

BifidoBiotic™

Multi-species probiotic formulation

Consumer Medicine Information

1. What is in the leaflet?

This leaflet answers some of the more common questions about BifidoBiotic™ capsules.

It does not contain all the available information. It does not take the place of talking to your healthcare professional.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking BifidoBiotic™ capsules against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your healthcare professional.

Keep this leaflet with the medicine.

You may need to read it again.

2. What BifidoBiotic™ is used for

A scientifically formulated combination of Bifidobacteria species supporting the health and function of the gastrointestinal tract, and to regulate healthy immune function. *Bifidobacterium longum*, *Bifidobacterium bifidum*, and *Bifidobacterium lactis* influence beneficial host gene expression of immune cells in the intestinal mucosa. These bacterial species have been documented to decrease in number with increasing age of the host, contributing to a decline in immune system efficacy associated with ageing. The probiotic *Bifidobacterium infantis* has been demonstrated in clinical trials to normalize intestinal permeability, improve gastrointestinal conditions and improve the symptoms of irritable bowel syndrome (IBS).

BifidoBiotic™ contains 50 billion Colony Forming Units (CFU) of bacteria per dose, including *Bifidobacterium longum subsp. infantis*, *Bifidobacterium longum*, and *Bifidobacterium bifidum*. These *Bifidobacterium* species are naturally found in the gastrointestinal tract.

Your healthcare professional may have prescribed BifidoBiotic™ for another reason.

Ask your healthcare professional if you have any questions concerning why BifidoBiotic™ is as been prescribed for you.

BifidoBiotic™ is not addictive.

3. Before you take BifidoBiotic™

If symptoms persist consult your healthcare professional.

Do not take BifidoBiotic™ if:

1. You have had an allergic reaction to BifidoBiotic™, or any ingredient in BifidoBiotic™ (listed in section 8).
2. The safety seal is broken, missing or shows signs of tampering.
3. The expiry date (EXP) printed on the pack has passed.

If you take this medicine after the expiry date has passed, it may not work as well.

If you are not sure you should start taking BifidoBiotic™ contact your health professional.

Before you take BifidoBiotic™, tell your doctor if:

1. You have any allergies to any other medicines, foods, preservatives, dyes or additives.

If you experience any allergic reaction or other side effects after consuming BifidoBiotic™ you should discontinue use and consult with your healthcare professional.

2. You are pregnant or planning to become pregnant .

3. You are breastfeeding or planning to breastfeed.

4. You have or have had any other health problems or issues including:

- Stomach or bowel disease
- Compromised immune system (HIV/ AIDS and cancer treatment patients)
- Short bowel syndrome

5. You drink large amounts of alcohol.

6. You are taking other medicines.

Tell your healthcare professional if you are taking any other medicines, including any that you get without a prescription, from a pharmacy, supermarket or health food store.

Some medicines may interfere with BifidoBiotic™. These include:

- Immunosuppressant Drugs
- Antibiotics

These medicines may be affected by BifidoBiotic™, or may affect how well it works. You may need to take different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

Your healthcare professional has more information on medicines to be careful with or avoid while taking BifidoBiotic™.

Ask your healthcare professional if you are not sure about this list of medicines.

If you have not told your healthcare professional about any of the above, tell them before you start taking BifidoBiotic™

4. How to take BifidoBiotic™

1. Follow all directions given to you by your healthcare professional carefully.

2. Take BifidoBiotic™ exactly as your healthcare professional has prescribed.

This may differ from the information contained in this leaflet.

3. How much BifidoBiotic™ should be taken?

Adults: two (2) capsules daily, Capsules not to be given to children under 4 years of age, to be administered as directed by your healthcare professional. Take BifidoBiotic™ at least 2 hours apart from prescription drugs.

Your healthcare professional will tell you how many BifidoBiotic™ capsules to take each day. This depends on the condition being treated and whether any other medicines are being used.

4. How to take BifidoBiotic™

Capsules should be swallowed whole.

Capsules can also be broken open and put on cold foods. Consult with your healthcare professional if you are unsure.

Do not take any capsules that are damaged.

3. When to take BifidoBiotic™

Take BifidoBiotic™ at least 2 hours apart from prescription/herbal drugs.

4. How long to take BifidoBiotic™

Take BifidoBiotic™ as long as your healthcare professional recommends.

5. If you forget to take BifidoBiotic™

Do not try to make up for missed doses by taking an extra dose. This may increase the chance of experiencing an unwanted side effect.

If it is almost time for your next dose, skip the dose you missed and take the next dose when you are supposed to.

If you are unsure of what to do, check with your healthcare professional.

6. If you have taken too much BifidoBiotic™(overdose)

Please visit your healthcare professional if there are signs of discomfort. Tell them how much BifidoBiotic™ you took and they will determine what action is best for your health.

5. While you are taking BifidoBiotic™

Things you **MUST** do:

1. If you become pregnant while taking BifidoBiotic™, tell your healthcare professional immediately.
2. If you are about to start taking a new medicine, tell your healthcare professional that you are taking BifidoBiotic™.
3. If you are planning to have surgery, including dental surgery, tell your healthcare professional that you are taking BifidoBiotic™.
4. Always follow your healthcare professional's instructions carefully.

Things you **MUST NOT** do:

1. Do not heat BifidoBiotic™ or add into hot foods.

2. Do not expose BifidoBiotic™ to extreme heat conditions for extended periods of time.

3. Do not reconstitute or mix contents of capsules with other medicines, herbal mixtures, or fermented products.

Things to be careful of:

As BifidoBiotic™ contains probiotic strains, taking antibiotics along with probiotics can reduce the effectiveness.

To avoid this interaction, take BifidoBiotic™ at least 2 hours before or after antibiotics.

You should discuss this with your healthcare professional.

6. Side Effects

BifidoBiotic™ has low risk of side effects when taken as directed.

Ask your healthcare professional to answer any questions you may have.

Tell your healthcare professional if you notice any of the following and they worry you:

- Cramps or pain in the stomach area
- Constipation
- Diarrhoea
- Mucus in the stool
- Swollen or bloated stomach area
- Gas
- Discomfort in the upper stomach area

These side effects are usually mild and dose related. Most of them disappear completely in a few days to a few weeks after the dose of BifidoBiotic™ is lowered or stopped.

Tell your healthcare professional immediately if you experience any of the following:

- loss of appetite
- itching
- shortness of breath
- nausea and vomiting

Tell your doctor if you notice anything else that is making you feel unwell.

7. After taking BifidoBiotic™

Storage

Keep BifidoBiotic™ in its bottle until it is time to take it. If you take the capsules out of the bottle they may not keep well.

Store BifidoBiotic™ at 2°C - 8°C. Refrigerate, do not freeze.

Do not store BifidoBiotic™, or any other medicine, in a bathroom or near a sink. Do not leave it in the car or on a window sill.

Heat and dampness can destroy the medicine.

Protect BifidoBiotic™ from light.

Keep out of the reach of children

8. Product description

What BifidoBiotic™ looks like:

BifidoBiotic™ is a hard clear capsule. BifidoBiotic™ is packed in a recyclable bottle

with a safety seal over the cap. BifidoBiotic™ is available in bottles containing 60 capsules.

Ingredients:

Active Ingredients:

Bifidobacterium longum subsp. infantis
..... 30 billion CFU*
Bifidobacterium longum..... 10 billion CFU*
Bifidobacterium bifidum..... 10 billion CFU*

***CFU: Colony Forming Unit**

Excipient Ingredients:

Cellulose
Silica
Magnesium stearate

The capsule shell contains

Vegetable Hydroxypropyl Methylcellulose

BifidoBiotic™ is suitable for vegetarians

BifidoBiotic™ is dairy and gluten free

9. Translation

Not available

10. Manufacturer

BifidoBiotic™ is supplied in Australia by:
Medlab Clinical Limited™
66 McCauley Street
Alexandria NSW 2015
Toll free: 1300 369 570

Australian Listing Number
AUST L 286501

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Medlab Clinical Limited™