

## PATIENT INFORMATION LEAFLET

### TUMMY BIOTIC GUMMIES®

**SCHEDULING STATUS:** **S0**

#### TUMMY BIOTIC GUMMIES®, 3 g, Gummies

*Bacillus coagulans*, 2 Billion CFU's (colony-forming units)

Contains sugar: sucrose 1.2 g per gummy and glucose syrup 1.46 g per gummy

#### D 34.9 Probiotics Complementary Medicine: Health Supplement

This unregistered medicine has not been evaluated by the South African Health Products Regulatory Authority (SAHPRA) for its quality, safety, or intended use.

Read this entire leaflet carefully because it contains important information for you. TUMMY BIOTIC GUMMIES is available without a doctor's prescription to treat a mild childhood illness or to maintain your child's health. Nevertheless, your child still needs to use TUMMY BIOTIC GUMMIES carefully to get the best results from it.

- Keep this leaflet; you may need to read it again.
- Do not share your child's TUMMY BIOTIC GUMMIES with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.
- Your child must see a doctor if his/her symptoms worsen or do not improve after 7 days.

#### What is in this leaflet

1. What TUMMY BIOTIC GUMMIES are and what it is used for
2. What you need to know before you give TUMMY BIOTIC GUMMIES to your child
3. How to give TUMMY BIOTIC GUMMIES to your child
4. Possible side effects
5. How to store TUMMY BIOTIC GUMMIES
6. Contents of the pack and other information

#### 1. What TUMMY BIOTIC GUMMIES are and what it is used for

TUMMY BIOTIC GUMMIES is a health supplement. It is a probiotic supplement that contains *Bacillus coagulans*. It offers the following health benefits for adults and children:

- Probiotics improve the functioning of the digestive tract/gut when ingested regularly, as probiotics should improve, normalise, or replenish/recolonise the microbial balance in the human intestines.
- In the gastrointestinal tract, probiotics help metabolise food and maintain intestinal health. A varied diet is the most effective and safe way to achieve good nutrition and health.

#### 2. What you need to know before you give TUMMY BIOTIC GUMMIES to your child

##### Do NOT give TUMMY BIOTIC GUMMIES:

- If you are hypersensitive (allergic) to any of the ingredients of TUMMY BIOTIC GUMMIES or any of the other components of the formulation (see **What TUMMY BIOTIC GUMMIES contains**).

##### Warnings and precautions

Take special care with TUMMY BIOTIC GUMMIES:

- Use this product in conjunction with food as part of a healthy, balanced diet, not as a substitute for such.
- 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.

##### Other medicines and TUMMY BIOTIC GUMMIES

Always tell your healthcare 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 1 hour apart from TUMMY BIOTIC GUMMIES.

##### TUMMY BIOTIC GUMMIES with food

TUMMY BIOTIC GUMMIES can be taken with or without food, but preferably in the morning, with breakfast (see **How to give TUMMY BIOTIC GUMMIES to your child**).

##### Pregnancy and breastfeeding

TUMMY BIOTIC GUMMIES are indicated for use in adults and children 2 years and older. 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 healthcare provider for advice before using this medicine.

##### Tasks requiring alertness and concentration

No specific studies have been conducted. Given its side-effect profile, it is unlikely that TUMMY BIOTIC GUMMIES will adversely affect the ability to perform tasks requiring alertness and concentration (see **Possible side effects**). Caution is advised before driving a vehicle or operating machinery until the effects of TUMMY BIOTIC GUMMIES are known.

#### 3. How to take TUMMY BIOTIC GUMMIES

Do not share your child's medicines with any other person.

##### Adults and Children 2 years and older

Always take TUMMY BIOTIC GUMMIES exactly as described in this leaflet or as your doctor, pharmacist, or healthcare provider has told you. Check with your doctor, pharmacist, or healthcare provider if you are not sure.

**Daily use:** Chew 1 gummy per day. Gummies can be taken with or without food. You should seek medical advice if your child's symptoms worsen or persist after 7 days.

**Acute use (During antibiotic therapy):** Chew 1 gummy at least 1 hour apart from any prescribed antibiotic. The dosage can be repeated 12 hours later.

##### Children younger than 2 years

TUMMY BIOTIC GUMMIES are not recommended for children under 2 years.

##### If your child takes more TUMMY BIOTIC GUMMIES than he/she should

There is no information about overdose with TUMMY BIOTIC GUMMIES. However, in the event of an overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. Take this leaflet and the rest of the TUMMY BIOTIC GUMMIES with you for identification.

##### If you forget to give TUMMY BIOTIC GUMMIES to your child

If you forget to give TUMMY BIOTIC GUMMIES to your child, give the forgotten dose as soon as you remember. If it is the next day, skip the missed dose and continue with the usual dose of 1 gummy per day. Do NOT give a double dose to make up for forgotten individual doses.

#### 4. Possible side effects

TUMMY BIOTIC GUMMIES can have side effects. Gastrointestinal upset: nausea, abdominal pain, constipation, diarrhoea, vomiting, poor appetite. Not all side effects reported for TUMMY BIOTIC GUMMIES are included in this leaflet. Should your child's general health worsen or if he/she experiences any untoward effects while taking TUMMY BIOTIC GUMMIES, please consult your healthcare provider for advice.

##### Reporting of side effects

If your child gets side effects, talk to your doctor, pharmacist, or nurse. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form" found online under SAHPRA's publications: <http://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of TUMMY BIOTIC GUMMIES. In addition, adverse events can also be reported to Vie & Sante (Pty) Ltd via email at [hello@vieandsante.co.za](mailto:hello@vieandsante.co.za).

#### 5. How to store TUMMY BIOTIC GUMMIES

Store at or below 25 °C in a cool, dry place. Keep the container tightly closed. Do not use it after the expiry date stated on the container. Do not dispose of unused TUMMY BIOTIC GUMMIES in drains or sewerage systems (e.g., toilets). Return all unused medicines to your pharmacist.

**STORE ALL MEDICINES OUT OF REACH OF CHILDREN.**

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

##### What TUMMY BIOTIC GUMMIES contain

Each gummy contains:

- *Bacillus coagulans*: 2 Billion CFU's
- Contains sugar: sucrose 1.2 g per gummy and glucose syrup 1.46 g per gummy

**Other ingredients are:** Citric acid, colourant (Beta-carotene), flavourant (Buchu), Glycerine BP, pectin, and water.

##### What TUMMY BIOTIC GUMMIES look like and contents of the pack

A PET container with a security cap, induction seal, and shrink sleeve that contains orange, dome-shaped gummies with Buchu flavour.

Pack size: 30 gummies

##### Holder of Certificate of Registration

Releaf Pharmaceuticals (Pty) Ltd  
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Dal Josaphat

Paarl

7646

South Africa

**Marketed by:** Vie & Sante

[www.vieandsante.co.za](http://www.vieandsante.co.za)

##### This leaflet was last revised in

First compiled in June 2024.

##### Registration/Application number

To be allocated by the Authority upon registration.

##### Access to the corresponding Professional Information

Please visit <https://www.vieandsante.co.za>.