

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 ACUTE CARE

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

| | | |
|--|--------------|--------|
| Serving Size | 1 capsule | |
| Servings Per Container: | 30 pack size | 30 |
| <hr/> | | |
| A Probiotic Blend of | | 20 mg |
| Bifidobacterium lactis HN019 Lactobacillus rhamnosus HN001 (4 billion CFU) | | |
| Saccharomyces boulardii (5.5 billion CFU) | | 275 mg |

Other Ingredients: Active dried yeast (*S. cerevisiae* var. *boulardii*, sorbitan monostearate), capsule (hydroxypropylmethylcellulose, sodium copper chlorophyllin), *B. lactis* HN019, stearic acid (vegetable), silica, *L. rhamnosus* HN001, magnesium stearate (vegetable), and microcrystalline cellulose.

For full list of excipients, see section 6.1

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

3. PHARMACEUTICAL FORM

Green capsules

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

UltraFlora Acute Care is a unique blend of "friendly" bacteria and *Saccharomyces boulardii* to support immune health and provide targeted relief for acute bowel distress including occasional loose stools. *

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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

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 Acute Care** 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 Acute Care** 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 Acute Care** product

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Stearic acid (vegetable)
Silica
Magnesium stearate (vegetable)
Microcrystalline cellulose
Capsule:
hydroxypropylmethylcellulose
sodium copper chlorophyllin

6.2 Incompatibilities

None known.

6.3 Shelf Life

24 Months.

6.4 Special precautions for storage

Keep tightly closed in a cool, dry place
For maximum stability and viability, keep refrigerated. However, product may be stored at room temperature (25°C) for up to one month without adversely affecting potency.
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.