Motility Assist™

Author: Joseph Katzinger, ND

Active Ingredients: Digexin® (Ashwagandha root extract and Okra fruit extract), 300 mg per serving; Triphala fruit extracts (10:1) [comprised of Amla (Amalaki) (Emblica officinalis) 4 parts – 40%, Bibhitaki (Terminalia bellirica) 2 parts – 20%, and Haritaki (Terminalia chebula) 1 part – 10%], 70 mg per serving; Fennel seed extract (Organic, 10:1), 70 mg per serving; Ginger root extract (5% gingerols), 60 mg per serving.

Other ingredients: Microcrystalline Cellulose, hypromellose (capsule), leucine complex, silica

Overview

Motility Assist™ is a unique, safe, and effective botanical formulation that promotes healthy digestion and regular bowel movements as a non-laxative, non-stimulant, and non-habit-forming solution. The botanicals in Motility Assist have extensive use as traditional medicines and foods, signifying their safety for both short and longer-term use. They also have complementary biological effects that promote healthy digestion and intestinal transit, including modulation of neurotransmitters found in the enteric nervous system, such as serotonin and GABA; protection of the intestinal barrier and upregulation of tight junctions; enhancement of peristalsis; and a reduction in gastrointestinal inflammation and oxidative stress.

Clinical trials have demonstrated robust responses to the ingredients in Motility Assist. Digexin®, a proprietary blend of Ashwagandha and Okra extracts, has been proven to rapidly reduce symptoms of constipation and improve intestinal transit. It also improves sleep quality, mood, and stress levels, with increases in serotonin and reductions in cortisol, suggesting multiple unique mechanisms that support digestive and overall health. Triphala has an extensive history of use in Ayurvedic and other traditional medicines as both a gastrointestinal tonic and a *tridoshic rasayana,* a promoter of longevity and rejuvenation. Lastly, extracts of fennel seeds and ginger root add carminative, anti-inflammatory, and anti-spasmodic effects that promote gastrointestinal motility and relief from gastrointestinal distress.

Active Ingredients

Digexin® (Ashwagandha root extract and Okra fruit extract)

Scientific Evidence:

A proprietary and standardized 1:1 blend of Ashwagandha (*Withania somnifera*) root and Okra (*Abelmoschus esculentus*) fruit extracts, Digexin® has been shown in two randomized and double-blind clinical trials not only to improve intestinal transit, symptoms of constipation, and various markers of gastrointestinal (GI) function, but to also improve non-gastrointestinal factors, including sleep quality and perception of stress.[1,2]

Ashwagandha, widely used in Ayurvedic and Unani medicine for many centuries, has a diverse phytochemistry of bioactive compounds, including 40 withanolides (steroidal lactones) to which many of its physiological effects are attributed, as well as alkaloids, steroids (β-sitosterol, stigmasterol, etc.), and flavonoids (kaempferol and quercetin). Many *in vitro* and preclinical studies indicate that Ashwagandha has anti-inflammatory, immunomodulatory, adaptogenic, and neuroprotective activities, and also modulates neurotransmitter activity, including both GABA and serotonin.[3,4,5] In clinical trials, this neuromodulation may explain observed improvements in sleep quality, mood, and perceived stress, as well as decreases in morning cortisol levels and increases in serum serotonin levels.[6,7,8]

Neuromodulation may also partly underlie Ashwagandha's influence on the GI system. In an additional randomized and double-blind controlled clinical trial, Ashwagandha was shown to reduce stress and anxiety among healthy adults, accompanied by increases in serotonin.[9] Serotonin's prevalence in the GI tract and its role in the enteric nervous system (ENS) has been established, with strong evidence that it activates motor responses and promotes neurogenesis, as evidenced by the use of serotonin agonists to treat constipation.[10] Ashwagandha also reduces sympathetic tone via GABAergic activity, likely a contributor to the observed improvements in anxiety and sleep in clinical trials.[11] This same GABAergic effect in the upper GI tract may enhance the secretion of gastrin and promote peristaltic movement.[12,13]

Okra is widely consumed as a vegetable but has also been used as a traditional medicine and is gaining recognition as a functional food. The majority of its biologically active components are flavonoids, polyphenols, polysaccharides, and fatty acids, with *in vitro* and experimental data indicating that okra has antioxidant effects and improves intestinal function, glycemic control, and hyperlipidemia.[14,15,16] The pectin-like rhamnogalacturonans found in the mucilage of Okra also have an anti-adhesive action in the gastric mucosa against *H. pylori.* Additionally, Okra extracts have been shown to reduce inflammation and modulate the intestinal microbiome (with an increase in the abundance of *Akkermansia*) in animal experiments.[17,18,19]

The unique combination of Okra and Ashwagandha found in Digexin® provides relief from constipation, with improvements in both GI and non-GI factors reflective of these underlying

mechanisms.[20] In the first of two recent double-blind and randomized controlled trials that enrolled adults with functional constipation, 300 mg and 500 mg per day of Digexin® significantly improved the Patient Assessment of Constipation-Symptoms (PAC-SYM) index within 7 days, with total scores improving by 78-93% after two weeks, including improvements in sub-scale scores that assessed abdominal, rectal, and stool symptoms. Additionally, significant improvements (compared to placebo and baseline) were also observed in the Patient Assessment of Constipation-Quality of Life (PAC-QOL) and Gastrointestinal Symptom Rating Scale (GSRS) scores, as were improved sleep quality and reduced stress, accompanied by increased serum serotonin, gastrin, and interleukin-10 and decreased interleukin-6 and cortisol levels. Notably, 87-93% of participants receiving Digexin® were free from constipation by the study's end, with increases of 106-127% in Complete Spontaneous Bowel Movement (CSBM) scores.[1]

The second controlled trial was larger and lasted for 60 days, and added additional assessments related to GI transit time, depression and anxiety, and functional laboratory markers, including diamine oxidase (DAO) and zonulin. The same doses of Digexin® had similar improvements in PAC-SYM scores, again with significant gains by day 7, and gradual improvement through day 60. Significant improvements were also observed in PAC-QOL, GSRS, and CSBM scores, along with improvements in gastrointestinal transit time (GIT), sleep quality, and symptoms of anxiety and depression. Digexin® supplementation was also associated with significant increases in DAO, serotonin, and gastrin, and a significant decrease in cortisol compared to placebo. Significant improvements compared to baseline (but not placebo) were also observed in IL-10, IL-6, and zonulin levels. An increase in DAO activity may indicate a greater tolerance toward dietary histamine, as it catalyzes the degradation of histamine and other biogenic amines, primarily in the digestive tract; notably, constipation is a frequent consequence of histamine intolerance.[21] Similarly, the reduction in zonulin suggests an improvement in intestinal barrier function, and the lack of significance (compared to placebo) may be reflective of the similarity in zonulin levels between healthy controls and people with functional constipation -- i.e., zonulin may not be a relevant marker for functional constipation.[22]

Triphala fruit extracts (Amla, Bibhitaki, and Haritaki)

Scientific Evidence:

Triphala is an Ayurvedic formula used in traditional medicine for over 1000 years, comprised of the fruits of three botanicals: Amla (also known as *Emblica officinalis*, *Phyllanthus emblica*, Indian Gooseberry, or Amalaki), Bibhitaki (aka *Terminalia bellirica*, or bastard myrobalan), and Haritaki (aka *Terminalia chebula*, or black myrobalan). Traditionally, Triphala has been used as a gastrointestinal tonic for constipation and to promote bowel frequency and digestion; it has also been utilized for inflammation, weight loss, and cardiovascular disease.[23,24]

Triphala contains many biologically active components which are responsible for antioxidant, anti-inflammatory, and antimicrobial effects.[24] For example, Amla contains alkaloids, polyphenols, and multiple hydrolyzable tannins (including ellagitannins and gallotannins), derived from ellagic acid and gallic acid, respectively, noted for antioxidant and anti-inflammatory qualities.[25] The antioxidant and anti-

inflammatory effects of an Amla extract plausibly underlie the reductions in C-reactive protein and improvements in endothelial function observed in two randomized and double-blind placebo-controlled trials.[26,27] Similarly, Bibhitaki contains phenols, flavonoids, tannins, terpenes, as well as gallic acid and chebulagic acid, with the latter shown to have activity against *H. pylori* both *in vitro* and in animal studies.[28] Haritaki contains nearly 150 biologically active compounds, including at least 60 tannins (broadly categorized as gallotannins, ellagitannins, and chebulic ellagitannins), as well as flavonoids (e.g., luteolin, rutin, isoquercetin, and quercetin), triterpenoids, and lignans, with established antioxidant, anti-inflammatory, and anti-bacterial effects.[29] Haritaki was shown to have a similar benefit to endothelial function in a randomized and controlled clinical trial.[30]

While human clinical trials evaluating Triphala's effects on gastrointestinal function are limited, animal studies indicate a prokinetic and laxative effect (Amla) mediated in part by activation of muscarinic receptors, as well as a protective effect against oxidative intestinal damage induced by methotrexate, particularly with higher concentrations of Amla (as found in Motility Assist).[31,32] Although each botanical in Triphala has been studied individually, they are often used in combination, and a recent metabolomic analysis provides evidence for complementary and synergistic activity when used together. Over 2,500 metabolites were detected in this analysis, with only 4.4% shared by all three fruits, and 74% contributed uniquely from one of the three. This diversity underscores the complementary nature of the combination; for example, polyphenols present in Haritaki appear to complement the flavonoids in Amla, allowing for a broader spectrum of antioxidant and anti-inflammatory activity when used together.[33]

Fennel seed extract

Scientific Evidence:

Fennel (Foeniculum vulgare) is thought to be one of the oldest medicinal botanicals, used primarily to promote improved digestion and bowel transit; to reduce gas, bloating, constipation, and intestinal spasm; and to regulate the motility of the smooth muscles of the GI tract.[34] Rich in volatile oils, phenolic compounds, and flavonoids, such as quercetin-3-glucuronide, isoquercitrin, and rosmarinic and chlorogenic acids, fennel has a wide range of bioactive compounds with antioxidant and anti-inflammatory activity. It is particularly rich in trans-anethole, which appears to have carminative activity (in part by relaxing intestinal smooth muscles) as well as effects that improve glycemic metabolism.[35,36] Animal models also indicate that anethole may restore delayed gastric emptying, which may explain its historical use for dyspepsia.[37] Fennel also contains fenchone, a bicyclic monoterpene shown to have both anti-inflammatory and cytoprotective activity related to the intestinal barrier in animal studies.[38] Extracts of fennel seed were shown to improve intestinal barrier function and increase intestinal tight junction complexes, using both *in vitro* and *in vivo* models, at least in part by inhibiting the phosphorylation of STAT1 (Signal Transducer and Activator of Transcription), thereby preventing transcription of inflammatory genes.[39]

Although clinical studies evaluating fennel in isolation are limited, fennel has been a component of combination herbal formulas shown to improve symptoms of constipation in clinical trials.[40,41] Fennel

has also been shown to reduce infantile colic in a randomized trial.[42] In controlled clinical trials, fennel tea has been shown to improve digestive function following laparoscopic surgery, including a more rapid recovery of bowel motility, and supplementation with fennel (standardized to anethole) was shown to reduce the flatulence rate following Cesarian section.[43,44]

Ginger root extract

Scientific Evidence:

Ginger has a long history of traditional use for treating a variety of gastrointestinal conditions, with many of its bioactive compounds associated with anti-inflammatory, hepatoprotective, and digestive-stimulant effects.[45] Ginger's many active constituents include volatile oils, gingerol analogues, diarylheptanoids, phenylalkanoids, and sulfonates. Over 70 compounds have been identified in the volatile oil alone, including sesquiterpenoids and monoterpenes, primarily α-zingiberene and smaller amounts of β-sesquiphellandrene, β-bisabolene, β-phellandrene, and geraniol. The pungent and warm sensation of ginger is largely attributed to the gingerol analogues, including gingerols (predominantly 6-gingerol), shogaols, paradols, and zingerone.[46] Over 40 diarylheptanoids compounds have been discovered in ginger, many with antioxidant, anti-inflammatory, and hepatoprotective properties. Various components of ginger have been shown to have protective effects on the gastrointestinal, nervous, and cardiovascular systems, as well as on the liver and kidneys.[46]

Many of ginger's constituents have also been shown to have anti-inflammatory effects. *In vitro* and animal studies have outlined several mechanisms of action for 6-gingerol, for example, including prevention of reactive oxygen species formation, upregulation of the Nrf2 pathway, inhibition of p38 MAPK activation, down-regulation of the NF-κB pathway, and protection against LPS-induced inflammation, all of which have been associated with the protection of the intestinal mucosa and maintenance of an intact barrier.[47,48,49,50] *In vitro* studies also suggest that ginger has favorable effects on the gut microbiome, promoting the growth of beneficial bacterial populations, such as *Bifidobacterium* and *Enterococcus*, as well as enhancing the production of short-chain fatty acids.[51] Animal models also indicate reductions at the genus level in *Escherichia, Shigella,* and *Bacteroides* despite overall increases in bacterial diversity, as well as restoration of the tight junction protein, zonula occludens-1 (ZO-1).[52]

Ginger is well-recognized for its ability to improve many digestive symptoms, partly attributed to an acceleration of gastric emptying and stimulation of antral contractions, helping to improve digestion within the stomach.[53] For example, several clinical trials have shown that ginger supplementation enhances gastric emptying and stimulates antral contractions in healthy people, those with functional dyspepsia, and patients hospitalized with acute respiratory distress syndrome.[54,55,56] Among people with functional dyspepsia, a high gingerol extract (>26%) was also shown to substantially improve symptoms such as postprandial fullness, upper abdominal bloating, and early satiation in a randomized and placebo-controlled trial, with 79% classified as "responders" to treatment.[57]

Additionally, ginger has also been shown to have a carminative effect, reduce intestinal cramping, and decrease pressure on the lower esophageal sphincter.[53] A combination of ginger and

artichoke leaf extracts significantly improved symptoms of dyspepsia, including nausea, epigastric fullness and pain, along with bloating within a 4-week period in a randomized and placebo-controlled clinical trial, potentially via a weak inhibition of cholinergic M_3 and serotonergic 5-HT_3 receptors.[58,59] Ginger has been shown to improve gastroduodenal motility in both a fasting and non-fasting state.[60]

Ginger's effectiveness for nausea relief is well established, and several mechanisms of action likely underlie ginger's anti-emetic effects, although 5-HT_3 receptor antagonism is perhaps the strongest candidate.[61] Interestingly, these receptors have been recently linked with inflammatory and metabolic disorders, providing another pathway for ginger's broad effects.[62] The antiemetic and antinausea activities of ginger have been demonstrated in numerous clinical trials and assessed in several systematic reviews and meta-analyses, demonstrating efficacy during pregnancy and post-operatively, as well as for nausea/vomiting associated with chemotherapy.[63,64,65,66]

Motility Assist Safety Summary

The botanicals in Motility Assist have no known warnings, precautions, or contraindications at the recommended dose. However, it is contraindicated in individuals allergic to any of the individual ingredients, including individuals with a known allergy to carrots, celery, or other plants in the Apiaceae family.[67] Several of the botanicals in Motility Assist may have a favorable effect on blood glucose levels, thus, careful monitoring of blood glucose should be done while taking anti-diabetic medications. Unlike pharmaceutical laxatives, no habit-forming effect has been observed for any of the ingredients. Although the botanicals in Motility Assist have a long history of use and are often consumed as foods, they do not all have available safety data during pregnancy and lactation, and should be used under supervision.[3,24,68,69]

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