

**“For the use of a Registered Medical Practitioner or Hospital or a Laboratory only”**

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**VIZYLAC HP**

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**1. Generic Name**

Lactobacillus reuteri Capsules

**2. Qualitative and quantitative composition**

Each serving per HPMC capsule contains:

Lactobacillus reuteri (DSMZ 17648).....100 mg

(Equivalent to NLT 10 billion Lactobacillus reuteri cells)

Ingredients: Bulking agent INS 460(i), Lactobacillus reuteri (DSMZ 17648) (Pylopass), Hydroxypropyl methylcellulose INS 464, Colour (INS 171), Glidant (INS 470(iii)), Binding agent (Carageenan gum), Gelling Agent (INS 508)

Nutritional Information contains (Approx)		
Serving Size: 1 Capsule (0.230 g)		
	Per 100 g	% RDA Per serve*
Energy**	398.95 Kcal	0.046
Protein	0.90 g	0.005
Carbohydrate	91.3 g	#
Total Sugars	0.0 g	#
Added Sugars**	0.0 g	0.0
Total Fat**	3.35 g	0.012
Saturated Fat**	2.61 g	0.027
Trans Fat**	0.0 g	0.0
Cholesterol	0.0 mg	#
Sodium**	0.0 mg	0.0

**3. Dosage form and strength**

**Dosage form:** Oral capsule

**Strength:** 100 mg Lactobacillus reuteri capsule

## **4. Clinical particulars**

### **4.1 Therapeutic indication**

It is indicated as health supplement for H. pylori control and for alteration of intestinal bacterial flora.

### **4.2 Posology and method of administration**

#### **Posology**

As prescribed by physician.

- Not to exceed the recommended daily usage.
- Recommended usage level: One capsule twice a day for gastric health in adults.
- Duration of Use: Daily intake as per recommended usage

#### **Method of administration**

Oral administration, Take Lactobacillus reuteri as advised by your doctor. The capsule should be swallowed as a whole with a glass of water. Do not crush, chew or break it. For children, the contents in capsule can be mixed with food or drink that is at room temperature.

### **4.3 Contraindications**

None known

### **4.4 Special warnings and precautions for use**

- Do not use if hypersensitive to the active ingredient or excipients.
- Product is not to be used as a substitute for a varied diet.
- NOT FOR MEDICINAL USE
- This product is not intended to treat, cure, mitigate or prevent any disease, disorder or condition.
- Physiological condition & Purpose of Product: This product is intended to support health function.
- It's a probiotic food.
- May contain milk, soy and nuts.
- If you are allergic to Lactobacillus reuteri or any other medicines, please tell your doctor.
- Pregnant or lactating women or people with medical conditions should consult a healthcare professional before use.
- Lactobacillus reuteri is not recommended for children unless advised by a doctor. Avoid alcohol consumption with Lactobacillus reuteri as it increases the risk of adverse effects.
- If you have chills, high fever or persistent cough, inform your doctor immediately as these might be signs of infection. You are recommended to complete the full course of treatment as prescribed by your doctor for effective results.

### **4.5 Drugs interactions**

**Drug-Drug Interaction:** Lactobacillus reuteri may interact with antifungals (ketoconazole, clotrimazole, griseofulvin, nystatin).

**Drug- Food Interaction:** Lactobacillus reuteri may interact with alcohol. Therefore, avoid alcohol consumption with Lactobacillus reuteri as it may increase adverse effects.

**Drug-Disease Interaction:** If you have diabetes, a weak immune system, recurring urinary tract or vaginal infections, inform your doctor before taking Lactobacillus reuteri.

#### **4.6 Use in special populations (such as pregnant women, lactating women, paediatric patients, geriatric patients etc.)**

Pregnant or lactating women or people with medical conditions should consult a healthcare professional before use.

#### **4.7 Effects on ability to drive and use machines**

Lactobacillus reuteri usually does not affect your ability to drive or operate machinery.

#### **4.8 Undesirable effects**

An increase in stomach gas or bloating may occur. If this effect lasts or gets worse, notify your doctor or pharmacist promptly.

Tell your doctor right away if you have any serious side effects, including: signs of infection (such as cough that doesn't go away, high fever, chills).

A very serious allergic reaction to this product is rare. However, get medical help right away if you notice any symptoms of a serious allergic reaction, including: rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing.

This is not a complete list of possible side effects. If you notice other effects not listed above, contact your doctor or pharmacist.

##### **Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via any point of contact of Torrent Pharma available at: [http://www.torrentpharma.com/index.php/site/info/adverse\\_event\\_reporting](http://www.torrentpharma.com/index.php/site/info/adverse_event_reporting).

#### **4.9 Overdose**

If someone has overdosed and has serious symptoms such as passing out or trouble breathing, contact physician.

Not to exceed the recommended daily usage.

### **5. Pharmacological properties**

#### **5.1 Mechanism of Action**

L. reuteri is able to recognize surface structures on Helicobacter pylori and to form co aggregates. These co-aggregates are eliminated from the organism through the gastrointestinal tract. This leads to a reduction of Helicobacter pylori load in the stomach.

L. reuteri can reduce the helicobacter pylori load of the stomach thus reducing the risk of developing gastritis and gastric ulcers.

## 5.2 Pharmacodynamic properties

ATC Classification: V01AA08 - food; Belongs to the class of allergen extracts. Used as antigenic substances capable of producing immediate-type hypersensitivity.

*L. reuteri* is obtained through fermentation of a unique and patented probiotic strain of *Lactobacillus reuteri* DSM 17648 (registered at the German collection of microorganism [www.dsmz.de](http://www.dsmz.de)).

*L. reuteri* is comprised of stabilized bacteria and is therefore stable at room temperature.

## 5.3 Pharmacokinetic properties

Not available

## 6. Nonclinical properties

### 6.1 Animal Toxicology or Pharmacology

Not available

## 7. Description

*Lactobacillus reuteri* Capsules are “2” size white/white HPMC capsules filled with white to off white blend. The ingredients used are Bulking agent INS 460(i), *Lactobacillus reuteri* (DSMZ 17648) (Pylopass), Hydroxypropyl methylcellulose INS 464, Colour (INS 171), Glidant (INS 470(iii)), Binding agent (Carageenan gum), Gelling Agent (INS 508).

## 8. Pharmaceutical particulars

### 8.1 Incompatibilities

None stated

### 8.2 Shelf-life

Do not use later than the date of expiry.

### 8.3 Packaging information

VIZYLAC HP is available in blister pack of 10 capsules

### 8.4 Storage and handing instructions

Store below 25°C, protected from light & moisture.

Product is required to be stored out of reach of children

## 9. Patient counselling information

**Package leaflet: Information for the user**

**VIZYLAC HP**

**Lactobacillus Reuteri Capsules**

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only.
- Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

## **What is in this leaflet?**

9.1. What VIZYLAC HP is and what it is used for

9.2. What you need to know before you take VIZYLAC HP

9.3. How to take VIZYLAC HP

9.4. Possible side effects

9.5. How to store VIZYLAC HP

9.6. Contents of the pack and other information

### **9.1 What VIZYLAC HP is and what it is used for**

VIZYLAC HP contains probiotic substance *Lactobacillus reuteri*.

VIZYLAC HP is used as a health supplement for *H. pylori* control and for alteration of intestinal bacterial flora.

### **9.2 What you need to know before you take VIZYLAC HP**

#### **Warnings and precautions**

- Do not use if hypersensitive to the active ingredient or excipients. Product is not to be used as a substitute for a varied diet.
- NOT FOR MEDICINAL USE
- This product is not intended to treat, cure, mitigate or prevent any disease, disorder or condition.
- Physiological condition & Purpose of Product: This product is intended to support health function.
- It's a probiotic food.
- May contain milk, soy and nuts.
- Product is not to be used as a substitute for a varied diet.
- If you are allergic to *Lactobacillus reuteri* or any other medicines, please tell your doctor.
- Pregnant or lactating women or people with medical conditions should consult a healthcare professional before use.
- *Lactobacillus reuteri* is not recommended for children unless advised by a doctor. Avoid alcohol consumption with *Lactobacillus reuteri* as it increases the risk of adverse effects.

- If you have chills, high fever or persistent cough, inform your doctor immediately as these might be signs of infection. You are recommended to complete the full course of medication as prescribed by your doctor for effective results.

#### **Other medicines and VIZYLAC HP**

- Drug-Drug Interaction: Lactobacillus reuteri may interact with antifungals (ketoconazole, clotrimazole, griseofulvin, nystatin).
- Drug- Food Interaction: Lactobacillus reuteri may interact with alcohol. Therefore, avoid alcohol consumption with Lactobacillus reuteri as it may increase adverse effects.
- Drug-Disease Interaction: If you have diabetes, a weak immune system, recurring urinary tract or vaginal infections, inform your doctor before taking Lactobacillus reuteri .

#### **VIZYLAC HP with food, drink and alcohol**

Lactobacillus reuteri may interact with alcohol. Therefore, avoid alcohol consumption with Lactobacillus reuteri as it may increase adverse effects.

#### **Pregnancy, breast-feeding and fertility**

Pregnant or lactating women or people with medical conditions should consult a healthcare professional before use.

### **9.3 How to take VIZYLAC HP**

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

As prescribed by physician.

- Not to exceed the recommended daily usage.
- Recommended usage level: One capsule twice a day for gastric health in adults.
- Duration of Use: Daily intake as per recommended usage

#### **Method of administration**

Oral administration, Take the capsules as advised by your doctor. Capsule should be swallowed as a whole with a glass of water. Do not crush, chew or break it. For children, the contents in capsule can be mixed with food or drink that is at room temperature.

### **9.4 Possible side effects**

An increase in stomach gas or bloating may occur. If this effect lasts or gets worse, notify your doctor or pharmacist promptly.

Tell your doctor right away if you have any serious side effects, including: signs of infection (such as cough that doesn't go away, high fever, chills).

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### Reporting of side effects

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[http://www.torrentpharma.com/index.php/site/info/adverse\\_event\\_reporting](http://www.torrentpharma.com/index.php/site/info/adverse_event_reporting).

By reporting side effects, you can help provide more information on the safety of this medicine.

### 9.5 How to store VIZYLAC HP

Store below 25°C, protected from light & moisture.

Product is required to be stored out of reach of children

### 9.6 Contents of the pack and other information

VIZYLAC HP contains Lactobacillus reuteri Capsules.

Nutritional Information contains (Approx)		
Serving Size: 1 Capsule (0.230 g)		
	Per 100 g	% RDA Per serve*
Energy**	398.95 Kcal	0.046
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Carbohydrate	91.3 g	#
Total Sugars	0.0 g	#
Added Sugars**	0.0 g	0.0
Total Fat**	3.35 g	0.012
Saturated Fat**	2.61 g	0.027
Trans Fat**	0.0 g	0.0
Cholesterol	0.0 mg	#
Sodium**	0.0 mg	0.0

VIZYLAC HP is available in blister pack of 10 capsules

### 10. Details of manufacturer

Manufactured by:

Tirupati Lifesciences Private Limited

Nahan Road, Paonta Sahib,

Distt. Sirmaur (HP) –173 025, India.

**11. Details of permission or licence number with date**

10012062000165 issued on 19.05.2022

**12. Date of revision**

Not applicable

**MARKETED BY**



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