**PROFESSIONAL INFORMATION**

Category D: Complementary Medicine

Health Supplement. 34.9 Probiotics

This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.

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

## 1. NAME OF THE MEDICINE

Lp299v Capsules, 1 Billion CFU*

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains:

*Lactobacillus plantarum* 299v 1 x $10^9$ CFU (1 Billion CFU)

*CFU = Colony Forming Units

Sugar free.

Excipient(s) with known effect: None

For a full list of excipients see section 6.1

## 3. PHARMACEUTICAL FORM

Capsules.

Hard, vegetable capsule with opaque white body and cap, containing a white coloured powder.

## 4. CLINICAL PARTICULARS

### 4.1 Therapeutic indications

- Helps to improve and restore the balance of good bacteria within the gut.
- Helps to improve the function of your digestive system.
- May assist in the relief of gastrointestinal symptoms such as abdominal discomfort, flatulence (gas) and bloating.
- Aids in the prevention of proliferation of pathogenic bacteria thus assisting in reducing the effects associated with antibiotic-associated diarrhoea (ADD).
- Improves iron absorption in the small intestine.

**4.2 Posology and method of administration**

Adults: 2 capsules orally once daily with meals or as directed by your health care practitioner.

Do not exceed the recommended daily doses.

Tell patients to separate administration of antibiotics and *Lactobacillus* preparations by at least two hours, as co-administration of *Lactobacillus* with antibiotic drugs might decrease the effectiveness of *Lactobacillus*.

**4.3 Contraindications**

- Lp299v capsules are contraindicated in persons who are hypersensitive to the active ingredient or any of the excipients listed in 6.1.
- *Lactobacillus* preparations might cause pathogenic colonization in patients with:
    - liver cirrhosis, avoid use in these patients.
    - serious gastrointestinal disorders, such as short bowel syndrome or inflammatory bowel disease.
    - severely weakened immune system.

**4.4 Special warnings and precautions for use**

- Consult a health care practitioner prior to use if you have nausea, fever, vomiting, bloody diarrhoea or severe abdominal pain.
- Discontinue use and consult a health care practitioner if symptoms of digestive upset (e.g. diarrhoea) occur, worsen, or persist beyond 3 days.

**4.5 Interactions with other medicines and other forms of interaction**

- Antibiotics medicines: Co-administration of *Lactobacillus* with antibiotic medicines might decrease the effectiveness of *Lactobacillus.*

**4.6 Fertility, Pregnancy and Lactation**

The safety of Lp299V in pregnancy and lactation has not been established. In the absence of sufficient data, the use during pregnancy and lactation is not recommended. No fertility data available.

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

Lp299V has no known influence on the effects of driving and the use of machinery.

### 4.8 Undesirable effects

The undesirable effects listed are based on the MedDRA system organ classes (SOC) classification system.

The frequency groupings listed conform to the following convention:

Very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1 000 to <1/100); rare (≥1/10 000 to <1/1 000); very rare (<1/10 000) and unknown (cannot be estimated from the available data).

| System organ class | Frequency | Undesirable effects |
|---|---|---|
| Gastrointestinal disorders | Uncommon | Epigastric discomfort, Abdominal pain, Dyspepsia, Bloating, Diarrhea and Burping |
| Immunologic disorders | Unknown | Pathological infection |

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the **"6.04 Adverse Drug Reactions Reporting Form"**, found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

You can report side effects to the Adcock Ingram Pharmacovigilance department by e-mail to: Adcock.AEReports@adcock.com.

### 4.9 Overdose

See section 4.8, Undesirable effects.

In overdose, side effects can be precipitated and/or be of increased severity.

## 5. PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

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**Mechanism of action**

*Lactobacillus* refers to a group of lactic acid producing, gram-positive rods that are obligate and facultative anaerobes. The intestinal flora population is severely compromised in patients with inflamed intestinal mucosa. The administration of Lp299v effects successful colonization in the intestine and a favourable increase in *Lactobacilli* probiotic flora population as well as a parallel reduction of gram negative, pathogenic bacteria. Lp299v has demonstrated antibacterial activity against numerous potentially pathogenic agents, such as *Listeria monocytogenes, Bacillus cereus, Escherichia coli, Yersinia enterocolitica, Citrobacter freundii, Enterobacter cloacae and Enterococcus faecalis.* Lp299v enhances the favourable flora composition in the intestinal tract, Lp299v actively promotes normal gastrointestinal function.

### 5.2 Pharmacokinetic properties

When taken orally, *Lactobacilli* pass through the gut and attach to the intestinal mucosa where they can persist for at least one week.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Magnesium stearate.
Potato starch.
Vegetable capsule (hypromellose).

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf life

18 months.

### 6.4 Special precautions for storage

Store in cool, dry place at or below 25°C.

### 6.5 Nature and contents of container

Packs of 20 and 60 capsules in Alu-Alu blister packed bearing the Lp299v logo on reverse side of foil.

### 6.6 Special precautions for disposal

No special requirements.

## 7. HOLDER OF CERTIFICATE OF REGISTRATION

Adcock Ingram Limited
1 New Road
Erand Gardens
Midrand, 1685
Customer Care: 0860 ADCOCK/232625

## 8. REGISTRATION NUMBER(S)

To be allocated.

## 9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

To be allocated.

## 10. DATE OF REVISION OF THE TEXT

December 2022.

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