Progast®
GASTROINTESTINAL SUPPORT

PROFESSIONAL INFORMATION: CONTENT UNDER EACH HEADING

- This product is a Complementary Medicine (Category D33.6);
- and is identified according to its discipline as a Western Herbal Medicine;
- 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® Multi-action Drops™

Strength

428,32 mg per 1 mL (approximately 20 drops; or 21,42 mg per drop)

Pharmaceutical form

Liquid, tincture drops, oral

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 mL (approximately 20 drops) contains:

Ulmus rubra Muhl. (Slippery Elm)	75 mg
[Bark, 1:10 ethanol extract, equivalent to 75 mg dried herb]	
Zingiber officinale L. (Ginger)	70 mg
[Root, 1:10 ethanol extract, equivalent to 70 mg dried herb]	
Matricaria chamomila L. (Chamomile)	66.67 mg
[Flower, 1:10 ethanol extract, equivalent to 66.67 mg dried herb]	
Angelica archangelica L. (Angelica)	33.33 mg
[Root, 1:10 ethanol extract, equivalent to 33.33 mg dried herb]	
Carum carvi L. (Carraway)	33.33 mg
[Fruit, 1:10 ethanol extract, equivalent to 33.33 mg dried herb]	
Silybum marianum Gaertn. (Milk Thistle)	33.33 mg
[Fruit, 1:10 ethanol extract, equivalent to 33.33 mg dried herb]	
Melissa officinalis L. (Lemon Balm)	33.33 mg
[Leaf, 1:10 ethanol extract, equivalent to 33.33 mg dried herb]	
Cynara scolymus L. (Artichoke)	33.33 mg
[Leaf, 1:10 ethanol extract, equivalent to 33.33 mg dried herb]	
Glycyrrhiza glabra L. (Licorice)	33.33 mg
[Root, 1:10 ethanol extract, equivalent to 33.33 mg dried herb]	
Mentha piperita L. (Peppermint)	16.67 mg
[Root, 1:10 ethanol extract, equivalent to 16.67 mg dried herb]	

Excipients:

- Alcohol ..... 31% m/m
- for a full list of excipients and the amounts of each excipient per 1 mL (approximately 20 drops), see section 6.1

Sugar-free:

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

3. PHARMACEUTICAL FORM

Liquid, tincture drops, oral dosage form, light green-brown color, vertical dropper bottle, comes in ranges of 20 mL, 50 mL, or 100 mL, sealed with a white screwcap, the bottle is labeled with the appropriate brand name.

4. CLINICAL PARTICULAR

4.1. Therapeutic indications

- These active substances support the digestive system and overall human health.
- This health supplement is indicated to support gastrointestinal health and symptomatic relief of indigestion, abdominal cramps, nausea, occasional constipation, mild diarrhea, bloating, irritable bowels, and food sensitivity.
- It is also indicated to support the management of symptoms related to Irritable Bowel Syndrome (IBS).
- While helping relieve occasional constipation, the mucilage may also benefit those who suffer from mild diarrhea. Making it a complementary medicine with therapeutic value to support the management of irritable bowel syndrome (IBS).
- Due to the active substances in this product, it is not suitable for those under 1 year of age.
- It is a health supplement that contains important health benefits that are due to demulcent, emollient, anxiolytic, antioxidant, antibacterial, weight loss, hepatoprotective, renoprotective, antispasmodic, anti-ulcer, glucose-moderating, immunomodulatory, spasmolytic, performance-enhancing, anti-emetic, anti-diabetic, and cholesterol-lowering properties.
- These properties can be used to support the liver, kidneys, and stomach, and promote overall human health. Supporting the gastrointestinal function and the gut-brain axis.
- Its active substances may also support the digestive function of asymptomatic individuals as a low-risk health supplement and can be used to maintain healthy levels of phytonutrients.
- Progast® Multi-action Drops™ 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® Multi-action Drops™ 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 monotherapy for serious conditions because Progast® Multi-action Drops™ are not intended (nor indicated) to diagnose, treat, prevent, or cure diseases.
- It is strictly indicated for symptomatic relief of minor ailments as a low-risk supportive supplement.

4.2. Posology and method of administration

Posology

Single dose, 428,32 mg per 1 mL (approximately 20 drops; or 21,42 mg per drop). The potency of this medicine is expressed in 1 mL (approximately 20 drops) units. These units may not be 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.

Please pay careful attention to the way a single full dose is adjusted lower for each progressively younger age group according to the recommended method of administration shown below:

Adults and children over 12 years

The dose is 1 mL (approximately 20 drops), 3 times daily. Dilute the drops in at least 30 to 60 mL of clean, room-temperature water. This is the maximum recommended daily and/or total dose.

Children 6 years of age to 11 years of age

The dose is reduced to ¾ of a single dose, or 0.75 mL (approximately 15 drops), 3 times daily. Dilute the drops in at least 30 to 60 mL of clean, room-temperature water. This is the maximum recommended daily and/or total dose.

Children 3 years of age to 5 years of age

The dose is reduced to ½ of a single dose, or 0.5 mL (approximately 10 drops), 3 times daily. Dilute the drops in at least 30 to 60 mL of clean, room-temperature water. This is the maximum recommended daily and/or total dose.

Children 1 year of age to 2 years of age

The dose is reduced to ¼ of a single dose, or 0.25 mL (approximately 5 drops), 3 times daily. Dilute the drops in at least 30 to 60 mL of clean, room-temperature water. This is the maximum recommended daily and/or total dose.

Duration of use

If the symptoms of a minor gastrointestinal ailment or discomfort persist for 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® Multi-action Drops™ is not established as safe for use in persons younger than 1 year 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

Progast® Multi-action Drops™ contain mucilage, which has a demulcent and emollient effect and may interfere with the usual absorption of other oral medications if taken together. This interaction is not considered major. However, it is important to be watchful and cautious, and not exceed the recommended maximum daily and/or total dose. 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.

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. Even if this medicine is not contraindicated for those with autoimmune diseases, we still recommend caution due to the use of plant extracts, as it is not always clear to what extent any specific plant extract can counteract immunosuppressant drugs.

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 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

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

The applicable part of *Ulmus rubra* Muhl. (Slippery Elm) is the inner bark rind. Mucilages are considered the principal active constituent, alongside tannins, and oleoresins. The applicable part of *Zingiber officinale* L. (Ginger) are the rhizome and root. Active constituents of ginger include gingerol, gingerdione, shogaol, and sesquiterpene and monoterpene volatile oils. The applicable part of *Matricaria chamomila* L. (Chamomile) is the flower. Active constituents of chamomile include quercetin, apigenin, luteolin, coumarins such as umbelliferone, sesquiterpenes such as matricin, terpenoids such as chamazulene, alpha bisabolol, and bisabolol oxides, spiroether, essential oil, polysaccharides, amino acids, fatty acids, and minerals. The applicable parts of *Angelica archangelica* L. (Angelica) are the root, seed, leaves, and fruit. The applicable parts of *Carum carvi* L. (Carraway) are the seed, fruits, and oils. The applicable parts of *Silybum marianum* Gaertn. (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. The applicable parts of *Melissa officinalis* L. (Lemon Balm) are the leaf and leaf oil. Lemon balm contains citronellal, neral, and geranial monoterpenoid aldehydes; flavonoids (including luteolin) and polyphenol compounds (including rosmarinic acid, caffeic acid, and tannins); monoterpene glycosides, and triterpenoids (including oleanolic acid and ursolic acid). The applicable parts of *Cynara scolymus* L. (Artichoke) are the leaf, stem, and root. The primary constituents include phenolic

acids, primarily chlorogenic acid, cynarin, and caffeic acid; sesquiterpene lactones such as cynaropicrin and grosheimol; and flavonoids including scolymoside, cynaroside, narirutin, apigenin, ferulic acid, and luteolin. Artichoke also contains the polysaccharide inulin. The applicable part of *Glycyrrhiza glabra* L. (Licorice) is the root. Although licorice contains saponins, flavonoids, isoflavonoids, flavones, and chalcones, the main active constituent is considered to be glycyrrhizin, otherwise known as glycyrrhizic acid or glycyrrhizinic acid. The applicable parts of *Mentha piperita* L. (Peppermint) are the aerial parts and oil. Peppermint oil is obtained by distilling the aerial parts of peppermint. Peppermint oil is a complex mixture of compounds, including 30% to 70% menthol, 15% to 30% menthone, 4% to 32% menthyl acetate, and 1% to 4% pulegone.

Pharmacodynamic effects

For each of the active substances, for which safety is also based on traditional use, the pharmacodynamic effects are listed as follows:

Due to the protective effects of mucilage for the gastrointestinal lining, Slippery Elm can help alleviate symptoms of food sensitivity and irritable bowels. The anti-ulcer effects are attributable to the mucilage effects that help protect the stomach lining. Slippery Elm's active constituents are responsible for the demulcent and emollient effects, causing reflex stimulation of nerve endings in the GI tract, leading to mucus secretion that helps protect the GI tract against stomach ulcers and excess acidity. It may also help relieve cough and sore throat due to the same active constituents. The consumption of water in addition to the phototherapeutic constituents of Slippery Elm supports the relief of occasional constipation. Bloating can be reduced through the same prokinetic benefits of Slippery Elm that relieve indigestion. This is also due to the demulcent, emollient, anxiolytic effects of the active constituents.

These gastrointestinal effects of ginger provide prokinetic benefits to alleviate indigestion. It also provides anti-nausea and anti-emetic effects for additional gastrointestinal benefits. Additionally, weigh loss benefits can be attributed to its active constituents. Ginger is traditionally used for stomach and gastrointestinal ailments. Gastroprotective effects of ginger might be due to increased levels of protective prostaglandins in the gut wall. In patients with rheumatoid arthritis (RA), it has been demonstrated that ginger increases FoxP3 gene expression, which help suppress the autoimmune response of effector T cells. Ginger also appears to decrease the expression of the ROR gamma t and T-bet genes, which are believed to be involved in the autoimmune process. There is interest in using ginger for weight loss. In vitro, ginger, possibly via one of the gingerols, enhanced adipocyte differentiation. Ginger is sometimes used for inflammatory conditions such as rheumatoid arthritis (RA). In human and laboratory research, ginger inhibited the production of inflammatory cytokines. The ginger constituents gingerols and shogaols might have antiemetic effects. Ginger is traditionally used for low back and stomach pain. In human research, ginger, with or without feverfew, effectively reduces pain associated with migraine headaches. This complements the anxiolytic properties of this combination. The consumption of water in addition to the phototherapeutic constituents of ginger supports the relief of occasional constipation. Bloating can be reduced through the same prokinetic benefits of ginger that relieve indigestion.

Due to these gastrointestinal effects, German chamomile provides soothing effects for abdominal cramps. Laboratory research suggests that German chamomile might produce spasmolytic effects on smooth muscle tissue by inhibiting cyclic adenosine monophosphate (cAMP) and cyclic guanosine monophosphate (cGMP) phosphodiesterases, and also block slow wave activity in the small intestine, which could slow peristaltic movement, contributing to the spasmolytic effects shown. Laboratory research suggests it can inhibit cyclooxygenase and lipoxygenase enzymes, reducing the production of prostaglandins and leukotrienes. Quercetin and apigenin can inhibit histamine release from mast cells after antigen stimulation. The consumption of water in addition to the phototherapeutic constituents of German chamomile supports the relief of occasional constipation. Bloating can be reduced through the same prokinetic benefits that relieve indigestion.

A constituent of Angelica archangelica called decursin is thought to be beneficial for dementia. Angelica archangelica extracts also seem to have an inhibitory effect on membrane lipid peroxidation and free radical formation, and may have free radical scavenging activity. The root appears to contain the constituents with the most benefit. In laboratory research, Angelica archangelica seems to reduce slow wave frequency and amplitude in the small intestine, which slows peristaltic movement, aiding in relieving digestive discomfort related to an upset stomach.

Components of the essential oil of caraway have been shown to cause local stimulation of the gastric mucosa, which activates the vagus nerve, leading to an increase of stomach tonus and rhythmic contraction. Additionally, weigh loss benefits can be attributed to its active constituents. The result of this action is an eructation of air from the stomach and an increase in gastric secretion. The carvacrol and fatty acids in caraway may contribute to its weight loss effects. It is thought these components may balance the microflora of the gut to help improve food digestion and absorption. These two components may also inhibit the growth of certain pathogenic bacteria, which may increase the amount of gut microflora present. Gut microflora disrupts the conversion of preadipocytes to mature adipocytes, preventing adipogenesis. Caraway may also possess antioxidant properties that lead to stimulation of apoptosis in pre-adipocytes and prevent adipogenesis via enhancement of lipolysis.

Liver detoxification effects of milk thistle, the benefits to maintaining kidney health, and improving digestion through bile stimulation can be attributed to its active constituents. 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. Silymarin and silibinin inhibit beta-glucuronidase, which is thought to reduce the hydrolysis of glucuronides into toxic metabolites in the liver and intestine. In vitro, milk thistle extract was able to bind to the mu-opioid receptor, the receptor involved in most of the effects of morphine. Additionally, there is interest in using silymarin for complications of diabetes, such as diabetic nephropathy, which is thought to be caused by oxidative stress and inflammation. Silymarin also possesses anti-fibrotic properties via downregulation of transforming growth factor-beta (TGF-beta). TGF-beta plays a role in diabetic nephropathy as it causes hardening of the glomerulus in the kidney as well as interstitial fibrosis. This demonstrates the hepatoprotective and renoprotective benefits.

Digestive health support through the the antiviral activity of lemon balm is attributed to its tannin and polyphenol constituents. The anti-inflammatory effect of rosmarinic acid is attributed to its ability to inhibit complement-dependent processes involved in inflammation. It is thought that this herbal combination reduces the growth and development of adipose tissue that contributes to obesity by inhibiting angiogenesis. In vitro research shows that lemon balm has antioxidant activity and can inhibit lipid peroxidation.

Preliminary research suggests that artichoke leaf extract might protect liver cells from damage. Artichoke extract also appears to reduce LDL oxidation in laboratory research. Artichoke's therapeutic benefit in dyspepsia has centered around its choleretic effects, or ability to stimulate bile

flow, which has been demonstrated in several studies. This might also explain its use as a hangover remedy. Constituents responsible for this effect are thought to be cynarin, chlorogenic acid, and scolymoside. Antiemetic, spasmolytic, and carminative effects of artichoke have also been described. These effects may be responsible for the potential beneficial effects in patients with irritable bowel syndrome (IBS). Artichoke might reduce cholesterol synthesis, possibly related to direct inhibition of HMG-CoA reductase by the constituents cynaroside and its derivative, luteolin. Research shows that artichoke leaf extract has renoprotective effects. The antioxidant effects of artichoke are thought to explain such findings. The consumption of water in addition to the phototherapeutic constituents of artichoke supports the relief of occasional constipation.

Licorice is commonly used for diabetes. It also possesses antioxidant and antibacterial properties, attributed to the active constituents. Preliminary clinical research suggests that taking licorice root extract reduces levels of alanine aminotransferase (ALT) and aspartate aminotransferase (AST) in patients with non-alcoholic fatty liver disease compared to pre-treatment. The antioxidant effects of licorice constituents may play a role in its clinical effects, including its anti-inflammatory effects. Various chalcone and flavonoid constituents from licorice have been shown to have antioxidant effects. Licorice has antispasmodic properties. In human research, a specific product containing licorice constituents (TJ-68) inhibited colonic spasms during colonoscopy. Licorice is traditionally used as an antimicrobial, with in vitro research showing it has antifungal activity, as well as activity against both Gram-positive and Gram-negative bacteria. Licorice contains constituents such as glabridin, glabrol, and 3-hydroxyglabrol that possess antimicrobial activity in vitro. Clinical research in adults shows that swishing a tablespoon of a mouthwash containing licorice extract 1% once nightly before bed for 5 days might modestly reduce the number of Streptococcus mutans and Actinomyces viscosus when compared with using a saline solution. Licorice appears to block metabolism of prostaglandins E and F2 alpha, which suggests a possible beneficial effect on peptic ulcer. Preliminary information suggests deglycyrrhizinated licorice (DGL) may accelerate the healing of peptic ulcers. DGL seems to be similar to carbenoxolone for ulcer reduction without the fluid retention or electrolyte imbalance of carbenoxolone. Carbenoxolone is a semisynthetic derivative of glycyrrhetic acid that is used outside the US for treating gastric and duodenal ulcer disease. The effect of licorice on body fat is thought to be due to the inhibition of 11beta-hydroxysteroid dehydrogenase type 1 by glycyrrhetinic acid. Glycyrrhizin- and glycyrrhizic acid-containing intravenous preparations (Stronger Neominophagen C and Remefa S) show activity against hepatitis B and C in humans, but the trials are too small to draw any definitive conclusions. Preliminary evidence suggests that glycyrrhizin may inhibit the growth of the coronavirus, which is associated with severe acute respiratory syndrome (SARS). The exact mechanism of the antiviral effect of glycyrrhizin is not known. In human research, glycyrrhizin reduced the findings of HIV viral antigen, possibly due to inhibited HIV-1 replication and reduced hepatocellular damage due to chronic hepatitis B and C. Clinical research in children and adults with autoimmune conditions (i.e. chronic urticaria and IgA vasculitis) shows that taking compound glycyrrhizin (containing glycyrrhizin, glycine, and N-acetyl-cysteine or methionine) for 1 month may increase CD4 T cells and decrease CD8 T cells and IgE when compared with control. Preliminary clinical research and laboratory research in animal models, suggests that licorice reduces levels of total and low density lipoprotein (LDL)-cholesterol. The glucose-moderating effects are also attributed to its active constituents.

Peppermint is used for irritable bowel syndrome (IBS) due to its antispasmodic effects. These same effects can support the digestive system to find symptomatic relief of mild diarrhea. The antispasmodic activity appears to result from direct relaxing effects on the gastrointestinal tract smooth muscle. Peppermint oil may also inhibit potassium depolarization-induced responses in the intestine. This is thought to provide relief from the hypercontractility that is commonly found in patients with IBS. Peppermint has been shown to act as a radical scavenger and inhibit lipid peroxidation. Research shows that peppermint has benefits that make it likely effective for irritable bowel syndrome (IBS), and possibly effective for tension headaches and pressure ulcers. There is an additional therapeutic potential to benefit human health, as preliminary research suggests that peppermint aroma may improve cognition, attention, alertness, and tactile performance. Peppermint oil may act centrally to alter pain perception. Peppermint oil may help relieve esophageal spasms by reducing esophageal contractions and improving the uniformity of contractions. Peppermint oil does not affect lower esophageal sphincter pressure. Peppermint has exhibited liver protective effects in animal and laboratory research, likely mediated by antioxidant mechanisms.

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

There is limited data available on the exact pharmacokinetic properties of Progast® Multi-action Drops™. It is important to consider the pharmacokinetics of each active substance for this combination to understand its efficacy which is largely based on traditional use.

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® Multi-action Drops™ is in accordance with low-risk guidelines.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Inactive substances per 1 mL (approximately 20 drops):

- Alcohol..... 31% m/m

6.2. Incompatibilities

Not applicable; Liquid, tincture drops, oral pharmaceutical forms.

6.3. Shelf life

Progast® Multi-action Drops™ has a shelf life of 60 months. This shelf-life is determined by stability testing results.

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® Multi-action Drops™ may come in bottles of 20 mL, 50 mL, and 100 mL. The active substances provide a total of 428,32 mg per 1 mL (approximately 20 drops; or 21,42 mg per drop). Inactive substances are also provided (see section 6.1 ‘List of excipients’).

Progast® Multi-action Drops™ has a 1 mL (approximately 20 drops) dosage form with a specific appearance: Liquid, tincture drops, oral dosage form, light green-brown color, vertical dropper bottle, comes in ranges of 20 mL, 50 mL, or 100 mL, sealed with a white screwcap, the bottle is labeled. 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® Multi-action Drops™ 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.