PROFESSIONAL INFORMATION

Category D: Complementary Medicine

Health Supplements: 34.9 Probiotics

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

SCHEDULING STATUS

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1. NAME OF THE MEDICINE

Probiflora Adult Everyday Flora Balance (2 Strain)

1 billion CFU, capsules

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains:

Lactobacillus rhamnosus LR-32	1 billion CFU*
Bifidobacterium longum BI-05	

***** Colony forming units

Contains sugar: Each capsule contains not more than 10 mg glucose/fructose/sucrose blend in inulin.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Capsules.

A white capsule containing cream coloured powder with light yellow granules.

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

When ingested on a regular basis, probiotics should improve or normalise the microbial balance in the human intestines and thereby improve the functioning of the digestive tract/gut.

4.2 Posology and method of administration

Posology

Adults: Take 1 capsule daily in the morning.

Dosage can be increased to 2 capsules a day if needed or as directed by your healthcare professional.

Take at least 2 hours before or after antibiotics (see section 4.5).

Method of administration

For oral use.

4.3 Contraindications

- Known hypersensitivity to any of the active substances or to any of the excipients listed under section 6.1.

4.4 Special warnings and precautions for use

- Patients should be advised to consult a healthcare provider before taking **Probiflora Adult Everyday Flora Balance (2 Strain)** if they have fever, vomiting, bloody diarrhoea or severe abdominal pain.
- Patients should stop taking **Probiflora Adult Everyday Flora Balance (2 Strain)** and consult a healthcare provider if symptoms of digestive upset (e.g. diarrhoea) occur or worsen.
- **Probiflora Adult Everyday Flora Balance (2 Strain)** contains:
    - **Fructose, glucose** and **sucrose**. Each capsule contains not more than 10 mg blend of fructose/glucose/sucrose. The additive effect of concomitantly administered products containing fructose (or sorbitol) and dietary intake of fructose (or sorbitol) should be taken into account. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take **Probiflora Adult Everyday Flora Balance (2 Strain)**.

4.5 Interaction with other medicines and other forms of interaction

- Since probiotics in **Probiflora Adult Everyday Flora Balance (2 Strain)** contain live and active organisms, concomitant use with antibiotic medicines may decrease its effectiveness. The administration of antibiotic medicines and **Probiflora Adult Everyday Flora Balance (2 Strain)** should be separated by at least 2 hours.

4.6 Fertility, pregnancy and lactation

Safety in pregnancy and lactation has not been established.

There is no fertility data available.

4.7 Effects on ability to drive and use machines

Probiflora Adult Everyday Flora Balance (2 Strain) has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

a) Summary of the safety profile

Probiflora Adult Everyday Flora Balance (2 Strain) is generally well tolerated.

b) Tabulated list of adverse reactions

SYSTEM ORGAN CLASS	FREQUENCY	ADVERSE REACTIONS
Gastrointestinal disorders	*Less frequent*	Mild gastrointestinal adverse effects (worsening diarrhoea, abdominal pain, constipation or flatulence)

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are requested to report any suspected adverse reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

4.9 Overdose

In overdose, side effects can be precipitated and/or be of increased severity (see section 4.8). Treatment should be symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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Theoretically, taking probiotics during antibiotic treatment can prevent or minimise normal flora depletion and pathogenic bacteria colonisation. When probiotics latch onto and colonise the intestinal and urogenital mucosa, it seems to prevent epithelial attachment by pathogenic bacteria. *Bifidobacteria* and *Lactobacilli* are considered “friendly” bacteria and taken for the purpose of re-colonising areas where they normally would occur.

Bifidobacteria longum and *Lactobacillus rhamnosus* are anaerobic, gram-positive, lactic acid-producing bacteria found in the gastrointestinal tract. *B. longum* normally colonises the human colon and *L. rhamnosus* can be found in the vagina. They pass through the gut and bind to the intestinal mucosa, preventing attachment of pathogenic coliform bacteria.

Probiotics might have immunomodulating effects. *Lactobacilli* seem to modulate non-specific cellular and humoral immunity possibly by stimulating lymphocyte and macrophage activity and

modulating cytokine production by mononuclear cells. They also seem to decrease markers of hypersensitivity reactions and intestinal inflammation.
Probiotics have also been shown to aid with the symptomatic relief of lactose intolerance.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Hypromellose (HPMC)
Inulin/oligofructose (containing fructose, glucose and sucrose)
Microcrystalline cellulose
Magnesium stearate.

6.2 Incompatibilities

Not applicable

6.3 Shelf life

24 months.

6.4 Special precautions for storage

Store at or below 25 °C.
Store away from direct sunlight and moisture.

6.5 Nature and contents of container

30 capsules in a white HDPE round jar with a white PP screw on flip top lid.

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

Not Applicable.

10. DATE OF REVISION OF THE TEXT

20 June 2024

adcock ingram

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