Professional Information for VIVOMIXX REVISE

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

VIVOMIXX REVISE 460 billion CFU powder

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each sachet contains 460 billion CFU (colony forming units) providing:

Lactobacilli (*L. acidophilus, L. paracasei, L. plantarum, L. rhamnosus*)	424 billion CFU
Bifidobacteria (*B. animalis subsp. lactis, B. breve*)	18 billion CFU
Lactococcus lactis	9 billion CFU
Streptococcus thermophilus	9 billion CFU

Excipient with known effect:

Contains sugar: Each sachet contains 3006 mg maltose.

Gluten and lactose free.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Powder.

Off-white to cream powder.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

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

4.2 Posology and method of administration

Posology

Take 1 – 2 sachets daily.

Do not exceed the recommended dosage.

Method of administration

For oral use.

Stir the contents of the sachet into cold water or any non-carbonated drink or food. Consume immediately. Do not take with hot foods or beverages.

4.3 Contraindications

- Hypersensitivity to any of the ingredients of VIVOMIXX REVISE 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.

VIVOMIXX REVISE contains maltose

Patients with rare glucose-galactose malabsorption should not take VIVOMIXX REVISE.

4.5 Interaction with other medicines and other forms of interaction

Antibiotics may decrease the effectiveness of VIVOMIXX REVISE. VIVOMIXX REVISE 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

VIVOMIXX REVISE 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 VIVOMIXX REVISE is important. It allows continued monitoring of the benefit/risk balance of VIVOMIXX REVISE. 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 34.9 Probiotics

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Corn starch,

magnesium salts,

maltose.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

18 months.

6.4 Special precautions for storage

Store between 2 – 8 °C.

Protect from light and moisture.

Keep in the original container until required for use.

6.5 Nature and contents of container

PET-Alu-PE sachets packed into an outer container.

Pack sizes: 10 or 30 sachets.

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

Tel: 041 363 0061

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.