

PROFESSIONAL INFORMATION

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

SCHEDULING STATUS: S0

1. NAME OF THE MEDICINE: ULTRAFLOA BALANCE

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Serving Size	1 capsule	
Servings Per Container:	30 pack size	30
	60 pack size	60
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A Probiotic Blend of		55 mg
Lactobacillus acidophilus NCFM and Bifidobacterium lactis Bi-07		(15 billion CFU)

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 Balance provides a dairy-free base for a blend of highly viable, pure strains of *L. acidophilus* NCFM and *B. lactis* Bi-07—friendly bacteria that have been shown to support a healthy intestinal environment and immune health*

* This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use. **UltraFlora Balance** does not intend to prevent or cure any form of illness or disease and should not replace any medication. If you suffer from a chronic medical condition, consult your healthcare practitioner before using this product.

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

None known.

4.4 Special warnings and precautions for use

None known.

4.5 Interaction with other medicines and other forms of interaction

None known.

4.6 Fertility, pregnancy and lactation

There are no adequate data from the use of **UltraFlora Balance** 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 Balance** on the ability to drive and use machines.

4.8 Undesirable effects

None known.

4.9 Overdose

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 Balance** product

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Microcrystalline cellulose
Magnesium stearate (vegetable)
Silica
Capsule:
Hydroxypropylmethylcellulose

6.2 Incompatibilities

None known.

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 and 60 capsules in amber glass bottles.
Pack-size: 30 and 60 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.