Category D: Complementary Medicine

Health Supplements: 34.9 Probiotics

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

SCHEDULING STATUS

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1. NAME OF THE MEDICINE

Probiflora Probiotic Infant Drops 3 Strain - Regular

1 billion CFU, drops

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

4 drops (0,167 ml) contain:	
Bifidobacterium lactis	400 million CFU
Lactobacillus rhamnosus	300 million CFU
Lactobacillus salivarius	300 million CFU

CFU - Colony forming units

Sugar free.

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Drops.

Oil containing white to cream-coloured suspended 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

Infants aged 0-1 years old

Give 4 drops daily or as recommended by a healthcare practitioner.

Shake well before use.

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

Method of administration

For oral use.

Invert or hold bottle at 45° angle to form drops. Can be dropped directly into the mouth or allow drops to collect in a spoon first and then give entire dose orally at once.

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

- A healthcare provider should be consulted before using **Probiflora Probiotic Infant Drops 3 Strain - Regular** if there is fever, vomiting, bloody diarrhoea or severe abdominal pain.
- Use of **Probiflora Probiotic Infant Drops 3 Strain - Regular** should be stopped, and a healthcare provider consulted if symptoms of digestive upset (e.g. diarrhoea) occur or worsen.

4.5 Interaction with other medicines and other forms of interaction

- Since probiotics in **Probiflora Probiotic Infant Drops 3 Strain - Regular** contain live and active organisms, concomitant use with antibiotic medicines may decrease its effectiveness. The administration of antibiotic medicines and **Probiflora Probiotic Infant Drops 3 Strain - Regular** 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 Probiotic Infant Drops 3 Strain - Regular has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

a) Summary of the safety profile

Probiflora Probiotic Infant Drops 3 Strain - Regular 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 authorisation 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 lactis, *Lactobacillus rhamnosus and Lactobacillus salivarius* are anaerobic, gram-positive, lactic acid-producing bacteria found in the gastrointestinal tract. *B. lactis* normally colonises the human colon and *L. rhamnosus* can be found in the gastrointestinal tract and 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

Caprylic/capric triglyceride

Colloidal silicon dioxide

6.2 Incompatibilities

Not applicable

6.3 Shelf life

24 months.

6.4 Special precautions for storage

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

Store away from direct sunlight and moisture.

6.5 Nature and contents of container

10 ml amber glass bottles with a red dropper insert and a white cap, containing 5 ml of oil, equivalent to 30 doses, enclosed in a carton.

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

09 October 2024

PI31991 01/2025

adcock ingram