

Echinacea Purpurea 1200 mg Capsule



Product Summary:

Echinacea purpurea has a long history of traditional use for fighting off colds, influenza and infections, especially upper respiratory infections. Best results are achieved with adequate dosing of the herb at onset of infection, requiring at least 2.5 grams in adults. Echinacea Purpurea 1200 mg capsule allows for more efficient dosing to fight infection and reduce duration of symptoms.

Properties/Uses:

The claim as approved by the *Natural Health Product Directorate* (NHPD): Supportive therapy in the treatment of upper respiratory tract infections (e.g., common colds). Helps to relieve the symptoms and shorten the duration of upper respiratory tract infections.



GENERAL HEALTH
& WELLNESS



Pharmacology:

Echinacea is a perennial herb found in Eastern and Central United States and Southern Canada. While there are nine species of Echinacea, three are most commonly used as medicinal products – *Echinacea angustifolia*, *E. purpurea*, and *E. pallida*.¹

Historically, Echinacea was the most commonly used herb amongst Native North Americans for a variety of conditions including wounds, insect bites, infections, toothache, joint pain, and as an antidote for rattlesnake bites. It was adopted for medicinal use by settlers and became part of the U.S. National Formulary from 1916 to 1950.² In the early 20th century it was established as the remedy of choice for cold and flu and was commonly used as an anti-infective until the advent of modern antibiotics.¹

Its use in North America declined until the 1980s when consumer interest grew in immune stimulants for conditions such as AIDS, cancer, and chronic fatigue syndrome. Since then, it has made resurgence as a remedy for viral infections including influenza and the common cold.¹ It has been one of the top selling herbal products in Canada and the United States for several years.³

While the immune-modulating or stimulating effects of *E. purpurea* have not been attributed to one single constituent, cichoric acid, polysaccharides and alkylamides are considered to be the most important for modulating the innate immune system.⁴ In vitro studies have demonstrated that *E. purpurea* increases proliferation of phagocytes in the spleen and bone marrow, stimulates phagocytic activity of macrophages⁵⁻⁸, increases the production of cytokines crucial to immune function such as interleukin-1 (IL-1), interleukin-6 (IL-6) and tumour necrosis factor-alpha (TNF-alpha)⁹⁻¹¹, and enhances natural killer (NK) cell function in human peripheral blood mononuclear cells (PMNs), as well as their adherence to endothelial cells.^{12,13} In particular, experiments conducted in healthy, elderly mice found that 2 weeks of oral doses of Echinacea returned NK cell numbers in bone marrow and spleen to levels of young adults and also resurrected the cell functional capacity for target cell binding and lysis.¹² These observations appear to be unique to Echinacea, as the researchers were unable to rejuvenate the NK cell-mediated component of the immune system in elderly mice by any other typical NK cell enhancers.¹⁴ It is thought such actions may be predominantly mediated via alkylamides and indicates the potent prophylactic role of Echinacea.

Emerging research presented at the Congress on Natural Products Research in Phoenix, Arizona in 2004 also signifies that alkylamides are critical to immunomodulation and thus prophylaxis. Two independent researchers reported the binding of alkylamides to the cannabinoid receptors, particularly acting as agonists of cannabinoid-2 receptors (CB-2).^{15,16} CB-2 receptors predominate in immune tissues, especially the spleen, and are believed to modulate immune function and inflammation.¹⁷ Furthermore, alkylamides from other plants have not been found to bind CB-2 receptors, pointing to Echinacea's unique ability to modulate the immune system.¹⁸

While in vitro evidence is strong for Echinacea's ability to modulate the immune system, debate still exists regarding its efficacy as a prophylactic and an acute treatment for upper respiratory tract infections in human. Great variation in the species of Echinacea used, types of preparations, study designs and populations are responsible for the discrepancy that exists in the literature. However, despite such discrepancy, several meta-analyses indicate positive trends amongst studies examining Echinacea's use in the common cold.





A 2006 Cochrane Database Review set out to assess whether Echinacea preparations were 1) more effective than no treatment; 2) more effective than placebo; and 3) similarly effective to other treatments in the prevention and treatment of the common cold. Randomized controlled trials that compared mono-preparations of Echinacea with a placebo, no treatment, or another treatment for prevention or treatment of common colds were included. Of the 16 trials reviewed, 22 comparisons of an Echinacea preparation and a control group (19 with placebo, 2 with no treatment, 1 with another herbal preparation) met inclusion criteria and the majority were considered to have good methodological quality. Three of the comparisons investigated prevention of colds and 19 comparisons tested treatment of colds. None of the three comparisons in the prevention trials showed an effect over placebo. However, comparing an Echinacea preparation to placebo for treatment, showed a significant effect in nine comparisons, a trend in one, and no difference in six. While the preparations varied greatly, evidence supported that the aerial parts of *Echinacea purpurea* might be effective for the early treatment of colds in adults. The authors concluded that Echinacea for preventative purposes might exist, but require more rigorous randomized trials.¹⁹

The following year, in 2007, a meta-analysis answered whether the incidence and duration of the common cold could be modified by Echinacea. The analysis of 14 unique trials indicated that Echinacea decreased the odds of developing the common cold by 58% and the duration of a cold by 1.4 days.²⁰

However, it has been suggested that studies of naturally occurring colds are hampered by variability in time from onset of symptoms to treatment and by heterogeneity in trial design. Experimental infection studies allow for the standardization of time to initiation of treatment, virus type and dose, and immune competence of volunteers. A meta-analysis of 3 trials of experimental infection found that the likelihood of experiencing a clinical cold was 55% higher with placebo than with Echinacea. Symptom score was also reduced in the treatment groups.²¹

The debate over the efficacy of Echinacea preparations as prophylactic, treatment, or both, marches on as new research continues to be published. A 2010 randomized, controlled trial²² found that a tablet formulation of 675 mg of *E. purpurea* root and 600 mg of *E. angustifolia* root did not statistically reduce the duration or severity of the common cold. However, the study did show a trend toward benefit, with Echinacea groups experiencing lower illness duration and global severity. Also, nasal neutrophil counts and IL-8 levels in nasal wash tended to increase faster in the Echinacea groups than control groups. Although Echinacea experts commented on the overall study being well designed, questions as to appropriate dose, timing of delivery and formulation were raised. Study author, Kerry Bone, feels that Echinacea has a limited value in altering the common cold once it has taken hold, reinforcing that animal experiments suggest Echinacea takes time to exert its immune effects and is best suited to prophylactic use.²³

The concept of prophylactic use was reinforced in a subsequent randomized, double blind, placebo-controlled clinical trial of 175 participants travelling return from Australia to North America, Europe or Africa for 1 to 5 weeks. Active tablets each contained 1.275 g Echinacea root (with 4.4 mg alkylamides). A priming dose was 2 pills per day until time of travel, then dose was increased to 4 pills per day and illness dose was 6 pills per day. The placebo group exhibited significantly higher average respiratory infection symptom score (almost double) compared with the Echinacea group 4 weeks after return from travel.²⁴





While the common cold or other viruses can cause upper respiratory tract infections, there is also the risk that secondary infections can occur, as well as possible concomitant symptoms such as pharyngitis. However, it has been demonstrated that *E. purpurea* has anti-bacterial properties against several organisms including *S. pyogenes*, *H. influenza*, *L. pneumophila*, and *S. aureus*. *E. purpurea* has been found to reverse proinflammatory activities as well readily kill certain organisms.²⁵

A 2012 review²⁵ of *E. purpurea* in infectious disease highlights that studies of *E. purpurea* indicate multiple actions of the herbal preparation, resulting either from the individual activities of several compounds or the synergistic effect of different compounds. The resulting benefits are: (1) direct virucidal activity/activities against several viruses involved in respiratory infections, at concentrations which are not cytotoxic; (2) direct bactericidal actions against certain potentially pathogenic respiratory bacteria; (3) inactivation of other microbial pathogens relevant to humans and their domesticated animals; (4) reversal of the proinflammatory response of epithelial cells and tissues to various viruses and bacteria; (5) modulation of certain immune cell functions; and (6) reversal of the excessive mucin secretion induced by rhinovirus. The author concluded that a combination of these beneficial activities could reduce the amount of prevailing viable pathogens, and their transmission and also lead to amelioration of the symptoms of the infection, supporting the role of Echinacea in infectious disease prophylaxis and treatment.





Manufactured product information:

Manufacturer:

WN Pharmaceuticals Ltd.

Size/UPC:

120's 7 77747 10263

NPN:

80031474

Expiry Date:

36 months from date of manufacture

Active Ingredient:

Each capsule contains:

Echinacea 3:1 Concentrate.....400 mg(equivalent to 1200 mg raw herb)
(*Echinacea purpurea*) (aerial parts and root)

Non-Medicinal Ingredients (in descending order):

Gelatin capsule (gelatin, purified water), dibasic calcium phosphate dihydrate, magnesium stearate

Appearance:

Green powder in a hard gelatin capsule.

Packaging:

225 cc white round bottle with safety seal under a 45 mm white induction sealed cap with vented interior seal and a label applied to the bottle. Lot number and expiry date are printed on label applied to exterior of bottle.

Storage:

Store in a tightly-closed container in a cool, dark and dry place. Protect from humidity.





Dose:

Research has examined a number of different dosage ranges, preparations and species of Echinacea. Dosing should be specific to the components of the plant utilized in the preparation, as well as preparation method. The following dosing is specific to the preparation of *E. purpurea* composed of dried herbal tops and root, as indicated in the NHPD monograph:

Children 2-4 years: 0.5-0.9 grams per day taken at the first sign of infection.

Children and adolescents 5-9 years: 0.8-1.4 grams per day taken at the first sign of infection.

Adolescents 10-14 years: 1.5-2.8 grams per day taken at the first sign of infection.

Adults and adolescents 15 and over: 3-5.5 grams per day taken at the first sign of infection.

Directions:

(Adults): 2 capsules, 4 times daily at the first sign of infection, or as recommended by a physician. Consult a physician for use beyond 8 weeks.

Caution:

The caution as approved by the *Natural Health Product Directorate* (NHPD): KEEP OUT OF THE REACH OF CHILDREN. Do not use if you are allergic to plants of the Asteraceae/Compositae/Daisy family. Hypersensitivity (e.g., allergy) has been known to occur, in which case discontinue use. Consult a physician prior to use if you have a progressive systemic disease such as tuberculosis, leucosis, collagenosis or multiple sclerosis. Consult a physician prior to use if you are taking immunosuppressants or if symptoms persist or worsen. STORE AT ROOM TEMPERATURE IN A DARK, DRY PLACE. DO NOT USE IF SEAL UNDER CAP IS BROKEN OR MISSING.

Deficiency Symptoms:

N/A

Drug Interactions /Contraindications:

E. purpurea should not be used by individuals with known allergy to the Asteraceae/Compositae/Daisy family. Herbs in this family include: ragweed, marigolds, daisies and chrysanthemums.



Theoretical contraindication was suggested by the German Commission E surrounding the use of Echinacea species in autoimmune conditions, due to the immunostimulatory effects of the herb. The contraindications for Echinacea preparations in cases of HIV and AIDS, tuberculosis, leukosis, collagenosis, and multiple sclerosis have been misinterpreted to mean that Echinacea use can exacerbate such conditions; however, there is no clinical evidence to support this concern.^{26,27} The reason for the Commission's caution was based on theoretical concerns and because such conditions are not amenable to self-medication.²⁶ As such, some believe caution may still be warranted.²⁷

However, a cogent argument by Australian phytotherapist, Kerry Bone, suggests that there is no rational basis for this contraindication and in fact, current clinical practice, previous prolonged use by Eclectic physicians in the United States in the latter nineteenth and early twentieth centuries, and proper evaluation of modern scientific data support long-term use of Echinacea preparations for autoimmune disorders.²⁸ Furthermore, recent research in mice with autoimmune diabetes did not show adverse effects when fed *E. purpurea* root²⁹, nor did a controlled clinical trial of patients with autoimmune uveitis who were able to reduce their time on prednisone when given *E. purpurea*.³⁰

Due to the theoretical concern of *E. purpurea* in autoimmune conditions, it has been suggested that patients using immunosuppressant drugs may need to exercise caution, as efficacy could be reduced. However, this is unlikely given the information outlined above.

In vivo research indicates *E. purpurea* may have the potential to affect the cytochrome P450 system. In particular, drugs metabolized by CYP 3A and 1A2 pathways may be affected. However, in clinical terms, there has been no practical body of human data indicating *E. purpurea* has significant adverse cytochrome P450 interactions.³¹

Concern has also been expressed that pyrrolizidine alkaloids (PA) found in *E. purpurea* might exert hepatotoxic effects when taken on a long-term basis, exacerbating the harmful effects of concurrently used hepatotoxic drugs. However, the magnitude of any hepatotoxic effect is questioned since *E. purpurea* lacks the specific class of PA that contains the 1, 2-unsaturated ring system responsible for hepatotoxicity.³²

A literature review¹, as well as the German Commission E monograph of *E. purpurea*²⁶ indicates that recommended doses during pregnancy are safe and do not confer any risk of teratogenicity. Further study is required to determine if any concern exists during lactation.¹



Toxicity/Adverse Reactions:

Toxicity

Standard toxicological assessment methods have not demonstrated any *E. purpurea* toxicity in animals.²⁷ The LD₅₀ in mice is over 2500 mg/kg³³ and the LD₅₀ of intravenous Echinacea juice is 50 mL/kg.³⁴ Four weeks of oral dosing of male and female rats at 800, 2400 and 8000 mg/kg per day of *E. purpurea*, demonstrated no evidence of toxic effects in laboratory tests or necropsy findings.³⁴ Such doses far exceed human therapeutic dosage. Tests for mutagenicity carried out on microorganisms and mammalian cells in vitro and in mice all yielded negative results. In vitro carcinogenicity testing using *E. purpurea* did not produce malignant transformation in hamster embryo cells.³⁴ The authors of these studies concluded that favourable toxicology results and several decades of experience in human use allow *E. purpurea* to be classified as non-toxic, particularly in reference to genotoxic risk.³⁴

Adverse Reactions

Historically, the incidence of adverse effects with *E. purpurea*, have been very low. The German Commission E monograph²⁶ only indicates adverse reactions associated with parenteral use of *E. purpurea*.

Between 1989 and 1995, there were only 13 adverse events reported to the German Federal Health Authority, of which, four were allergic skin rashes determined to be clearly caused by Echinacea exposure.³⁵

Australian researchers have noted that individuals with atopy may be more likely to encounter an allergic reaction.^{36,37}

Echinacea adverse effects reported in California all fit into a category of mild, manageable at home and rarely resulting in severe outcomes or sequelae.³⁸

It should be noted that epidemiological evidence supports the safe use of Echinacea, given that the ratio of reported serious adverse effects, compared to the estimated number of courses of Echinacea treatment, is respectively 100 to more than 10 million, yielding a risk estimate of 1 in 100,000.²⁷



Allergen Content/Ingredient Sensitivity:

NO	YES
Artificial Colours	Sulphites (<10 ppm)
Artificial Flavours	
Artificial Sweeteners	
Corn Products	
Egg Products	
Fish	
Gluten	
Hydrolyzed Plant Protein	
Lecithin	
Milk Products	
Peanuts	
Preservatives	
Sesame Products	
Shellfish	
Soy Products	
Starch/Modified Starch	
Tartrazine	
Tree Nuts	
Wheat Products	
Yeast	

NOT ACCEPTABLE FOR THE FOLLOWING DIETARY RESTRICTIONS

Free of animal products

Kosher





References:

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