PROFESSIONAL INFORMATION

Category D: Complementary Medicine

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 JUNIOR FIT FOR SCHOOL 12,5 billion CFU, chewable tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each chewable tablet contains:	
L. acidophilus (Lactobacillus acidophilus) CUL60	5 billion CFU
L. acidophilus (Lactobacillus acidophilus) CUL21	5 billion CFU
B. animalis (Bifidobacterium animalis subsp. Lactis) CUL34	2,375 billion CFU
B. bifidum (Bifidobacterium bifidum) CUL20	125 million CFU
Ascorbic acid (Vitamin C)	50 mg

Contains xylitol: 1,3 g.

Contains sweetener: Each tablet contains 200 mg fructo-oligosaccharides (FOS) [chicory root extract].

Sugar free.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM:

Chewable tablets.

Cream coloured, round, uncoated chewable tablet with speckles and a fruit odour.

4. CLINICAL PARTICULARS:

4.1 Therapeutic Indications

When ingested on a regular basis by children aged 3 years and older PROBIFLORA JUNIOR FIT FOR SCHOOL improves or normalises the microbial balance in the child's intestine and thereby improve the functioning of the digestive tract/gut.

PROBIFLORA JUNIOR FIT FOR SCHOOL contains vitamin C which assists in the maintenance of a healthy immune system.

4.2 Posology and method of administration

Children 3 years and older : Chew One (1) tablet daily.

Do not exceed the recommended dose.

PROBIFLORA JUNIOR FIT FOR SCHOOL should be taken with food. The tablet should be chewed and not swallowed whole.

4.3 Contraindications

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

4.4 Special warnings and precautions for use

- Patients should consult a health care provider prior to use if they have fever, vomiting, bloody diarrhoea or severe abdominal pain.
- Patients should stop use and consult a health care provider if symptoms of digestive upset (e.g. diarrhoea) occur, worsen and/or persists beyond 3 days.
- Patients should consult a health care provider prior to use if they have ulcerative colitis, short bowel syndrome or valvular heart disease.

PROBIFLORA JUNIOR FIT FOR SCHOOL should be used with caution in patients with immunodeficiency (including acquired immune deficiency syndrome (AIDS), lymphoma or patients undergoing long-term corticosteroid treatment).

PROBIFLORA JUNIOR FIT FOR SCHOOL may cause pathogenic colonisation in immunocompromised patients.

4.5 Interaction with other medicines and other forms of interaction

Concomitant use of certain antibiotic and antifungal medicines with PROBIFLORA JUNIOR FIT FOR SCHOOL may decrease its effectiveness. The administration of antibiotic and/or antifungal medicines and PROBIFLORA JUNIOR FIT FOR SCHOOL should be separated by at least 2 hours.

4.6 Fertility, pregnancy and lactation

Safety in fertility, pregnancy and lactation has not been established.

4.7 Effects on ability to drive and use machines

PROBIFLORA JUNIOR FIT FOR SCHOOL is not likely to affect a child's ability in performing tasks requiring their attention.

4.8 Undesirable effects

Gastrointestinal disorders

Frequent: Nausea, vomiting, heartburn, abdominal cramps, gastrointestinal obstruction, diarrhoea

Less frequent: Bloating, flatulence.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions of PROBIFLORA JUNIOR FIT FOR SCHOOL 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 the Adcock Ingram Pharmacovigilance department by e-mail to

Adcock.Aereports@adcock.com, fax to +27 86 553 0128 or call 011 635 0134.

Alternatively, it can be reported to the South African Health Products Regulatory Authority (SAHPRA) via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

4.9. Overdose

See section 4.8, Undesirable effects.

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

In the event of overdosage, treatment should be symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES:

Category D: Health Supplements. 34.12: Multiple Substance Formulation

5.1 Pharmacodynamic properties

Bifidobacteria are anaerobic, rod-shaped, Gram-positive bacteria that normally colonise in the human colon.

Bifidobacteria belong to a group of bacteria called lactic acid bacteria.

Bifidobacteria strains might vary in their effectiveness due to differences in their ability to adhere to epithelial cells.

Lactobacilli are lactic acid producing, Gram-positive rods that are obligate and facultative anaerobes.

Lactobacilli stabilise the mucosal barrier and decrease intestinal permeability.

Bifidobacteria and lactobacilli are considered “friendly” bacteria and taken for the purpose of re-colonising areas where they normally would occur.
Vitamin C is a water-soluble vitamin and plays a factor in the maintenance of good health.

5.2 Pharmacokinetic properties

Bifidobacteria are not commonly absorbed in the gastrointestinal tract.
Bifidobacteria disappear from the faeces within 2 weeks of discontinuation of bifidobacteria, suggesting that there is no long-term colonisation.
For continued effect, bifidobacteria must be used regularly.
Lactobacilli pass through the gut and attach to the intestinal mucosa where they can persist for at least one week after oral administration.
Vitamin C is well absorbed after oral administration. Most of the absorbed vitamin C is excreted in the urine.

5.3 Preclinical safety data

No further information of relevance available.

6. PHARMACEUTICAL PARTICULARS:

6.1 List of excipients

- Fructo-oligosaccharides (FOS) [chicory root extract]
- Flavourants (vanilla & strawberry)
- Magnesium stearate (E572)
- Silicon dioxide
- Xylitol (E967).

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

18 months.

Store at or below 25 °C.

6.4 Special precautions for storage

Store away from direct sunlight.

Do not use if the seal is broken.

6.5 Nature and contents of container

30 chewable tablets in PVC/PE/PVDC/Alu/Vinyl acrylic blister strips packed in an outer 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

Not Applicable.

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