Consumer Medicine Information

1. What is in the leaflet?

This leaflet answers some common questions about SB 5BTM capsules.

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

All medicines have risks and benefits. Your doctor has weighed the risks of you taking SB 5BTM capsules against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine.

You may need to read it again.

2. What SB 5B™ is used for

Saccharomyces boulardii is an evidenced-based beneficial probiotic yeast. It demonstrates efficacy in relieving diarrhoea due to numerous causes and managing symptoms associated with medically diagnosed Irritable Bowel Syndrome such as abdominal pain and bloating, flatulence and altered bowel habits. S. boulardii supports healthy immune function, encourages healthy gastrointestinal function and integrity and supports optimal beneficial microbial growth.

There are many different types of medicines used to improve gastrointestinal symptoms.

Your healthcare professional or pharmacist may have prescribed SB $5B^{\text{TM}}$ for another reason.

Ask your healthcare professional or pharmacist if you have any questions concerning why SB 5BTM has been prescribed for you.

SB 5BTM is not addictive.

3. Before you take SB 5B™

3a) When you must not take it

Do not take SB 5BTM if:

- You have had an allergic reaction to SB 5BTM, or any ingredient listed in section 8b.
- 2. The packaging is torn 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 if you should start taking SB 5BTM contact your healthcare professional or pharmacist.

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.
 SB 5BTM contains Cellulose,
 Silica, and Magnesium Stearate.
 If you experience any allergic reaction or other side effects after consuming SB 5BTM you should discontinue use and consult with

- your healthcare professional or pharmacist.
- 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 or during cancer treatment)
- Fungal infections

If you have not told your healthcare professional or pharmacist about any of the above, tell them before you start taking SB 5BTM.

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 either of the following:

- Immunosuppressant Drugs
- Antibiotics
- Anti-fungals

Some medicines may be affected by SB 5BTM, 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 SB $5B^{TM}$.

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

4. How to take SB 5B™

4a) How much to take

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

Take SB 5B[™] exactly as your healthcare professional or pharmacist has prescribed.

They may differ from the information contained in this leaflet.

4b) How much SB 5B™ should be taken?

Take one (1) capsule, one (1) to two (2) times daily, or as directed by your healthcare professional.

Your healthcare professional or pharmacist will tell you how many SB 5B™ capsules to take each day. This depends on the condition being treated and whether any other medicines are being used.

4c) How to take SB 5B™

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 SB 5B™

Before meals, unless otherwise advised by your healthcare practitioner.

4e) How long to take SB 5B™

Take SB 5B[™] as long as your healthcare practitioner or pharmacist prescribes.

4f) If you forget to take SB 5B™

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 SB 5B™ (overdose)

Visit your healthcare professional or pharmacist as soon as possible. Tell them how much SB 5BTM 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 SB 5B™

5a) Things you MUST do:

If you become pregnant while taking, SB 5B[™] 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 $SB\ 5B^{TM}$.

If you are planning to have surgery, including dental surgery, tell your healthcare professional or pharmacist that you are taking SB 5BTM.

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

5b) Things you MUST NOT do

Do not heat SB $5B^{\text{TM}}$ or add into hot foods.

Do not expose SB 5BTM to extreme heat conditions for extended periods of time.

5c) Things to be careful of

As SB 5BTM contains a probiotic yeast, taking anti-fungals along with this probiotic can reduce the effectiveness.

To avoid this interaction take SB 5BTM at least 2 hours before or after an anti-fungal medication.

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
- Swollen or bloated 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 SB 5BTM 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 throat
- Difficulty breathing
- Itching of the skin

Seek medical advice is diarrhoea persists for more than; 6 hours in infants under 6 months, 12 hours in children under 3 years; 24 hours in children aged 3-6 years and 48 hours in children over 6 years and adults.

Calcium hydrogen phosphate Magnesium Stearate

SB $5B^{TM}$ is suitable for vegetarians.

SB $5B^{TM}$ is dairy and gluten free.

7. After taking SB 5B™

7a) Storage

Keep SB 5BTM 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 SB 5B[™] only in its original container.

Keep SB 5BTM refrigerated. Do not freeze

Do not store SB 5BTM 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.

Protect SB 5BTM from light.

8. Product description

8a) What SB 5B™ looks like

SB 5BTM is a granulated brown powder in a hard clear capsule. SB 5BTM is packed in a recyclable plastic bottle with a safety seal over the cap. SB 5BTM is available in bottles containing 60 capsules.

8b) Ingredients

Active ingredients

Saccharomyces cerevisiae ssp. boulardii 250 mg Equiv. 5 billion CFU

Inactive ingredients

Cellulose Silica

9. Translation

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

10. Manufacturer

SB 5BTM is supplied in Australia by:

A division of Medlab Clinical LimitedTM 66 McCauley Street Alexandria NSW 2015 Toll free: 1300 369 570

SB 5B[™] 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 268232

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Medlab Clinical LimitedTM