ADVANCED Naturals

PRODUCT MONOGRAPH

Deep Colon Cleanse

Product composition
Medicinal Ingredients:
Each scoop contains:
Organic Flax Seed (Linum usitatissimum).....9650 mg
Organic Gluten Free Oat Bran (Avena sativa) .....825 mg
Rhubarb Root (Rheum officinalis).....500mg
Organic Acacia Gum (Acacia senegal) .....550 mg
Organic Marshmallow Root (Althaea officinalis).....50 mg
Organic Slippery Elm Bark (Ulmus rubra) .....50 mg
Okra fruit (Abelmoschus esculentus).....25 mg
Phytogest Blend:
Organic Ginger Rhizome (Zingiber officinale).....25 mg
Organic Fennel Seed (Foeniculum vulgare).....25 mg
Papaya Leaf (Carica papaya).....10 mg
Organic Cayenne Pepper (Capsicum annuum) .....5 mg
Organic Coriander Seed (Coriandrum sativum).....5 mg
Organic Cumin Seed (Cuminum cyminum).....5 mg
Gentian Root (Gentiana lutea).....5 mg
Organic Black Pepper (Piper nigrum) .....5 mg
Organic Peppermint Leaf (Mentha piperita) .....5 mg
Organic Spearmint Leaf (Mentha spicata) .....5 mg
Cellulase 750 CU (Trichoderma reesei).....5 mg

Non-medicinal ingredients: FOS (Fructooligosaccharides), Cinnamon bark

Recommended dose: Adults: Take two scoops (25g) with 250ml (1 cup) of water in the evening. Drink plenty of water throughout the day while using this product.

Duration of use: None

Indication:
- Bulk-forming laxative.
- Promotes bowel movement by increasing bulk volume and water content.
- Gentle relief of occasional constipation (irregularity).

Contraindications: Do not take within 2 hours of other medications.
Do not use if you are pregnant, breastfeeding and/or if you have abdominal pain, nausea, fever or vomiting or if you have a chronic gastrointestinal disorder.

Warnings: Keep out of reach of children.
Consult a health care practitioner prior to use if you are taking blood thinners, or if constipation persists after one week of use.

Precautions: Not to be used by children

Adverse Effects: Some people may experience headaches when using gentian root.

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
Organic Flax Seed (*Linum usitatissimum*)
The usual cause of chronic constipation is a lack of adequate dietary fiber. In people who eat too little of fiber-containing foods, the stool becomes hard, dry and small. Whereas the soft, bulky stool can move easily along the passage of the colon, the hard, dry stool sticks to the dry wall of the colon and requires that the colon develop high-pressure waves to be moved. This straining produces pressure on all of the abdominal wall, forcing the development of hernias, varicose veins (due to pressure on the long veins of the legs), hiatus hernia (upward pressure forcing the stomach into the chest), diverticulitis and diverticulosis (weakening and infection of the colon wall), hemorrhoids, anal fissures and fistulae. Colorectal cancers may also be more common in patients with lifelong habit constipation. This may be due to the concentrated exposure of carcinogens to the colonic surface, as a result of the hard dry stool and its slow movement or evacuation. The primary focus of a bowel cleansing program is to promote mucosal detoxification to rid toxins from bowel bacteria and excretion through feces. This is mainly accomplished through increasing fiber which absorbs toxins for elimination, stimulates natural muscular movement in the colon, and reduces inflammation and soothes the bowel/colon.
Flax seed has been used traditionally for its laxative effects by increasing volume and initiating intestinal peristalsis, and for its protective effects on the intestinal mucosa (**Blumenthal et al, 2000; Willoughby *et al,* 1996; ESCOP, 2003**).
In a study to investigate the effects of flax supplement on physiological responses characteristic of soluble and insoluble fibre (i.e., laxation and glycemic response), 26 healthy adults consumed up to 15 g of fibre from either a proprietary flax fibre supplement or as psyllium supplement for 2 weeks. Results showed that flax fibre supplementation provides the benefits of soluble and insoluble fibre. Fecal weights and dietary fibre intake were measured at baseline. Changes in dietary fibre intake and acceptability of both products were evaluated. Increased fecal weight was found with both fibre treatments; supplemental fibre at intakes of 9.0 g/day (flax) and 10.4 g/day (psyllium) gave fecal bulking capacity of approximately 2.9 and 4.8 g of fecal weight/g of fibre, respectively. In a second trial to study the effect of flax bread versus control white bread on glycemic response, 11 subjects were fasted and completed four test periods under standardized glycemic testing conditions. Results showed that glycemic response was improved with ingestion of flax fiber. (**Dahl *et al,* 2005**)

Organic Gluten Free Oat Bran (*Avena sativa*)
Oat preparations are used for diseases and complaints of the GI tract including constipation. With oat bran consumption, bacteria and lipids contribute to increases in stool weight. Oat bran increases stool weight by providing rapidly fermented soluble fiber in the proximal colon for bacterial growth, which is sustained until excretion by fermentation of the insoluble fiber. (**Chen *et al,* 1998**) Additional safety evidence is provided below.
In an open-label prospective 12-week study to assess the benefit of bran in constipation, 50 elderly patients were given bran biscuits ('Lejfibre') twice daily in their diet. Treatment with bran produced a marked improvement in bowel frequency, stool consistency, and pain on defecation; no patients complained of side-effects. In addition to the improvement in bowel symptoms, mean body weight was significantly reduced at the end of the study (**Valle-Jones JC, 1985**).
In a randomized, controlled, repeated measures study (five 2-h meal glucose tolerance tests) to determine the postprandial glycemic response following ingestion of two different oat bran products, 12 patients with type 2 diabetes received either oat bran flour, oat bran crisp, or a glucose load (12.5 g glycemic carbohydrate). Separately, the effects of oat bran flour on postprandial glucose response were examined: 5 g glucose load alone vs. 25 g glucose load with 30 g oat bran flour. Finger-prick capillary blood analysis was carried out fasting and at 15, 30, 45, 60, 90 and 120-min intervals after the start of the meal. Results showed that oat bran flour high in beta-glucan had a low glycemic response than oat bran crisp in response to an oral glucose load in subjects with type 2 diabetes. (**Tapola *et al,* 2005**)
In a randomized open-label prospective 6-month safety study to assess the long-term effects of gluten-free oat bran (kilned) in patients with celiac disease (CD), 32 patients were given either kilned oats (regular industrially processed form) or unkilned oats. After 6 months, patient treatments were switched. The targeted daily intake was 100 g oats over one year. Food intake, symptoms, histology of the small intestine and the levels of endomysial antibodies were documented. No marked changes in duodenal biopsies, levels of endomysial antibodies, or in patient well-being were observed. Oats in either form were not harmful, indicating that its antigenic nature is not changed by common industrial food processing in such a way that would provoke CD. (**Kemppainen *et al,* 2008**)

Rhubarb Root (*Rheum officinalis*)
Rhubarb root (*Rheum officinalis*) has been used traditionally for occasional constipation (laxative properties) where soft stool is desirable. Doses up to 4 g daily have been shown to be safe and effective. (**Bradley, 1992; Newall, 1996**) The ingredient is supportive to the flaxseed in this product and provides complementary effect to the formula.
Chinese herbalists have relied on rhubarb rhizomes and roots for thousands of years. The rhizomes and roots contain powerful anthraquinones and tannins that act as stimulant laxatives and astringents, respectively. In traditional Chinese medicine, rhubarb root is also used to treat gastric ulcers.

Organic Acacia Gum (*Acacia senegal*)
Acacia gum (*Acacia seyal*), also known as gum Arabic, provides a source of soluble fibre to this product, aiding in constipation. Safety evidence is provided below.
In a randomized prospective 3-month study to assess the effect of gum arabic oral treatment on the metabolic profile of patients with chronic renal failure (CRF), 46 subjects (36 patients with CRF managed by hemodialysis; 10 healthy subjects) received either low-protein diet (LPD) and 50 g/day gum Arabic (n=12 patients with CRF); LPD, gum arabic, iron (ferrous sulphate, 200 mg/day), and folic acid (5 mg/day) (n=14 patients with CRF); LPD, iron, and folic acid treatment (n=10 patients with CRF); or normal diet and gum Arabic 50g/day (n=10 healthy subjects). Blood samples for the analysis of urea, creatinine, uric acid, calcium, and phosphorus were collected from each subject before admission to the study and twice per month (pre-dialysis) for 3 months. Serum creatinine levels were significantly decreased in Arabic gum users vs. the control group, suggesting that fermentation of the gum arabic by colonic bacteria aids in the reduction of the host's nitrogen waste products. However, no changes in serum uric acid levels were observed between the two treatment groups. Half of the subjects reported flatulence, which generally subsided after the second week of treatment; all patients completed the study. (**Ali *et al,* 2008**)
In a randomized prospective 4-week study to compare the cholesterol-lowering effects of two different mixtures of dietary fiber, 29 patients with hypercholesterolemia received either a medium viscosity mixture of water-soluble dietary fiber (WSDF: psyllium, pectin, guar gum and locust bean gum) or an equal amount of a low viscosity WSDF derived from acacia gum. WSDF treatments were provided in a low-calorie powder form for mixing into beverages. Patients were instructed to mix the powders into their usual beverages and to consume the beverage three times daily (5 g WSDF per serving) for 4 weeks. Patients consumed their regular fat-modified diets. Decreases in plasma lipid parameters were observed in the WSDF mixture (plasma total cholesterol decreased by 10%; low-density lipoprotein cholesterol decreased by 14%). No changes in lipid parameters were observed in the group treated with acacia gum. The data supported previous findings that diets rich in select WSDF may be useful in hypercholesterolemia. (**Jensen *et al,* 1993**)
In a randomized prospective 31-day study to compare the effects of psyllium, gum arabic, and placebo in patients with incontinence, supplementation with dietary fiber from psyllium or gum arabic was associated with decreased percentage incontinent stools and improved stool consistency. Patients were randomly assigned to receive psyllium, gum arabic, or a placebo, and recorded their diet intake and stool characteristics for 8 days before and at the end of the study. The dietary fiber supplements appeared to be completely fermented, as indicated by non-significant differences in stool total fiber, SCFAs and pH. (**Bliss DZ *et al,* 2001**)

Organic Marshmallow Root (*Althaea officinalis*)
Marshmallow root (*Althaea officinalis*) has been used traditionally for its diuretic and demulcent effects in gastro intestinal aliments such as ulcerations. Safety of the ingredient is well established up to doses of 5g daily. (**Bradley, 1992; Newall, 1996**) The ingredient is included in this product as supportive to flaxseed and provides minor complementary diuretic action.
Aqueous extracts from the roots of *Althea officinalis* are widely used for the treatment of irritated mucosa. Their clinical proven effects are related to the presence of bioadhesive and mucilaginous polysaccharides, leading to the physical formation of mucin-like substances on top of the irritated tissues. In vitro investigations of aqueous *A. officinalis* extract (AE) and raw polysaccharides on epithelial KB cells and primary dermal human fibroblasts (pNHF) showed that AE (1, 10 microg/mL) had stimulating effects on cell viability, vitality, and proliferation of epithelial KB cells. Aqueous extracts and polysaccharides from the roots of *A. officinalis* are effective stimulators of cell physiology of epithelial cells, supporting the traditional use of Marshmallow preparations for treatment of irritated mucous membranes within tissue regeneration (**Deters *et al,* 2010**).

Organic Slippery Elm Bark (*Ulmus rubra*)
Slippery elm bark (*Ulmus rubra*) has been used traditionally to treat inflammatory conditions of the digestive tract such as gastritis, peptic ulcer disease, or enteritis. The herb possesses demulcent properties and daily doses of up to 4 g in 500mL boiling water three times daily have been used. Equivalent tablets or other dosage forms are also permissible. (**Bradley, 1992; Newall, 1996**)

Okra fruit (*Abelmoschus esculentus*)
Okra (*Abelmoschus esculentus*) is a common food item and as such, poses no safe concerns (**Facciola, 1998**); daily ingestion of 100g okra was shown to be safe. (**Jenkins *et al,* 2005**). Okra is included in this product as an additional source of fiber.
In a randomized prospective 3-month study to compare the cholesterol-lowering potential of a dietary portfolio with that of a statin, 34 hyperlipidemic outpatients received either a very-low-saturated-fat diet (control), control diet plus 20 mg lovastatin (statin diet), or a diet high in plant sterols, soy-protein foods, almonds, and viscous fibers (oats, barley, psyllium, okra and eggplant) Subjects ingesting Okra daily reported no adverse events. (**Jenkins *et al,* 2005**)

Phytogest Blend:
Organic Ginger Rhizome (*Zingiber officinale*)
Ginger rhizome has been used traditionally to help relieve digestive upset and disturbances including lack of appetite, nausea, digestive spasms, indigestion, dyspepsia and flatulent colic (carminative) (**NHPD, 2009; Newall, 1996**) The inclusion of the ingredient provides digestive health support.
Ginger shares pharmacological properties with non-steroidal anti-inflammatory drugs; ginger suppresses prostaglandin synthesis through inhibition of cyclooxygenase-1 and cyclooxygenase-2. Ginger extract derived from *Zingiber officinale* (family Zingiberaceae) inhibits the induction of several genes involved in the inflammatory response, modulating biochemical pathways activated in chronic inflammation. (**Grzanna *et al,* 2005**)
Ginger has also been shown to improve gastroduodenal motility. The effect of a ginger rhizome extract (2 x 100 mg) was studied in 12 healthy subjects using stationary manometry. Fasting and postprandial gastroduodenal motility was measured and results showed significant increases in inter-digestive antral motility with ginger use. A trend to an increased motor response during ginger treatment was also seen in all other regions of interest. (**Micklefield *et al,* 1999**)

Organic Fennel Seed (*Foeniculum vulgare*)
Fennel seed (*Foeniculum vulgare*) has been used traditionally for digestive disturbances, including bloating and flatulence. (**NHPD, 2009; Blumenthal, 1998**) Individuals requiring laxative action may commonly experience such symptoms, which may be ameliorated by sweet fennel. The ingredient provides minor supportive action to flaxseed.

Papaya Leaf (*Carica papaya*)
Papaya leaf (*Carica papaya*) has been used traditionally for worm infestation under the property

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of vermifuge The ingredient provides very minor supportive action in the prevention of worm infestations and ultimately, provides gastrointestinal health. Daily doses of 60-120mg of the dried leaf have been proven safe (**Williamson, 2002**).

The anti-ulcer potential of extracts of papaya fruit were evaluated in a gastric ulcer model in rodents. Aqueous and methanol extracts of whole unripe Carica papaya fruit were tested using ethanol- and indomethacin-induced gastric ulcer in rats. The effect of the extracts on small intestinal propulsion was also investigated. Significant reductions in the ulcer index in both experimental models were observed compared to the control group. Intestinal motility was also significantly inhibited, with methanol extracts showing greater activity. The cytoprotective and antimotility properties of the extracts could account for the anti-ulcer property of the unripe fruit. (**Ezike *et al,* 2009**)

Organic Cayenne Pepper (*Capsicum annuum*)

Cayenne pepper (*Capsicum annuum*) has been used traditionally to aid digestion (**NHPD, 2009**). This property further supports digestive health in people seeking laxative action. The ingredient is minor supportive in the formula and proven to be safe based on the monograph .

In a randomized, double-blind 5-week study to investigate the effects of capsaicin in digestion, 30 patients with functional dyspepsia (without gastro-oesophageal reflux disease or irritable bowel syndrome) received either 2.5 g/day red pepper powder or placebo. Red pepper was more effective than placebo in decreasing the intensity of dyspeptic symptoms (60% vs. 30% decrease, respectively), using overall symptom score and epigastric pain, fullness and nausea scores. (**Bortolotti *et al,* 2002**)

Organic Coriander Seed (*Coriandrum sativum*)

Coriander seed (*Coriandrum sativum*) has been used traditionally for dyspeptic complaints and for stimulating the digestion. (**Blumenthal, 1998; Bradley, 2006**) In Germany, coriander is used as a medicinal tea and a component of carminative and laxative remedies (**Blumenthal, 2000**). This further supports its use in digestive health for individuals seeking laxative action. The ingredient is minor supportive to flaxseed and its safety is very well established for doses up to 3g daily.

Organic Cumin Seed (*Cuminum cyminum*)

Cumin seed (*Cuminum cyminum*) has been used for digestive complaints, especially for cramp-like stomach and intestinal problems, flatulence, and diarrhea (Teuscher, 2006). Safety evidence is presented below. The inclusion of the ingredient is minor supportive to Flaxseed claim.

The safety of the ingredient is supported by a clinical study that used multi ingredient product of which containing 25mg of Cumin seeds per tablet. The daily dose was one tablet before every meal which would account for a minimum of 3 meals daily. The daily dose in the study would have been providing a minimum of 75mg curcumin seeds. The current product provides 10mg of curcumin seeds daily. (**Said *et al,* 2008**)

A 3-month prospective study to examine the safety and tolerability of mixture of extracts including curcumin seeds (25 mg three times daily), was conducted in 80 healthy subjects. In vitro and preclinical components were also part of the study. The mixture of extracts was prepared with the leaves of *Alchemilla vulgaris* (60 mg), *Olea europaea* (50mg), *Mentha longifolia L.*(20 mg), and *Cuminum cyminum* (25 mg). Subjects were asked to continue with their regular diet of three meals daily, and to take one tablet 30 minutes before each meal. Fourteen subjects were excluded from the study results due to protocol non-compliance. The extract was well tolerated and no adverse effects were reported. (**Said *et al,* 2008**)

Gentian Root (*Gentiana lutea*)

Gentian root (*Gentiana lutea*) has been used traditionally to help relieve digestive disturbances and dyspepsia (**NHPD**). This ingredient may therefore be of benefit in individuals using laxative products. Doses of 0.1 to 6 grams per day of the dried root have been proven safe. Gentian root provides a minor supportive role to flaxseed in this product.

Organic Black Pepper (*Piper nigrum*)

Black pepper (*Piper nigrum*) has been used traditionally for stomach and digestive disorders. (Williamson, 2002) Evidence of safety is presented below. The ingredient provides a minor supportive role to flaxseed, in support of digestive health for individuals using laxative products.

In a study to examine the effects of red and black pepper on small intestinal peristalsis, 16 healthy subjects were given either powdered red pepper (2 g) or black pepper (1.5 g) in gelatin capsules, followed by measurements of orocecal transit time (OCTT) using the lactulose hydrogen breath test. Increases in OCTT were observed after red pepper and black pepper consumption, which was attributed to the known effects of capsaicin, a potent stimulator of many biologically active peptides. Although the effect of spices on OCTT is likely to vary depending upon the dose and nature of the product, it is of clinical importance in the management of various gastrointestinal tract disorders. (**Vazquez-Olivencia *et al,* 1992**)

In a 6-week randomized, double-blind study to assess the effects of red and black pepper on the gastric mucosa, 8 healthy subjects received meals containing red pepper (0.1g, 0.5g, and 1.5 g), black pepper (1.5 g), aspirin (655 mg; positive control) and distilled water (negative control). Each subject received 6 spice preparations, separated by a 1-week interval. Serial gastric washes were performed after test meal administration and gastric contents were analyzed for DNA, pepsin, blood, sodium, potassium, parietal cell secretion, and nonparietal cell secretion. Both red pepper and black pepper caused significant increases in parietal secretion, pepsin secretion, and potassium loss. Gastric cell exfoliation was also increased. Effects of both red and black pepper were comparable to aspirin in all parameters studied. The only adverse reaction reported was mucosal microbleeding, which was possibly dose-related. The current product provides 10mg daily. (**Myers *et al,* 1987**)

Organic Peppermint Leaf (*Mentha piperita*)

Peppermint leaf (*Mentha piperita*) has been used traditionally to aid digestion and for the relief of flatulence and dyspepsia. (**NHPD**). The daily dose of the ingredient provided by the product is well within safety limits of the NHPD Monograph.

Organic Spearmint Leaf (Mentha spicata)

Spearmint leaf (*Mentha spicata*) shares many of the properties of traditional digestive aids, commonly used as an antispasmodic. (**Bulat *et al,* 1999**) The safety of this species of mint is fully established, used commonly as a food item eaten ad libitum. (**Facciola, 1998**)

Cellulase 750 CU (*Trichoderma reesei*)

Cellulase enzyme has been included in the formula to support digestive function. Evidence of safety is provided in studies by Bonilla, 1999, Heiwinkel, 1960, and in case reports provided by Wortzel, 1977. No significant adverse reactions were observed in any of these studies.

In a 1-year prospective study to analyze the efficacy of cellulase in gastric phytobezoars, 7 patients diagnosed with gastric phytobezoars by gastroscopy were treated with cellulase. Complete dissolution of the gastric phytobezoars was observed in all 7 patients after 1 year. No side effects or recurrence was reported in follow-up. Researchers concluded that cellulase should be regarded as the treatment of choice for gastric phytobezoars. (**Bonilla *et al,* 1999**)

Cellulose activity was examined following oral administration of different cellulose preparations isolated from Penicillium notatum. The enzyme concentration necessary for significant breakdown of vegetable foodstuffs was determined; and subsequently, each tablet was formulated as 200 units (enzyme activity was 5 units per mg). Each patient took 2 to 3 tablets three times per day: total 1200 to 1800 cellulase units per day. Patients were asked to record any adverse effects throughout the trial. One of the 50 patients complained of nausea and one patient elected to withdraw from the study. No toxic effects were observed based on the dosages studied. (**Heiwinkel *et al,* 1960**)

Ingredient Summary:

Artichoke leaf (*Cynara scolymus*) 4:1 extract
- Bulk-forming laxative.
- Promotes bowel movement by increasing bulk volume and water content.
- Gentle relief of occasional constipation (irregularity).

Organic Gluten Free Oat Bran (*Avena sativa*)
- Bulk-forming laxative.
- Promotes bowel movement by increasing bulk volume and water content.
- Gentle relief of occasional constipation (irregularity).

Rhubarb Root (*Rheum officinalis*)
- Rhubarb has been used traditionally both as a laxative and an antidiarrhoeal agent.

Organic Acacia Gum (*Acacia Senegal*)
- Acacia gum is included in this product as a source of soluble fibre, aiding in constipation.

Organic Marshmallow Root (*Althaea officinalis*)
- Marshmallow root has been used traditionally as a demulcent; in gastro-enteritis, peptic and duodenal ulceration, common and ulcerative colitis, and enteritis.

Organic Slippery Elm Bark (*Ulmus rubra*)
- Slippery Elm Bark has been used traditionally for inflammation or ulceration of the stomach or duodenum, convalescence, colitis, diarrhoea and locally for abscesses, boils and ulcers.

Okra fruit (*Abelmoschus esculentus*)
- Okra is included in this product as an additional source of fiber

Phytogest Blend:

Organic Ginger Rhizome (*Zingiber officinale*)
- Ginger rhizome has been used traditionally to help relieve digestive upset/disturbances including lack of appetite, nausea, digestive spasms, indigestion, dyspepsia and flatulent colic (carminative).

Organic Fennel Seed (*Foeniculum vulgare*)
- Fennel seed has been used traditionally to help relieve digestive disturbances including bloating and flatulence.

Papaya Leaf (*Carica papaya*)
- Contributes to liver health

Organic Cayenne Pepper (*Capsicum annuum*)
- Cayenne pepper has been used traditionally to aid digestion.

Organic Coriander Seed (Coriandrum sativum)
- Coriander seed has been used traditionally for dyspeptic complaints and loss of appetite.
- Coriander seed has been used traditionally as a carminative (flatulence), weakly spasmolyic, and as a stimulant to the digestion.

Organic Cumin Seed (*Cuminum cyminum*)
- Cumin seed has been used traditionally to for digestive complaints, especially for cramp-like stomach and intestinal problems, flatulence, and diarrhea.

Gentian Root (*Gentiana lutea*)
- Gentian Root has been used traditionally to help relieve digestive disturbances/dyspepsia.

Organic Black Pepper (*Piper nigrum*)
- Black Pepper has been used traditionally for stomach and digestive disorders and colds and bronchitis.

Organic Peppermint Leaf (*Mentha piperita*)
- Peppermint Leaf has been used traditionally to aid digestion (stomachic) and to help relieve flatulent dyspepsia.

Organic Spearmint Leaf (*Mentha spicata*)
- Spearmint leaf has been included in the formula to support digestive health.

Cellulase 750 CU (Trichoderma reesei)
- Cellulase has been included in the formula to support digestive function.

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