Professional Information for ATHLE-PRO™

COMPLEMENTARY MEDICINE: HEALTH SUPPLEMENT

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

ATHLE-PRO™ 15 billion CFU capsules

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains 15 billion CFU (colony forming units) providing:

Lactobacilli (*L. rhamnosus, L. paracasei*)	15 billion CFU
Cholecalciferol (Vitamin D_3)	25 µg (1000 IU)

Sugar free.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Capsules.

Off-white to cream powder in size 2 transparent capsules.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

When ingested on a regular basis, **ATHLE-PRO™** should improve or normalise the microbial

balance in the human intestine and thereby improve the functioning of the digestive tract/gut. Combined with Vitamin D_3, **ATHLE-PRO™** assists in the absorption and use of calcium and phosphorous in the body and contributes to the maintenance of good health and the normal functioning of the immune system and muscles.

4.2 Posology and method of administration

Posology

Adults and children aged 14 years and older: Take 1 capsule daily.

Do not exceed the recommended dosage.

Method of administration

For oral use.

Take the capsules with a glass of water.

Should the capsule be too difficult to swallow, open and dissolve contents in water or any other cold, non-carbonated drink.

4.3 Contraindications

- Hypersensitivity to any of the ingredients of **ATHLE-PRO™** listed in section 2 or 6.1.
- Patients with immune-compromised conditions (e.g. acquired immunodeficiency syndrome (AIDS), lymphoma, patients undergoing long-term corticosteroid treatment).

4.4 Special warnings and precautions for use

- Patients with symptoms such as fever, vomiting, bloody diarrhoea or severe abdominal pain should consult a health care provider prior to use.
- Patients should stop use and consult a health care provider if symptoms of digestive upset (e.g. diarrhoea) occur, worsen and/or persist beyond 3 days.

4.5 Interaction with other medicines and other forms of interaction

Antibiotics may decrease the effectiveness of **ATHLE-PRO™**. **ATHLE-PRO™** should be taken at least 2 – 3 hours before or after antibiotics.

4.6 Fertility, pregnancy and lactation

Safety during pregnancy and lactation has not been established.

4.7 Effects on ability to drive and use machines

ATHLE-PRO™ is unlikely to affect the ability to drive and use machines.

4.8 Undesirable effects

Gastrointestinal disorders:

Less frequently: diarrhoea, dyspepsia, abdominal pain, nausea, bloating, belching, flatulence.

Skin and subcutaneous tissue disorders:

Less frequently: rash, itching, redness, dermatitis.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of **ATHLE-PRO™** is important. It allows continued monitoring of the benefit/risk balance of **ATHLE-PRO™**. Health care providers are requested to report any suspected adverse drug 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.

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

5. PHARMACOLOGICAL PROPERTIES

Category and class: D 34.12 Multiple substance formulation

Mechanism of action:

When ingested on a regular basis, probiotics should improve or normalise the microbial balance in the intestines and thereby improve the functioning of the digestive tract/gut.

Vitamin D_3 assists in the absorption and use of calcium and phosphorous in the body and contributes to the maintenance of good health and the normal functioning of the immune system and muscles.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Corn starch,

vegetable capsule (containing hypromellose).

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Store at or below 25 °C.

Protect from light and moisture.

Keep in the original container until required for use.

6.5 Nature and contents of container

Amber glass bottles containing 30 capsules.

6.6 Special precautions for disposal and other handling

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Orphan SA Pharmaceuticals (Pty) Ltd

260 Cape Rd, Mill Park

Gqeberha 6001

South Africa

8. REGISTRATION NUMBER

Will be allocated by SAHPRA upon registration.

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Will be allocated by SAHPRA upon registration.

10. DATE OF REVISION OF THE TEXT

March 2026.