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

Inolax® Forte Capsules

Strength

665 mg per capsule

Pharmaceutical form

Solid, hydroxypropyl methylcellulose capsules, oral

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains:

Aloe Ferox Mill. (Cape Aloe) powder [Leaf]	180 mg
Potassium chloride (Providing potassium (elemental) 52,45 mg	100 mg
Magnesium oxide (Providing magnesium (elemental) 48,16 mg	80 mg
Frangula purshiana Cooper (Cascara) powder [Bark]	80 mg
Senna alexandrina Mill. (Senna) powder [Leaf, 20% Sennosides extract]	70 mg
Foeniculum vulgare Mill. (Fennel) [Seed]	60 mg
Taraxacum campylodes G.E. Haglund (Dandelion) [Root, 4:1 extract]	35 mg
Rheum × *hybridum* Murray (Rhubarb) [Root, 5:1 extract]	30 mg
Malus domestica Borkh (Apple) pectin [Fruit]	25 mg
Zingiber officinale Roscoe (Ginger) [Root, 4:1 extract]	5 mg

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

- Inolax® Forte Capsules is for supporting the body to detox by helping relieve occasional constipation and stimulating bowel movement while benefitting overall health and wellbeing with a therapeutic antioxidant effect.
- Due to the active substances, Inolax® Forte Capsules are indicated for therapeutic use only from the age of 18 years and older.
- The active substances are useful for symptomatic relief of occasional constipation by supporting the digestive system. Its active substance potassium chloride may also support the maintenance of potassium levels given the laxative effect.
- It is a health supplement that contains important bowel stimulating and antioxidant properties and can be used to support the digestive system, supporting the small intestine and colon as a herbal laxative.
- Inolax® Forte 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.
- Inolax® Forte Capsules is a medicinal health supplement not intended (nor indicated) for maintenance or alternative maintenance therapy, but rather for symptomatic relief when this medicine is needed. It is not indicated as a cure-all or monotherapy for serious conditions because Inolax® Forte Capsules is 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, 665 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, 2 times daily, or 2 capsules, 1 time daily, for no longer than 10 days. This is the maximum recommended daily and/or total dose.

Duration of use

If the symptoms persist longer than 2 days during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.

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 antihypertensive medications, such as those used for blood pressure. However, if you are on heart medication used to treat arterial fibrillation, heart flutter, or heart failure, do not use this product. 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’).

Inolax® Forte 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. Inolax® Forte 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 antihypertensive medication, such as those used for blood pressure, may be safe. However, the concomitant use of this medicine with heart medication used to treat arterial fibrillation, heart flutter, or heart failure is not recommended and should be avoided. This is due to the herbal laxative substances which are likely to have an interaction with patient heart medication, and this interaction is based on theoretical pharmacology.

It is recommended that those who are already using prescription heart 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 part of aloe is the leaf. Aloe Ferox contain different active constituents and have different pharmacological effects. Potassium is essential in physiological processes. These processes include nerve impulse transmission, cardiac processes, smooth and skeletal muscle contractions, gastric secretion, as well as renal function and tissue synthesis. It is also important for carbohydrate synthesis. Magnesium is a component in many compounds and is an essential for non-inflammatory processes. The applicable part of alder buckthorn is the bark. Sennosides are prodrugs, which are not absorbed in the upper gastrointestinal tract. Instead, they are activated by bacterial enzymes in the colon. There is very little systemic absorption of senna. The applicable parts of fennel are the fruit (seed) and oil. Fennel seed is a rich source of beta-carotene and vitamin C. The applicable parts of dandelion are the above ground parts and root. Dandelion leaves and root contain quercetin, luteolin, p-hydroxyphenylacetic acid, germacranolide acids, chlorogenic acid, chicoric acid, and monocaffeyltartaric acid. The applicable parts of rhubarb are the stem, rhizome, and root. The active constituents include hydroxyanthracene derivatives, anthraquinones, tannins, and calcium oxalate. The applicable part of apple is the fruit. Apple contains polyphenols, ursolic acid, and pectin that may be responsible for some of its effects. The peel is a higher source of polyphenols than the flesh. 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

Aloe is commonly used for inflammatory bowel diseases and ulcers. In colorectal mucosa in vitro, aloe gel has an antioxidant effect, decreasing levels of colorectal prostaglandin E2 and interleukin-8. These effects may explain why aloe gel seems to help some patients with inflammatory bowel disease. There is interest in using potassium to alter calcium and phosphate homeostasis and improve bone health. A post-hoc analysis of a clinical trial has found that taking potassium supplements is associated with a lower level of fibroblast growth factor 23 (FGF23), decreased calcium excretion, and increased phosphate levels, but with no effect on parathyroid hormone or vitamin D levels. Theoretically, potassium supplements might increase markers of bone resorption and improve calcium and phosphate homeostasis. The laxative effects and diarrhea produced by magnesium salts are due to the osmotic effects of unabsorbed salts in the intestine and colon, and stimulation of gastric motility due to the release of gastrin and cholecystokinin. The anthraglycosides and the diglycosides of alder buckthorn are cathartic in the large intestine. They can increase intestinal motility by stimulating propulsive as opposed to stationary contractions, stimulating active chloride secretion, hence the use of an additional potassium chloride compound, while helping to increase water and electrolytes in the intestinal contents. Senna leaf and fruit contain sennosides, which are stimulant laxatives. The cathartic properties of the leaf are greater than the fruit. Senna is thought to exert its laxative effect by a selective action at the nerve plexus of intestinal smooth muscle, which increases colonic motility and speeds colonic transit. Fennel aids digestion. Theoretically, fennel extract reduces levels of triglycerides and total and low-density lipoprotein (LDL)-cholesterol. Levels of high-density lipoprotein (HDL)-cholesterol were increased in animal studies. This may also aid digestion for healthier cholesterol levels, and is traditionally used for diabetes and its known weight loss effects. Dandelion is traditionally used to increase appetite and bile stimulation. It further reduces symptoms of dyspepsia, flatulence, and gallstones. Moreover, as a choleretic, dandelion theoretically, based on pharmacology, increases both bile production

and flow to the gallbladder, and as a cholagogue, and so it may exert a direct effect on the gallbladder, causing contraction. The pectin in apple probably accounts for its effect on diarrhea and constipation. Pectin absorbs water in the gastrointestinal (GI) tract and swells to a gummy mass. The mass provides bulk which tends to alter gastrointestinal transit time and normalize bowel function. Ginger is a well-known gastroprotective, and has gastroprotective pharmacodynamic effects, traditionally used for stomach and gastrointestinal ailments. The gastroprotective effects, based on preliminary research and theoretical pharmacology, is due to increases in levels of protective prostaglandins in the gut wall.

It is also 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.

Although it may be safe for those using antihypertensive drugs, and no interactions have been observed, such as with blood pressure medication, theoretically, herbal laxatives may be unsafe for those using specific heart medications as they may interact with those medications used to treat arterial fibrillation, heart flutter, and heart failure. 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 Inolax® Forte 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 Inolax® Forte Capsules is in accordance with low-risk guidelines.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Inactive substances per capsule:

- Magnesium stearate

6.2. Incompatibilities

Not applicable; solid oral pharmaceutical forms.

6.3. Shelf life

Inolax® Forte 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

Inolax® Forte 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 665 mg per capsule. Inactive substance per capsule are provided also (see section 6.1 'List of excipients').

Inolax® Forte 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 Inolax® Forte 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.