Progast®
LIVER HEALTH SUPPORT
LEWER ONDERSTEUNING

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® Pro-liver Ultra Capsules

Strength

619 mg per capsule

Pharmaceutical form

Solid, hydroxypropyl methylcellulose capsules, oral

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains:

Silybum marinarum Gaertn. (Milk Thistle)	200 mg
[Seed extract, standardised to 80% Silymarin]	
Cynara scolymus L. (Artichoke)	150 mg
[Leaf, 4:1 extract, standardised to 600mg dried herb equivalent]	
Choline Bitartrate	100 mg
(providing Choline 41,13mg / verskaf Cholien 41,13mg)	
Taraxacum campylodes G.E Haglund (Dandelion)	50 mg
[Root 4:1 extract, standardised to 200mg dried herb equivalent]	
Zingiber officinale Roscoe (Ginger)	50 mg
[Root extract, standardised to 5% Gingerol]	
Emblica officinalis Gaertn. (Amalaki)	23.33 mg
[Fruit, 3:1 extract, standardised to 70mg dried herb equivalent]	
Terminalia bellirica Retz. (Bibhitaki)	23.33 mg
[Fruit, 3:1 extract, standardised to 70mg dried herb equivalent]	
Terminalia chebula Roxb. (Haritaki)	23.33 mg
[Fruit, 3:1 extract, standardised to 70mg dried herb equivalent]	

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

Solid, hydroxypropyl methylcellulose capsules, transparent, 23.4 mm lock-length, no markings.

4. CLINICAL PARTICULAR

4.1. Therapeutic indications

- Progast® Pro-liver Ultra Capsules is for supporting the body to detox by helping provide liver health support, promoting healthy excretions and absorptions while benefitting overall health and wellbeing with hepatotherapeutic effects.

- Due to the active substances, Progast® Pro-liver Ultra Capsules are indicated for therapeutic use only from the age of 18 years and older.
- The active substances are useful for liver health support and reducing the risk of an unhealthy liver which supports the digestive system. Its active substance choline bitartrate may also support the maintenance of choline levels which play an important role in maintaining overall health and wellness.
- It is a health supplement that contains important liver detoxifying properties important in liver cellular repair activities used to support the digestive system, supporting the small intestine and colon as a liver health and detox promoting supplement.
- Progast® Pro-liver Ultra 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.
- Progast® Pro-liver Ultra Capsules is a medicinal health supplement not intended (nor indicated) for alternative maintenance therapy, but rather for symptomatic relief from a liver in need of support with this medicine and to promote liver health and liver detox. It is not indicated as a cure-all or monotherapy for serious conditions because Progast® Pro-liver Ultra Capsules is not intended (nor indicated) to diagnose, treat, prevent, or cure diseases.
- It is strictly indicated for symptomatic relief and to promote liver health and liver detox as a low-risk supportive supplement.

4.2. Posology and method of administration

Posology

Single dose, 619 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 over the age of 18 years

1 capsule, 3 times daily, or 3 capsules, 1 time daily. This is the maximum recommended daily and/or total dose.

Method of administration

Oral use only.

4.3. Contraindications

Allergic to the active substances. Hypersensitivity to the active substances. No interactions have yet been observed or reported regarding antidiabetes medications, such as those that have a glycemic effect. However, if you are on antidiabetes medication used to treat or prevent diabetes, it is advised that take caution or avoid this health supplement due to theoretical hypoglycemic risks. Please be cautious when using blood thinners, as it may increase the effects of blood-thinning medication.

Do not use this product concomitantly with morphine as it may increase or decrease the effects of morphine. 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® Pro-liver Ultra Capsules 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 precaution for use with antiplatelet or anticoagulant medication as the coumarins already contained in this medicine may potentiate the effects of other medicines that are coumadins such as Warfarin.

The maximum recommended daily and/or total dose should not be exceeded. Progast® Pro-liver Ultra Capsules contains coumarins that acts as a plant-based blood-thinning agent. Because of coumarin, those who are using prescription anticoagulants especially on a chronic basis should not use this medicine without consulting their healthcare provider. For the same reason, 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

The use of this medicine with antidiabetes medication may or may not be appropriate and a healthcare practitioner should be consulted. However, the concomitant use of this medicine with morphine is not recommended and should be avoided. This is due to the herbal substances which are likely to have an interaction with patient morphine medication, either increasing or decreasing its effects. This interaction is based on theoretical pharmacology.

It is recommended that those who are already using prescription morphine medications observe the contraindication of concomitant use and consult their healthcare provider before using this medicine. Although this medicine 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.

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 to 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 to 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

The applicable parts of milk thistle are the seed and above ground parts. The seed is most commonly used medicinally. A standard milk thistle seed extract contains 70% to 80% silymarin, which is a mixture of flavonolignans including silybin A, silybin B, isosilybin A, isosilybin B, silydianin, silychristin A and B, and silibinin. Milk thistle is known to support liver health, while artichoke may help with digestion. The applicable parts of artichoke are the leaf, stem, and root. Choline is an important nutrient that supports brain function, and dandelion is a natural diuretic. Choline has traditionally been considered a B vitamin, which became controversial due to it being manufactured by the body. It is required for the structure of cell membranes and for lipid metabolism and transport, as well as for the formation of compounds involved in neurotransmission and platelet function. Ginger has anti-inflammatory properties and triphala is a blend of three fruits that is often used in Ayurvedic medicine to support digestion and overall health. The applicable parts of ginger are the rhizome and root. Active constituents of ginger include gingerol, gingerdione, shogaol, and sesquiterpene and monoterpene volatile oils.

Pharmacodynamic effects

Antioxidant and free radical-scavenging actions of milk thistle constituents such as silymarin and silybin are thought to be important mechanisms for their hepatoprotective effects. Antioxidant and free radical-scavenging actions of milk thistle constituents such as silymarin and silybin are thought to be important mechanisms for their hepatoprotective effects. Preliminary research suggests that artichoke leaf extract might protect liver cells from damage. Artichoke has also demonstrated protective activity against the hepatitis C virus in vitro, possibly due to the sesquiterpene lactones cynaropicrin and grosheimol. Deficiency of choline is uncommon except in people receiving long-term total parenteral nutrition (TPN). Choline deficiency, related to long-term TPN use, can result in increased alanine aminotransferase (ALT) and fatty liver. Adding choline to the TPN solution usually improves liver function. This indicates that dietary choline is required in addition to the choline normally synthesized by the body. Clinical evidence suggests that taking ginger reduces triglyceride and cholesterol levels in patients with hyperlipidemia. Ginger is traditionally used for stomach and gastrointestinal ailments. Also, gastroprotective effects of ginger have been shown in various animal models. Triphala contains three fruits; alcoholic and aqueous extracts of Indian gooseberry show protective and healing effects in alcohol-induced gastric ulcers in animal experiments; Terminalia bellirica and Terminalia chebula are reported to have beneficial effects in bowel irregularity and indigestion; these benefits are attributed to astringent properties; Terminalia bellirica contains gallic acid, and is thought to have hepatoprotective properties.

It is important to consider the pharmacokinetics of each active substance as opposed to a single abstract pharmacokinetic property for this combination (see section 5.2 ‘Pharmacokinetic properties’).

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 plausible therapeutic benefits for patients with constipation symptoms and indigestion-related symptoms as well as bloating. However, these active substances are not used to diagnose, treat, cure, or prevent any disease. This is also understood based on the contraindications (see section 4.3 ‘Contraindications’).

5.2. Pharmacokinetic properties

There is limited data available on the exact pharmacokinetic properties of Progast® Pro-liver Ultra Capsules.

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 plausible therapeutic benefits also provides real-world evidence and data. The use of Progast® Pro-liver Ultra Capsules is in accordance with low-risk guidelines.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Inactive substances per capsule:

- Microcrystalline cellulose
- Magnesium stearate
- Silicon dioxide

6.2. Incompatibilities

Not applicable; solid oral pharmaceutical forms.

6.3. Shelf life

Progast® Pro-liver Ultra Capsules 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, the use of specialized containment bins may be used for repacking individual sealed units.

6.5. Nature and contents of the container

Progast® Pro-liver Ultra Capsules may come in blister packs of 10 capsules per blister inside of cartons containing 1, 2, or 3 blister packs. The active substances provide a total of 619 mg per capsule. Inactive substance per capsule are provided also (see section 6.1 ‘List of excipients’).

Progast® Pro-liver Ultra Capsules has a capsule dosage form with a specific appearance: Solid, hydroxypropyl methylcellulose capsules, transparent, 23.4 mm lock-length, no markings. The carton acts as the secondary packaging for storage, also showing the proper labeling.

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 Progast® Pro-liver Ultra Capsules 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.