget to take TRUBIOTIC:

Always take TRUBIOTIC as prescribed. If you miss a dose, take it as soon as you remember. If you do not remember the missed dose until the next dose is due, skip the missed dose and go back to your regular dosing schedule. Do not take a double dose to make up for forgotten individual doses.

## POSSIBLE SIDE-EFFECTS:

TRUBIOTIC may have side-effects.

Not all side-effects reported for TRUBIOTIC are included in this leaflet. Should your general health worsen while taking TRUBIOTIC, please consult your doctor, pharmacist or other healthcare professional for advice.

Consult your doctor, pharmacist or healthcare professional if you experience any of the following signs and symptoms:

- Flatulence is a common side-effect associated with the use of *Lactobacilli*, *Bifidobacteria* and oligofructose. However, it is usually mild and subsides

with continued use.

- Bloating may occur due to *Bifidobacteria* and oligofructose; however, it is usually mild and subsides with continued use.
- Infections, including *Lactobacillus bacteraemia* (presence of bacteria in the bloodstream), have been reported in severely ill and/or immuno-compromised patients, following the use of *Lactobacilli* containing preparations. This side-effect is however rare.
- Olive oil can have a laxative effect and may cause diarrhoea.
- Metabolic acidosis (high levels of acid in the blood) due to the live microorganism, *Lactobacillus acidophilus*. This condition includes symptoms such as rapid breathing, confusion and lethargy.
- TRUBIOTIC contains oligofructose, a dietary fibre, which may cause flatulence, belching, abdominal pain, intestinal sounds and bloating.

Please report/inform your doctor or pharmacist if you notice any side-effects not mentioned in this leaflet.

## STORAGE AND DISPOSING OF TRUBIOTIC:

Store at or below 25°C in a dry place.

Protect from heat and light.

No need to refrigerate.

Keep the blisters in the outer carton until required for use.

Do not take the capsules after the expiry date stated on the package.

Return all unused capsules to your pharmacist.

Do not dispose of unused capsules in drains or sewerage systems (e.g. toilets).

**KEEP OUT OF REACH AND SIGHT OF CHILDREN.**

## PRESENTATION OF TRUBIOTIC:

Blister packs of 10 capsules each packed in an outer carton in pack sizes of 10's and 30's.

## IDENTIFICATION OF TRUBIOTIC:

White, enteric coated, vegetable capsule containing a fine white powder.

## NAME AND BUSINESS ADDRESS OF THE APPLICANT:

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