

# Colon Therapy

(NPN 80008040)

ADVANCED Naturals

PRODUCT MONOGRAPH

## Product composition

Medicinal Ingredients:

Each capsule contains:

Magnesium (Magnesium hydroxide) .....	125mg
Cape Aloe leaf ( <i>Aloe ferox</i> ) .....	250mg
Slippery elm bark ( <i>Ulmus rubra</i> ) .....	50mg
Marshmallow root ( <i>Althaea officinalis</i> ) .....	50mg
Rhubarb root ( <i>Rheum palmatum</i> ) .....	200mg
Triphala: a blend of:	
Indian gooseberry fruit ( <i>Emblica officinalis</i> ) .....	16.7mg
Belleric myrobalan fruit ( <i>Terminalia bellirica</i> ) .....	16.7mg
Tropical almond fruit ( <i>Terminalia catappa</i> ) .....	16.7mg

Non-medicinal ingredients: Hypromellose, water

Recommended dose: Adults: Take one or two capsules in the evening on an empty stomach as needed. Produces action in 6-12 hours.

Duration of use: Consult a health care practitioner if constipated for more than 7 days.

## Indication:

- Supports the process of a colon cleanse by relieving occasional constipation.
- Relieves occasional constipation.
- Promotes bowel movement by direct action on the intestine.
- Promotes bowel movement.
- Laxative
- Cathartic

Contraindications: Do not use in the presence of abdominal pain, nausea, fever or vomiting (this refers to signs of appendicitis or inflamed bowel).

Do not use if you are pregnant or breastfeeding, or if you have Crohn's disease or ulcerative colitis.

Warnings: Keep out of reach of children.

Consult a health care practitioner prior to use if you have diabetes.

Precautions: Overuse or extended use may cause dependence for bowel function.

Laxatives should not be taken within two (2) hours of another medicine because the desired effect of the other medicine may be reduced.

Loose stools or diarrhea may occur. If loose stools persist, discontinue use.

Not to be used by children.

Adverse Effects: Loose stools or diarrhea may occur. If loose stools persist, discontinue use.

Not to be used by children.

Overdose: For management of suspected product overdose it is recommended to contact your physician.

Symptoms of Overdose: Has not been investigated nor any reports have been filed.

## Supporting Research and Traditional Evidence

### Magnesium (Magnesium hydroxide)

Magnesium is the fourth most abundant cation in the body mainly stored intracellularly or in the bones (Rude and Singer, 1981). Physiologically, magnesium is absorbed along the entire length of the small intestine and to some extent within the large intestine (Brannan *et al.* 1976). Magnesium can be taken safely in doses up to 500 mg/day for healthy adults (NHPD, 2007). Gastrointestinal effects associated with magnesium deficiency include dysphagia, a difficulty swallowing. The magnesium deficiency associated with dysphagia was found to be reversible upon magnesium supplementation (Flink, 1978). Clinical studies have been performed to assess the impact of a combination laxative treatment consisting of magnesium hydroxide and senna syrup, a traditionally used laxative. One hundred and nineteen constipated children were treated with either a bulk laxative or a combination of magnesium hydroxide/senna syrup at an average dose of approximately 4 teaspoons/day for 2 months. Following the completion of the study, 63% of the children taking the Magnesium/senna combination were no longer constipated suggesting that treatment with magnesium hydroxide in addition to herbal laxative remedies may contribute to increased bowel movements (Borowitz *et al.* 2005). A randomized, placebo-controlled, double-blind, crossover pilot study was conducted to evaluate the effects of magnesium hydroxide as a laxative in a dose dependent-manner. Six patients were given either placebo or

magnesium hydroxide at doses 1200, 2400 or 3600 mg/day for 5 days. The patients' stool output was monitored and the results suggested that magnesium hydroxide is effective as a laxative in a dose-dependent manner (Donowitz and Rood, 1992). The NHPD (2007) recognizes magnesium as a dietary supplement which contributes to the maintenance of good health, and scientific studies have demonstrated a good safety profile and a potential role as a laxative when taken at doses up to 500 mg/day.

### Cape Aloe leaf (*Aloe ferox*)

Aloe leaf has been traditionally used as a laxative when taken orally, as well as a treatment for certain skin conditions when applied topically (NHPD, 2006; Newall *et al.* 1996). Aloe contains anthrone-C-glycosides (Van Wyk *et al.* 1995) which are metabolized to yield 1,8-dihydroxy-anthracene, an pharmacologically active metabolite. 1,8-dihydroxy-anthracene has a stimulatory influence on the colon resulting in colonic motility through propulsive contractions to increase the rate of passage of material through the intestine. Alongside the increase in colon contractions, aloe also promotes chloride secretion into the intestinal lumen which increases water secretion and electrolyte diffusion into the lumen (Blumenthal *et al.* 1998). The anthraquinones present in aloe have stool-softening properties but do not disrupt the normal pattern of fecal excretion (Gruenwald *et al.* 2007). The recommended dose for aloe leaf is standardized to 20-30 mg hydroxyanthracene derivatives/day. The NHPD (2007) has recognized the dried leaf gel of *Aloe ferox* as effective as a natural laxative with a good safety profile at doses of 50-250 mg per day.

Clinical evidence suggests a role for *Aloe ferox* as a laxative. One placebo-controlled, double-blind clinical trial assessed the effects of a combination laxative therapy consisting of aloe, psyllium and celandine in 35 chronically constipated patients. The ingredients in the study preparation have similar effects on the gastrointestinal tract as the herbs present in this formulation of Colon Therapy. Psyllium has high mucilage content, similar to slippery elm bark, and celandine is a traditional herb used to soothe gastric irritation (Blumenthal *et al.* 1998). The study confirmed the effects of herbal combination therapy as an effective laxative for the treatment of constipation (Odes and Madar, 1991).

### Slippery elm bark (*Ulmus rubra*)

Slippery elm bark has been used traditionally to treat certain ailments such as constipation. The inner rind of the bark contains large amounts of mucilage. When ingested this mucilage mixture of polysaccharides coats the enteric lining. The ability of the mucilage to coat the gastrointestinal tract makes the herb useful as a traditional treatment for gastric inflammation by acting as a demulcent (Gruenwald *et al.* 2007; Bradley, 2006). The effective recommended dose for slippery elm is a decoction made with ethanol in a ratio of 1:8 and a daily dose of 4 -16 ml of the decoction (Gruenwald *et al.* 2007). A study by Langmead *et al.* (2002) evaluated the antioxidant properties of a slippery elm water extract on the treatment of irritable bowel syndrome. A dose-dependent scavenging of superoxide was observed suggesting that slippery elm may be implicated in the treatment of irritable bowel syndrome by reducing colonic inflammation-associated oxidative stress.

### Marshmallow root (*Althaea officinalis*)

Marshmallow has been used traditionally for the treatments of certain ailments and has also been classified as a food in Europe and the United States (Newall *et al.* 1996). The medicinal parts of the plant include the leaves, roots, syrup and flowers. Marshmallow root, in particular has been traditionally used in treatment of mild inflammation of the gastric mucosa. Constituents of the root include various mucilage polysaccharides, pectin, few tannins and aspariginines. Marshmallow root works in a similar manner as slippery elm bark. High levels of polysaccharide mucilage help reduce gastric inflammation by coating and soothing irritation of the enteric lining (Hoffman, 2003). The recommended effective dose with a good safety profile of Marshmallow root is 6 -15 g of root/day with a good safety profile (Blumenthal *et al.* 1998).

### Rhubarb root (*Rheum palmatum*)

Various parts of the rhubarb plant have been used traditionally for the treatment of certain ailments and as foods. Rhubarb stem has been classified as a food by the Council of Europe, and the root has been traditionally used to treat gastrointestinal irregularities, such as constipation (Newall *et al.* 1996). Rhubarb Root, like *Aloe ferox*, contains  $\beta$ -glycosides, including 1,8-dihydroxy-anthracene.



1,8-dihydroxy-anthracene is the active constituent and is responsible for the laxative properties of rhubarb (Bradley, 2006). This anthraquinone has a stimulatory influence on the colon resulting in colonic motility and propulsive contractions to increase the rate of passage of material through the intestine and reduce liquid absorption (Blumenthal *et al.* 1998). The recommended dose for Rhubarb root is 200 mg - 1000 mg/day to be efficacious as a laxative with a good safety profile (Newall *et al.* 1996). A recent review article summarized a few clinical studies which were not published in English. These studies focused on rhubarb root as a traditional Asian medicine. The article suggested that rhubarb root helped alleviate the symptoms associated with the treatment of various gastrointestinal conditions in a clinical setting, specifically gastric bleeding and enteroparalysis as well as contributing to the natural pH of the gastric mucosa (Chen and Wong, 2009).

### **Triphala: a blend of:**

#### **Indian gooseberry fruit (*Emblica officinalis*)**

Various parts of the Indian gooseberry plant have been traditionally used in Ayurvedic medicine. The leaves of the plant traditionally are used to treat respiratory ailments, while the fruits have been used to alleviate gastrointestinal discomfort, such as constipation and vomiting. The fruits are also a good source of nutrition (Williamson, 2002). The major constituents of *E. officinalis* are polyphenols, ascorbic acid, cytokinins and fatty acids. The fruit exhibits antioxidant activity in the presence of tannins to maintain gastrointestinal health. Studies have been conducted to assess the antioxidant properties of *E. officinalis*. A study by Pozharitskaya *et al.* (2007) quantified the free-radical scavenging activity and found it to be similar to that of ascorbic acid. A study by Bandyopadhyay *et al.* (2000) assessed the impact of seeds from *E. officinalis* as an antioxidant for the treatment of gastric ulcers in Sprague-Dawley rats. Prior to gastric injury, the rats were treated with dried gooseberry seed in increasing doses for 10 days. The antioxidant effect was measured by determining the abundance of superoxide dismutase, a free-radical scavenger in serum, abundance of lipid peroxidation and mucous secretion/ulcer formation of the gastric tissue. The results indicated that increased antioxidant activity correlated with a reduction in the formation of ulcers in the pre-treatment group. Lastly, a study by Scartezzini *et al.* (2006) suggests that 45-70% of the antioxidant activity of *E. officinalis* is derived from the high levels of vitamin C which it contains. In traditional Ayurvedic medicine, the recommended doses of Gooseberry fruit are 3-6 g or powder/day (Williamson, 2002). *E. officinalis* has demonstrated a good safety profile has been effectively used for the treatment of gastrointestinal discomfort as an ingredient in Triphala (Dhanao, 2001).

#### **Belleric myrobalan fruit (*Terminalia bellirica*)**

In traditional Ayurvedic medicine, Belleric myrobalan fruit has been used as a "health-harmoniser". The fruit of *T. bellirica* has been used in the treatment of various conditions affecting the liver, vasculature system, respiratory system, skin and gastrointestinal tract. The active constituents are mainly triterpenoids, such as  $\beta$ -sitosterol, and polyphenols (Williamson, 2002). Studies have been conducted to assess the role of *T. bellirica* in the treatment of gastric ulcers and obesity. Studies have implicated an antioxidant activity of Belleric myrobalan fruit in the presence of tannins, present in many of the additional herbs in this formula. A study by Soubir (2007) evaluated the antioxidant activities of a number of ethanolic plant extracts. Of the plant extracts assessed, *T. bellirica* was found to be the second most potent antioxidant, second only to *Averrhoa carambola*, commonly known as starfruit. The blend of *T. bellirica*, *E. officinalis* and *T. catappa* is known in Ayurvedic medicine as Triphala. *T. bellirica* has been traditionally used for the treatment of gastrointestinal problems in doses from 3 – 6 g of powder/day with an established good safety profile (Dhanao, 2001).

#### **Tropical almond fruit (*Terminalia catappa*)**

In Asian medicine, tropical almond fruit has been used as a food as well as an ethnobotanical treatment for certain gastrointestinal conditions, such as dysentery, gastritis and diarrhoea (USDA, 2002). Studies have implicated a strong antioxidant activity of *T. catappa* in the presence of tannins, which are present in the herbs of Triphala. A study by Kinoshita *et al.* (2007) demonstrated the ability of a water extract of *T. catappa* to scavenge various forms of reactive oxygen species, such as superoxide and peroxyl radicals. The study suggests that *T. catappa* extract provided protection to liver cells by reducing the quantity of oxidative species present within the tissue. *T. catappa* has demonstrated a good safety profile and has been shown to be an effective antioxidant and ethnobotanical supplement for the treatment of certain gastrointestinal ailments.

### **Ingredient Summary**

#### **Magnesium (Magnesium hydroxide)**

- Contributes to the maintenance of good health with a potential role for use as a laxative.

#### **Cape Aloe leaf (*Aloe ferox*)**

- Traditionally used as a laxative.

#### **Slippery elm bark (*Ulmus rubra*)**

- Traditionally used to reduce mild inflammation of the gastric mucosa.

#### **Marshmallow root (*Althaea officinalis*)**

- Traditionally used to reduce mild inflammation of the gastric mucosa.

#### **Rhubarb root (*Rheum palmatum*)**

- Traditionally used as a laxative.

### **Triphala: a blend of:**

#### **Indian gooseberry fruit (*Emblica officinalis*)**

- Provides antioxidant properties and traditionally used to support gastrointestinal health.

#### **Belleric myrobalan fruit (*Terminalia bellirica*)**

- Provides antioxidant properties and traditionally used to support gastrointestinal health.

#### **Tropical almond fruit (*Terminalia catappa*)**

- Provides antioxidant properties and traditionally used to support gastrointestinal health.

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