

Total Lung Therapy

ADVANCED Naturals

PRODUCT MONOGRAPH

Product composition

Medicinal Ingredients:

Each capsule contains:

Hyssop Leaf (<i>Hyssopus officinalis</i>) 10:1 Extract (equivalent to 1000 mg).....	100 mg
N-Acetyl-Cysteine.....	200 mg
Fenugreek Seed (<i>Trigonella foenum-garicum</i>) 10:1 Extract (equivalent to 1500 mg)	150 mg
Thyme Leaf (<i>Thymus vulgaris</i>) 4:1 Extract (equivalent to 400 mg) ..	100 mg
Mullein Leaf (<i>Verbascum thapsus</i>).....	100 mg
Vitamin C (as ascorbic acid)	50 mg
Ginger Root, Rhizome (<i>Zingiber officinale</i>) 4:1 Extract (equivalent to 200 mg)	50 mg

Non-medicinal ingredients: Hypromellose

Recommended dose: Adults: Take 3 capsules in the morning on an empty stomach.

Duration of use: For prolonged use please consult a health care practitioner.

Indication:

- Provides Hyssop which traditionally is used as a tonic to strengthen and soothe the mucous tissue of both respiratory and gastrointestinal tract.
- Provides Hyssop which traditionally is used as an expectorant to relieve coughs and other affections of the chest.
- Provides Hyssop which traditionally is used to strengthen the respiratory system (a pectoral).
- Provides Fenugreek which traditionally is used in Herbal Medicine as an expectorant to help relieve excess mucous of the upper respiratory passages (anti-catarrhal).
- Provides Thyme which traditionally is used in Herbal Medicine as an expectorant to help relieve the symptoms of bronchitis and catarrhs of the upper respiratory tract (anti-catarrh).
- Provides Thyme which traditionally is used in Herbal Medicine to help relieve coughs (spasmodic).
- Provides Ginger which traditionally is used in Herbal Medicine as an expectorant and anti-tussive to help relieve bronchitis as well as coughs and colds.
- An antioxidant for the maintenance of good health.
- Provides Fenugreek which is used in Herbal Medicine as a nutritive tonic.

Contraindications: Do not use if you are pregnant, breastfeeding, and/or if you have a fever.

Warnings: Keep out of reach of children.

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

Precautions: Not to be used by children.

Adverse Effects: If symptoms are severe or persist for more than 2 days, consult a health care practitioner. If cough worsens, persists for more than 7 days or is accompanied by high fever, consult a health care practitioner. Consult a health care practitioner if symptoms persist or worsen.

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

Hyssop Leaf (*Hyssopus officinalis*)

Hyssop Leaf has been used in traditional herbal medicine for the treatment of certain respiratory ailments, such as common colds, bronchitis and asthma (Blumenthal *et al.* 1998; Bradley, 2006). The leaf of the plant contains pharmacologically active constituents including essential oils, phenylpropanoids, tripterenes, tannins and the principal flavonoid diosmin (Bradley, 2006).

Hyssop leaf is generally recognized as safe (GRAS) in the US and permitted for use as a flavouring in Europe (Bradley, 2006). The NHPD (2006) recognizes Hyssop leaf as an effective remedy for coughs, as well as to soothe the mucous tissue of the respiratory tract with a good safety profile when taken at recommended doses up to 12 g daily.

N-Acetyl-Cysteine

N-acetyl-cysteine is a derivative of the amino acid L-cysteine. L-cysteine can be acquired through diet and metabolized to generate N-acetyl-cysteine which is a commonly prescribed mucolytic in Europe. Scientific evidence suggests that N-acetyl-cysteine is an effective treatment for acute respiratory tract infections. A systematic review of the literature was recently compiled by Duijvestijn *et al.* (2009) to assess the safety and efficacy of N-acetyl-cysteine in the treatment of upper and lower respiratory infections. Six randomized clinical trials were evaluated to assess the efficacy and 34 studies were evaluated to assess the safety of the amino acid-derivative. The authors conclude that beneficial effects on prevalence and severity of respiratory infections were associated with treatment with N-acetyl-cysteine. This review demonstrates a role for N-acetyl-cysteine as effective for the reduction of frequency, intensity and duration of symptoms associated with acute respiratory infections with a good safety profile when taken in recommended doses.

Fenugreek Seed (*Trigonella foenum-garicum*)

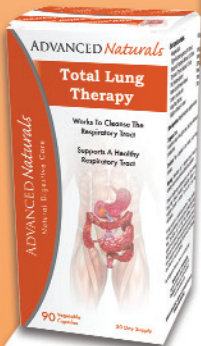
Fenugreek seed has been traditionally implicated in herbal medicine as a secretolytic to increase mucous production and soothe the respiratory tract (Blumenthal *et al.* 1998; Newall, 1996). The medicinal component includes steroidal saponins, mucilage polysaccharides, flavonoids, lipids, sterols and various volatile phytochemicals (Blumenthal *et al.* 1998; Bradley, 2006).

In vitro studies have been conducted to assess the antioxidant properties of fenugreek seeds. A study by Nautiyal *et al.* (2008) investigated the antioxidant properties of several dietary vegetables and fruits. Of the fruits and vegetables assessed, *T. foenum-garicum* demonstrated one of the highest phenolic contents and free radical scavenging abilities when compared to the other vegetables or fruits. A second study compared the antioxidant effects of the aerial parts of the fenugreek with antioxidant properties of the seeds. The results of the study suggest that the seeds possess higher levels of antioxidants when compared to the aerial parts of the plant (Bajpai *et al.* 2005). Furthermore, a study by Dixit *et al.* (2005) also assessed the antioxidant properties of germinated fenugreek seeds and found that even germinated seeds possess antioxidant potential. Supplements of antioxidants are important for the maintenance of good health. Fenugreek seed is generally recommended as a safe (GRAS) for consumption as a food in the US and is permitted as a flavouring by the Council of Europe (Bradley, 2006). The NHPD (2009) recognizes fenugreek as effective as an anti-catarrhal and nutritive tonic with an established safety profile when taken at recommended doses of 2-30 g of seed daily.

Thyme Leaf (*Thymus vulgaris*)

Thyme has traditionally been used as an expectorant, antitussive and antispasmodic to alleviate the symptoms associated with bronchitis and coughs (Blumenthal *et al.* 1998; Newall, 1996). Various phytochemical constituents are present in thyme, including essential oils, such as thymol and carvacrol, monoterpene glycosides, biphenyls, flavonoids, phenylpropanoids, hydroxybenzoic compounds, acetophenone glycosides, triterpenes and polysaccharides (Bradley, 2006).

Clinical trials have been performed to assess the effects of thyme on the symptoms associated with bronchitis and coughs. A randomized, double-blind, placebo-controlled, multicentred phase IV study was conducted to evaluate the effects of a combination bronchitis therapy containing thyme and evening primrose. The treatment lasted 11 days and the results suggested that treatment with the evening primrose/thyme therapy was more effective in reducing the symptoms associated with bronchitis when compared to placebo-control (Kemmerich, 2007). Furthermore, the researchers evaluated the effects of thyme when combined with ivy leaves in patients suffering from bronchitis. The patients were randomly given ivy/thyme tablets or placebo for a duration of 11 days. The results of the study suggest that the ivy/thyme therapy was more effective than placebo for the relief of coughs associated with bronchitis (Kemmerich *et al.* 2006). Thyme leaf and oil are commonly used in cooking as flavourings (Newall, 1996). The NHPD (2008) recognizes thyme leaf when taken orally at recommended doses of 1 – 8.4 g daily as effective for relief of coughs associated with bronchitis as well as an anti-catarrh with a good safety profile.



Mullein Leaf (*Verbascum thapsus*)

Parts of the mullein plant, such as petals and leaves, have been used in traditional herbal medicine as anti-cattarhals (Blumenthal *et al.* 1998; Bradley, 2006). Active phytochemical in the leaf include iridoid glycosides, such as aucubin, flavonoids, aponins, polysaccharides, triterpenes and sterols (Bradley, 2006). *In vitro* evidence suggests a role for mullein leaf as an anti-viral. Extracts of mullein leaf were found to protect cultured cells from influenza A infection (Rajbhandari *et al.* 2007). Mullein has been accepted as a flavouring agent in the US and Europe (Bradley, 2006). Scientific and traditional evidence has suggested mullein leaf as effective for use as an expectorant and demulcent with a good safety profile.

Vitamin C (as ascorbic acid)

Vitamin C is a potent antioxidant which is important for the maintenance of good health. Clinical evidence suggests that supplementation with antioxidants has a beneficial effect on the respiratory health by reducing the symptoms associated with infections of the respiratory tract. A randomized double-blind study by Romieu *et al.* (2001) investigated the effects of a combination antioxidant therapy on lung function in children living in highly-polluted areas. Children were given a supplement containing 50 mg of vitamin E and 250 mg of vitamin C daily for 6 months. The results of the study suggest that antioxidant supplementation was associated with improvements in lung function in areas with poor air quality. A second randomized double-blind multi-centred study assessed the effects of an herbal preparation containing vitamin C in preventing respiratory tract infections in 430 children. Subjects were given 50 mg/mL echinacea, 50 mg/mL propolis, and 10 mg/mL vitamin C, or placebo twice daily for 12 weeks. Results of the clinical trial suggest that combination herbal therapy, containing the antioxidant vitamin C, reduced the prevalence and severity of respiratory tract infections in children (Cohen *et al.* 2004). Finally, the effects of vitamin C supplementation alone on the symptoms of upper respiratory tract infection in athletes were assessed. In a double-blind randomized clinical trial, runners were supplemented with 600 mg vitamin C, or placebo daily for 21 days. Supplementation with vitamin C was associated with a reduction in the prevalence of upper respiratory infections (Peters *et al.* 1992). Overall, clinical evidence suggests vitamin C is a potent antioxidant which contributes to respiratory health when taken as a daily supplement. The NHPD (2007) recognizes vitamin C as effective as an antioxidant with a good safety profile when taken in recommended doses of 6 – 2000 mg daily.

Ginger Root, Rhizome (*Zingiber officinale*)

Traditionally ginger root has been used as an anti-tussive and expectorant. The root contains various phytochemicals including starch, lipids, oleo-resins, such as gingerol, and volatile oils, such as zingiberene, ar-curcumene, β -sesquiphellandrene and β -bisabolene (Blumenthal *et al.* 1998). Studies have been conducted to assess the clinical effects of ginger. In a randomised, double-blind, placebo-controlled, cross-over study the effects of ginger extract on gastric emptying and clinical symptoms associated with acute respiratory distress syndrome (ARDS) were assessed. Thirty-two patients suffering from ARDS were supplemented with 120 mg of ginger root extract or, 1 g coconut oil as placebo, daily for 21 days. Supplementation with ginger extract was associated with a reduction in the development of nosocomial pneumonia and gastric emptying when compared to placebo control (Shariatpanahi *et al.* 2010). Lastly, an anti-bacterial study was conducted to evaluate the effects of ginger on the treatment of respiratory pathogens. Bacterial swabs were taken from 333 patients suffering from various respiratory infections. Ginger extract was observed to elicit anti-bacterial effects on *Staphylococcus aureus*, *S. pyogenes* and to a lesser extent *S. pneumoniae* and *H. influenza* based on inhibition of bacterial growth *in vitro* (Akoachere *et al.* 2002). Scientific evidence suggests that ginger may be effective in alleviating the symptoms associated with respiratory infections. The Council of Europe and the US have classified ginger as a GRAS (Generally Recognised as Safe) food and states it is generally used as a spice (Newall *et al.* 1996). The NHPD recognizes ginger as effective as an expectorant and anti-tussive with an established safety profile at doses of 0.3-3 g dried rhizome, per day (NHPD, 2009).

Ingredient Summary:

Hyssop Leaf (*Hyssopus officinalis*)

- Traditionally used as a tonic to strengthen and soothe the mucous tissue of both respiratory and gastro-intestinal tract.
- Traditionally used as an expectorant to relieve coughs and other affections of the chest.
- Traditionally used to strengthen the respiratory system (a pectoral).

N-Acetyl-Cysteine

- Helps reduce symptoms associated with acute respiratory infections.

Fenugreek Seed (*Trigonella foenum-garicum*)

- Traditionally used in Herbal Medicine as an expectorant to help relieve excess mucous of the upper respiratory passages (anti-cattarhal).
- Used in Herbal Medicine as a nutritive tonic.

Thyme Leaf (*Thymus vulgaris*)

- Traditionally used in Herbal Medicine as an expectorant to help relieve the symptoms of bronchitis and cattarhs of the upper respiratory tract (anti-cattarh) ingredient.
- Traditionally used in Herbal Medicine to help relieve coughs (spasmolytic).

Mullein Leaf (*Verbascum thapsus*)

- Traditionally used as an expectorant and demulcent.

Vitamin C (as ascorbic acid)

- An antioxidant for the maintenance of good health.

Ginger Root, Rhizome (*Zingiber officinale*)

- Traditionally used in Herbal Medicine as an expectorant and anti-tussive to help relieve bronchitis as well as coughs and colds.

References

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