Progast®
GUT-BRAIN SUPPORT

PROFESSIONAL INFORMATION: CONTENT UNDER EACH HEADING

- This product is a Complementary Medicine, Category D33.7;
- and is identified according to its discipline as a Combination Product;
- which is not registered by the Authority.
- **This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.**

SCHEDULING STATUS:

S0

1. NAME OF THE MEDICINE

Progast® Butyrate Complex

Strength

585,5 mg per capsule

Pharmaceutical form

Solid, DR® delayed-release oral capsule

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains:

Sodium 3-hydroxybutyrate (Butyric acid)	300 mg
L-Glutamine	200 mg
Calcium hydroxide	40 mg
(providing calcium (elemental) 21,6 mg)	
Zinc gluconate	25 mg
(providing zinc (elemental) 3,5 mg)	
Magnesium hydroxide	20 mg
(providing magnesium (elemental) 8,4 mg)	
Copper bisglycinate	0,5 mg
(providing copper (elemental) 50 µg)	

Excipients:

- Non-essential to proper administration;
- for a full list of excipients and the amounts of each excipient per capsule, see section 6.1

Sugar-free:

- Does not contain sugar.
- Does not contain sweeteners.

3. PHARMACEUTICAL FORM

Progast® Butyrate Complex capsules has a delayed-release capsule dosage form with a specific appearance: white, fully opaque, 23 mm lock-length, no markings on the capsule.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

- This product promotes digestive health and support overall well-being with a unique blend of Butyric acid, L-Glutamine, Calcium hydroxide, Zinc gluconate, Magnesium hydroxide, and Copper bisglycinate.

- Due to the active substances, Progast® Butyrate Complex capsules are indicated for therapeutic use only from the age of 18 years and older.
- These active substances are useful for symptomatic relief of mild digestive discomfort such as bloating, gas, and occasional indigestion by supporting the digestive and gastrointestinal system, promoting healthy colon wall integrity. Its active substances may also support bone health, nerve function, and muscle contraction. It supports the immune system, promotes healthy skin, aids in wound healing. It also supports those who are asymptomatic as a low-risk health supplement and can be used to maintain healthy mineral balance.
- It is a health supplement that contains important properties aiding in nutrient absorption, and supporting overall well-being. It be used to support the microbiome, gut-brain axis, and acts as a source of nutrients to healthy bacteria in the small intestine. The unique DR capsules (delayed release) ensure targeted delivery of the key ingredients for the greatest possible effectiveness. Progast® Butyrate Complex capsules are indicated for self-administration as a low-risk health supplement, although only a healthcare provider may indicate it as an adjunct treatment to an existing treatment regimen for individual persons. It is not indicated as an alternative therapy to replace conventional medicines or any other treatments prescribed by a healthcare provider. When using Progast® Butyrate Complex capsules for maintenance therapy, it is specifically indicated for the purposes of maintaining healthy levels of its key ingredients and is not indicated for alternative maintenance therapy.
- It is not indicated as a cure-all or mono therapy for serious conditions because Progast® Butyrate Complex capsules are not intended (nor indicated) to diagnose, treat, prevent, or cure diseases. It is strictly indicated for symptomatic relief as a low-risk supportive supplement.

4.2. Posology and method of administration

Posology

Single dose, 585,5 mg per capsule.

The potency of this medicine is expressed in capsule units. These units are not interchangeable with the units used to express the potency of other preparations that contain the same active substances. No more than the recommended dosage should be taken, and persons should not take or use a double dose to make up for forgotten individual doses.

Adults of the age 18 years and older

1 to 2 capsules, once daily. This is the maximum recommended daily and/or total dose.

Duration of use

If the symptoms persist longer than 1 week during the use of the medicinal product, a doctor or a qualified healthcare practitioner should be consulted.

Method of administration

For oral use only.

4.3. Contraindications

Allergic to the active substances. Hypersensitivity to the active substances.

The maximum recommended daily and/or total dose should not be exceeded.

Based on an existing treatment regimen or pre-existing condition there may be other contraindications (see section 4.5 ‘Interaction with other medicines and other forms of interaction’).

4.4. Special warnings and precautions

In the absence of sufficient data, the use during pregnancy and lactation is not recommended (see section 4.6 ‘Fertility, pregnancy, and lactation’).

Progast® Butyrate Complex is not established as safe for use in persons younger than 18 years of age. Adequate care must be taken to keep this medicine out of the reach of children.

Take special precautions for liver injury or liver diseases. In the absence of sufficient data, the use of this medicine by those with liver injury or liver diseases is not recommended. Due to the possibility of potentiating the effects of blood-thinning medication, or having blood-thinning effects, this medicine should not be used for at least two weeks before surgery or a dental procedure.

4.5. Interaction with other medicines and other forms of interaction

Recommendations

There are no known interactions, but it is recommended to be watchful during concomitant use of this medicine with another medicine as there may be interactions with any supplement where substances may potentiate, intensify, and/or prolong an activity. It is recommended that those who are already using prescription medications observe the contraindication of concomitant use for those medications, and consult their healthcare provider before using this health supplement. Although this health supplement is indicated for self-administration, and no other forms of interaction have been reported, it is still recommended that a healthcare provider be consulted to avoid patients making dose adjustments to an existing treatment regimen, where the risks may outweigh the benefits.

We recommend caution for those with autoimmune diseases. The use of this medicine may activate the antibodies that trigger autoimmune responses in those with autoimmune diseases, as it may have immune boosting effects which can counteract immunosuppressants.

4.6. Fertility, pregnancy, and lactation

Although it is unlikely to affect fertility, there is no fertility data available. Safety during pregnancy and lactation has not been established. In the absence of sufficient data, the use during pregnancy and lactation is not recommended. No adverse effects on fertility, pregnancy, and lactation have yet been reported.

4.7. Effects on the ability to drive and use machines

Although it is unlikely to affect the ability to drive and use machines, no studies on the effect on the ability to drive and use machines have been performed. No adverse effects on the ability to drive or use machines have yet been reported.

4.8. Undesirable effect

No adverse reaction has been reported.

4.9. Overdose

No case of overdose has been reported.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Mechanism of action

For each of the active substances, the mechanism of action is listed as follows:

Butyric Acid: Butyric acid is a short-chain fatty acid that plays a crucial role in supporting the health of the digestive system. It acts as an energy source for the cells lining the gastrointestinal tract and promotes the growth of beneficial bacteria in the gut. It also supports the integrity of the intestinal barrier and modulates immune responses.

L-Glutamine: L-Glutamine is an amino acid that serves as a fuel source for rapidly dividing cells, such as those in the intestines. It supports the regeneration and maintenance of the intestinal lining, helps to strengthen the gut barrier function, and promotes the growth of intestinal cells. L-Glutamine also has immune-modulating properties.

Calcium Hydroxide: Calcium hydroxide, also known as slaked lime, is an alkaline compound. It is commonly used as a dietary supplement to provide a source of calcium, which is essential for the maintenance of strong bones and teeth. Calcium hydroxide helps support proper nerve function, muscle contraction, and blood clotting.

Zinc Gluconate: Zinc is an essential trace mineral that plays a vital role in numerous physiological processes. Zinc gluconate is a form of zinc that is easily absorbed by the body. Zinc supports immune function, DNA synthesis, cell division, wound healing, and plays a role in the metabolism of proteins, carbohydrates, and fats. It also acts as an antioxidant, protecting cells from oxidative stress.

Magnesium Hydroxide: Magnesium hydroxide is an inorganic compound that is commonly used as an antacid and laxative. It works by neutralizing excess stomach acid and relieving symptoms of indigestion and heartburn. Magnesium, as a mineral, is involved in various enzymatic reactions in the body and is necessary for proper muscle and nerve function, as well as maintaining a steady heart rhythm.

Copper Bisglycinate: Copper bisglycinate is a chelated form of copper, where copper is bound to the amino acid glycine. Copper is an essential trace mineral involved in several enzymatic reactions, including energy production, connective tissue synthesis, and iron metabolism. It also acts as an antioxidant and plays a role in the functioning of the immune system and nervous system.

Pharmacodynamic effects

For each of the active substances, the pharmacodynamic effects is listed as follows:

Butyric Acid: Modulates immune responses. Supports the integrity of the intestinal barrier. Promotes the growth of beneficial gut bacteria. Provides a source of energy for gastrointestinal cells. Supports the health of the digestive system.

L-Glutamine: Supports the regeneration and maintenance of the intestinal lining. Strengthens the gut barrier function. Promotes the growth of intestinal cells. Exhibits immune-modulating properties. Provides a fuel source for rapidly dividing cells, such as those in the intestines.

Calcium Hydroxide: Provides a source of calcium for the maintenance of strong bones and teeth. Supports proper nerve function. Facilitates muscle contraction. Supports normal/healthy blood clotting.

Zinc Gluconate: Supports immune function. Facilitates DNA synthesis and cell division. Aids in wound healing. Supports the metabolism of proteins, carbohydrates, and fats. Acts as an antioxidant, protecting cells from oxidative stress.

Magnesium Hydroxide: Neutralizes excess stomach acid. Provides relief from symptoms of indigestion and heartburn. Supports proper muscle and nerve function. Helps maintain a steady heart rhythm.

Copper Bisglycinate: Supports various enzymatic reactions in the body. Plays a role in energy production. Supports connective tissue synthesis. Aids in iron metabolism. Acts as an antioxidant. Supports the functioning of the immune system and nervous system.

Clinical safety and efficacy

Administered or used according to the recommended maximum and/or total daily dose is likely safe in adults and children, as the substances are generally well-tolerated. However, insufficient data is available to support safety during pregnancy and lactation. Effectiveness studies on the active substances show likely and additionally plausible therapeutic benefits for patients using this product as intended and indicated.

However, these active substances are not used to diagnose, treat, cure, or prevent any disease. This information further supports the use of contraindications (see section 4.3 'Contraindications') as well as warnings and special precautions that recommend remaining watchful and cautious (see section 4.4 'Special warnings and precautions'). It may be unsafe for those relying on immunosuppressants.

5.2. Pharmacokinetic properties

Release/Liberation

Calcium hydroxide, when taken orally as a supplement, undergoes dissolution in the stomach acid. After oral ingestion of magnesium hydroxide, it reacts with stomach acid to form magnesium chloride.

Absorption

Butyric acid is a short-chain fatty acid that is typically absorbed in the colon. L-Glutamine is an amino acid that is readily absorbed in the small intestine. Zinc gluconate, upon oral administration, undergoes dissociation in the stomach and is absorbed primarily in the small intestine. Magnesium hydroxide which turns into magnesium chloride is then absorbed in the intestines. Copper bisglycinate is a chelated form of copper, which enhances its absorption in the intestines.

Distribution

The absorbed calcium ions are then transported via active transport mechanisms in the intestines and are distributed to various tissues, with the majority being deposited in bones. L-Glutamine is transported into the bloodstream and distributed to various tissues. The absorbed calcium ions are then transported via active transport mechanisms in the intestines and are distributed to various tissues, with the majority being deposited in bones. Zinc binds to various proteins and is distributed throughout the body. Copper is distributed to various tissues, with the liver being the primary site of copper storage.

Biotransformation/Inactivation/Metabolism

Butyric acid can be metabolized by colonocytes for energy production. Glutamine metabolism occurs in several organs, including the liver, kidneys, and skeletal muscle.

Clearance/Elimination/Excretion

Calcium is primarily eliminated through feces and urine. Zinc is mainly eliminated through feces, urine, and sweat. Magnesium is distributed throughout the body and excreted mainly through urine. Copper is primarily eliminated through bile and feces.

Half-life

As butyric acid is intended to be metabolized by colonocytes for energy, which occurs relatively quickly, it does not have a specific half-life. However, as a short-chain fatty acid, it is typically metabolized relatively quickly within the colonocytes for energy production. The elimination half-life of glutamine is relatively short, estimated to be around 1-2 hours, and it is primarily metabolized into glutamate and other metabolites. As calcium is primarily involved in providing calcium rather than being directly metabolized, it does not have a specific half-life. The half-life of zinc in the body can vary depending on various factors, such as dosage, route of administration, and individual characteristics. However, the estimated half-life of zinc in the blood is around 2-3 days. It is important to note that zinc turnover rates and elimination may differ between tissues and bodily compartments. The half-life of magnesium in the body can vary depending on the individual and specific circumstances. However, it is estimated to be around 30 hours. The half-life of copper in the body can vary depending on various factors, including dosage, route of administration, and individual characteristics. However, the estimated half-life of copper in the blood is around 12-16 hours.

The exact pharmacokinetic parameters, such as absorption, distribution, metabolism, and elimination, may vary depending on the specific formulation and route of administration. It is important to consider the pharmacokinetics of each active substance for this combination (see section 5.2 'Pharmacokinetic properties').

5.3. Preclinical safety data

Non-clinical data obtained on the use of the active substances reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential, and toxicity to reproduction and development.

The long-standing and traditional use of the active substances for which studies reveal likely and additionally plausible therapeutic benefits in addition to the extent of evidence and real-world data that motivates use.

The use of Progast® Butyrate Complex is in accordance with low-risk guidelines.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Inactive substances per capsule:

- Microcrystalline cellulose
- Magnesium stearate

6.2. Incompatibilities

Not applicable; solid oral pharmaceutical forms.

6.3. Shelf life

Progast® Butyrate Complex has an estimated shelf life of 23 months.

6.4. Special precautions for storage

Protect from direct sunlight or moisture. Do not refrigerate or freeze this product. Store in a cool, dry place at temperatures of 59-77° F, equivalent to 15-25° C, and with ambient humidity between 35% and 65%. Contents must remain sealed before use, shrink-wrapping, or packing into boxes for transport and storage. For express delivery in smaller batches, specialized containment bins may be used for repacking individually sealed units.

6.5. Nature and contents of the container

Progast® Butyrate Complex capsules come in cartons of 30 capsules within blister packs of 10 capsules each for added hygienic use. The active substances provide a total of 585,5 mg per capsule. Inactive substances per capsule are also provided (see section 6.1 ‘List of excipients’).

Progast® Butyrate Complex capsules come in cartons of 30 capsules within blister packs of 10 capsules each for added hygienic use. The blister packs are the primary packaging containing the name markings of the product on the outer foil. Progast® Butyrate Complex capsules has a delayed-release capsule dosage form with a specific appearance: white, fully opaque, 23 mm lock-length, no markings on the capsule. The carton acts as the secondary packaging for storage, also showing the proper labeling on the carton.

6.6. Special precautions for disposal and other handling

Return all unused medicine to your pharmacist. Do not dispose of remaining medicines in drains or sewerage systems. Please recycle the empty containers. Expired stock of [name of medicine] is to be quarantined in a special holding facility. Upon quarantine, they must be scheduled for destruction and may accumulate to certain holding levels depending on quarantine capacity.

The expired medicines should be destroyed by those duly authorized to carry out or conduct the destruction.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Tara Pharmaceuticals (Pty) Ltd

36 Sovereign Drive, Route 21 Corporate Park, Irene, Gauteng, 0062, South Africa

8. REGISTRATION NUMBER(S)

Item to be completed by SAHPRA or by the Holder of Certificate of Registration once the authorization has been granted.

9. DATE OF FIRST AUTHORIZATION / RENEWAL OF AUTHORIZATION

Not yet assigned.

10. DATE OF REVISION OF TEXT

Not yet assigned.