PROFESSIONAL INFORMATION

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

1. NAME OF THE MEDICINE: ULTRAFLORA IB

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Serving Size 1 capsule

Servings Per Container: 30 pack size

30

(60 billion CFU)

Lactobacillus acidophilus NCFM and Bifidobacterium lactis Bi-07

268.75 ma

Other Ingredients: Microcrystalline cellulose, capsule (hydroxypropylmethylcellulose), magnesium stearate (vegetable), and silica.

For full list of excipients, see section 6.1

This product is non-GMO, gluten-free and vegetarian.

3. PHARMACEUTICAL FORM

Cream, off-white powder in clear capsules.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

UltraFlora IB is a clinically tested blend of friendly bacteria in a dairy free base. This advanced formula is designed to help address gastrointestinal symptoms such as abdominal discomfort, bloating, cramping, and occasional urgency

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4.2 Posology and method of administration

Take one capsule one or two times per day or as directed by your healthcare practitioner

4.3 Contraindications

4.4 Special warnings and precautions for use

None known.

4.5 Interaction with other medicines and other forms of interaction

4.6 Fertility, pregnancy and lactation

There are no adequate data from the use of UltraFlora IB in pregnant or breast-feeding woman.

4.7 Effects on ability to drive and use machines

There are no adequate data from the use of UltraFlora IB on the ability to drive and use

4.8 Undesirable effects

None known.

Treatment is symptomatic and supportive

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category of medicine: D (Complementary Medicine)

Class of medicine: 34.13 Health supplements - Other

5.2 Pharmacokinetic properties

Pharmacokinetic studies have not been conducted on UltraFlora IB product

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Microcrystalline cellulose

Magnesium stearate (vegetable)

Capsule:

Hydroxypropylmethylcellulose

6.2 Incompatibilities

6.3 Shelf Life

24 Months.

6.4 Special precautions for storage

For best results, store in a cool dry place or keep refrigerated. Keep capsules in original container until required for use KEEP OUT OF REACH OF CHILDREN.

6.5 Nature and contents of container

Packs of 30 capsules in amber glass bottles

Pack-size: 30 capsules.

6.6 Special precautions for disposal

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Amipro Advanced Development Products (pty) Ltd

Unit 3 Eastgate Business Park, 1 South Road, Marlboro, Sandton, Johannesburg 2063 Tel: 011 802 8101

8. REGISTRATION NUMBER

Will be allocated by SAHPRA upon registration.

9. DATE OF FIRST AUTHORISATION

Will be allocated by SAHPRA upon registration.