

Consumer Medicine Information

1. What is in the leaflet?

This leaflet answers some common questions about EnBiotic™ capsules.

It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

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

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

2. What EnBiotic™ is used for

EnBiotic™ is a digestive enzyme and multi-strain probiotic formulation.

EnBiotic™ is used to assist with digestion of dietary proteins, carbohydrates and fats. It supports and assists with a healthy gastrointestinal microbial profile and helps maintain healthy skin.

EnBiotic™ contains 241.6mg of plant and fungal-derived digestive enzymes and 8.75 billion CFU (colony forming units) of bacteria per capsule. This combination may support digestive function of dietary proteins, carbohydrates and fats and assist in the management of indigestion, and relieves gastrointestinal discomfort. EnBiotic™ may also assist in managing the symptoms of Irritable Bowel Syndrome.

There are many different types of medicines used to improve the digestion of dietary proteins, carbohydrates and fats.

Your healthcare professional or pharmacist may have prescribed EnBiotic™ for another reason.

Ask your healthcare professional or pharmacist if you have any questions concerning why EnBiotic™ as been prescribed for you.

EnBiotic™ is not addictive.

3. Before you take EnBiotic™

3a) When you MUST NOT take it

Do not take EnBiotic™ if:

- You have had an allergic reaction to EnBiotic™ or any ingredient listed in section 8b.**
- The packaging is torn, missing or shows signs of tampering**
- The expiry date (EXP) printed on the pack has passed.** If it has expired or is damaged, return it to your pharmacist for disposal.
If you take this medicine after the expiry date has passed, it may not work as well.

If you are not sure if you should start taking EnBiotic™ contact your healthcare professional or pharmacist.

Do not give EnBiotic™ to children.

There is limited information on the use of EnBiotic™ in children.

3b) Before you start to take it

You must tell your doctor if:

- You have any allergies to any other medicines, foods, preservatives, dyes**

or additives.

EnBiotic™ capsules contain magnesium stearate, maltodextrin, silica and soy protein hydrolysate trace,

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

- You are pregnant or planning to become pregnant**
- You are breastfeeding or planning to breastfeed**
- You have or have had any other health problems or issues including:**
 - Stomach or bowel disease
 - Compromised immune system (HIV/AIDS or during treatment of cancer)
 - Short bowel syndrome

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

3c) Taking other medicines

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

Tell your healthcare professional or pharmacist if you are taking any of the following:

- Immunosuppressant Drugs
- Antibiotics
- Acarbose
- Miglitol / Amylase
- Pancreatin
- Creon and Creon Forte

Some medicines may be affected by EnBiotic™ 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 or pharmacist has more information on medicines to be careful with or avoid while taking EnBiotic™

Ask your healthcare professional or pharmacist if you are not sure about the above list of medicines.

4. How to take EnBiotic™

4a) How much to take

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

Take EnBiotic™ exactly as your healthcare professional or pharmacist has prescribed.

They may differ from the information contained in this leaflet.

4b) How much EnBiotic™ should be taken?

For adults, take two capsules with water daily before meals, up to two times per day.

Your healthcare professional or pharmacist will tell you how many EnBiotic™ capsules to take each day. This depends on the

condition being treated and whether any other medicines are being used.

4c) How to take EnBiotic™

Capsules should be swallowed whole with water daily before meals.

Capsules can be broken open and put on cold foods. Consult with your healthcare practitioner or pharmacist if you are unsure.

Do not take any capsules that are damaged.

4d) When to take EnBiotic™

Before meals, unless otherwise advised by your healthcare practitioner.

4e) How long to take EnBiotic™

Take EnBiotic™ as long as your healthcare practitioner prescribes.

4f) If you forget to take EnBiotic™

Do not try to make up for missed doses by taking an extra dose.

This may increase the chance of getting 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 meant to.

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

4g) If you have taken too much EnBiotic™ (overdose)

Visit your healthcare professional or pharmacist as soon as possible. Tell them how much EnBiotic™ you took and he/she can determine what action is best for your health. Please visit your healthcare professional or pharmacist even if there are no signs of discomfort or poisoning.

5. While you are taking EnBiotic™

5a) Things you MUST do:

If you become pregnant while taking, EnBiotic™ tell your healthcare professional or pharmacist immediately.

If you are about to start taking a new medicine, tell your healthcare professional or pharmacist that you are taking EnBiotic™.

If you are planning to have surgery, including dental surgery, tell your healthcare professional or pharmacist that you are taking EnBiotic™.

Always follow your healthcare professional or pharmacist's instructions carefully.

5b) Things you MUST NOT do

Do not heat EnBiotic™ or add into hot foods.

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

5c) Things to be careful of

As EnBiotic™ contains probiotic strains, taking antibiotics along with probiotics can reduce the effectiveness. To avoid this interaction take EnBiotic™ at least 2 hours before or after antibiotics.

You should discuss this with your healthcare professional.

6. Side Effects

All medicines can have side effects. Sometimes they are serious, most of the time they are not.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

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

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

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

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

Serious allergic reactions to these ingredients are rare; however tell your healthcare professional or pharmacist immediately if you experience any of the following:

- Skin rash
- Swelling of the face and/or mouth
- Difficulty breathing
- Itching of the skin

7. After taking EnBiotic™

7a) Storage

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

Always store EnBiotic™ only in its original container.

Keep EnBiotic™ refrigerated. Do not freeze.

Do not store EnBiotic™, or any other medicine, in a bathroom or near a sink.

Do not leave it in the car or on windowsills.

Heat and dampness can destroy the medicine.

A locked cupboard at least one-and-a-half meters above the ground is a good place to store medicines,

Protect EnBiotic™ from light.

8. Product description

8a) What EnBiotic™ looks like

EnBiotic™ is a hard clear capsule.

EnBiotic™ is packed in a recyclable plastic bottle with a tamper evident seal. Each bottle contains 60 capsules.

8b) Ingredients

Active Ingredients

Bacterial Strains

- *Lactobacillus acidophilus* 5 billion
- *Lactobacillus rhamnosus* 2.5 billion
- *Bifidobacterium bifidum* 125 million
- *Bifidobacterium animalis ssp. lactis* 1.125 billion

Digestive Enzymes

- Amylase (from *Aspergillus oryzae*) 165mg (750 DU)
- Protease – acid / alkaline active (from *Aspergillus oryzae*) 11mg (3790 HUT)

- Lipase (from *Rhizopus oryzae*) 16.5mg (525 LipU)
- Bromelain (from *Ananas comosus*) 9.9mg
- Papain (from *Carica papaya*) 39.2mg

Inactive Ingredients

- Potato Maltodextrin
- Soy Protein
- Hydrolysate Trace
- Magnesium Stearate
- Silica

The capsule shell contains

Vegetable Hydroxypropyl Methycellulose

EnBiotic™ is suitable for vegetarians

EnBiotic™ is gluten and dairy free

EnBiotic™ Patent (number)

9. Translation

To read this information in other languages go to www.medlab.co/translate

10. Manufacturer

EnBiotic™ is supplied in Australia by:

A division of Medlab Clinical Limited™

66 McCauley Street
Alexandria NSW 2015
Toll free: 1300 369 570

EnBiotic™ is supplied in Northern America by:

A division of InMed Technologies™
Suite 400, 29883 Santa Margarita Pkwy
Rancho Santa Margarita CA 92688
Toll free 1800 921 1710

Australian Listing Number
AUST L 227586

This Leaflet was prepared in September 2014

Last Updated May 2015

Medlab Clinical Limited™