

V CLEAR EPs 7630™ UPPER RESPIRATORY SUPPORT

V Clear EPs 7630 is a homeopathic preparation containing a proprietary extract—EPs 7630—obtained from the roots of the South African *Pelargonium sidoides* plant. V Clear EPs 7630 does more than mask symptoms; it addresses the cause to help shorten the duration of upper respiratory tract irritations. When taken at the first sign of symptoms, V Clear EPs 7630 has been clinically shown to reduce symptom severity in a variety of conditions, including the common cold, bronchial irritations, nasal congestion, and sore throat.

A Clinically Proven Solution

In one multicenter study, the EPs 7630 group recovered from bronchial irritations nearly twice as fast as placebo (84.4 vs. 45.0% on day 7).¹ In another study involving children and adolescents, use of EPs 7630 resulted in nearly three times the improvement in symptoms versus placebo on day 7 (Change in BSS) of 3.4 vs. 1.2.²

- Exclusive, clinically proven extract with more than 20 clinical trials
- Shortens duration and reduces severity of upper respiratory tract irritations
- Studied in more than 9,000 patients, including 3,900 children
- Proven tolerability in adults and children
- Available in original drops or 99.9% alcohol-free cherry flavor syrup



wheat free



gluten free



soy free



dairy free



1. Chuchalin AG, et al. Treatment of ... in adults with a *Pelargonium sidoides* preparation (EPs 7630): a randomized, double-blind, placebo-controlled trial. *Explore* 2005;1:437-445.
2. Kamin W. *Pelargonium sidoides* extract EPs 7630 in the treatment of ... in children and adults—an overview of recent results. *Planta Med* 2007;73:822.

V CLEAR EPs 7630™

Background

A member of the Geraniaceae family, *Pelargonium sidoides* DC. is native to the coastal regions of South Africa.¹ The plant is notable for its narrow deep red flowers and its large heart-shaped leaves.

How It Works

The EPs 7630 extract contains primarily polyphenols (mainly catechin and gallic acid), proteins, minerals, and, in lower concentrations, 7-hydroxycoumarin derivatives.² These coumarin derivatives differ in chemical structure from the known anticoagulant coumarins and are not associated with anticoagulant activity.³

Pharmacological studies have suggested that the mechanism of action of EPs 7630 is multifactorial.⁴ Studies have found that EPs 7630 may act as an immunomodulator, help support the body's defense mechanisms, and possess antimicrobial actions *in vitro*. These actions are mediated mainly by the release of tumor-necrosis factor (TNF- α) and nitric oxide, stimulation of interferon- α synthesis, and increase of natural killer cell activity.⁵ Studies have also found that EPs 7630 increases phagocytosis.⁶ Finally, EPs 7630 has also been found to stimulate ciliary activity *in vitro*.⁷ This action may support a mucolytic effect during acute upper respiratory tract irritations.

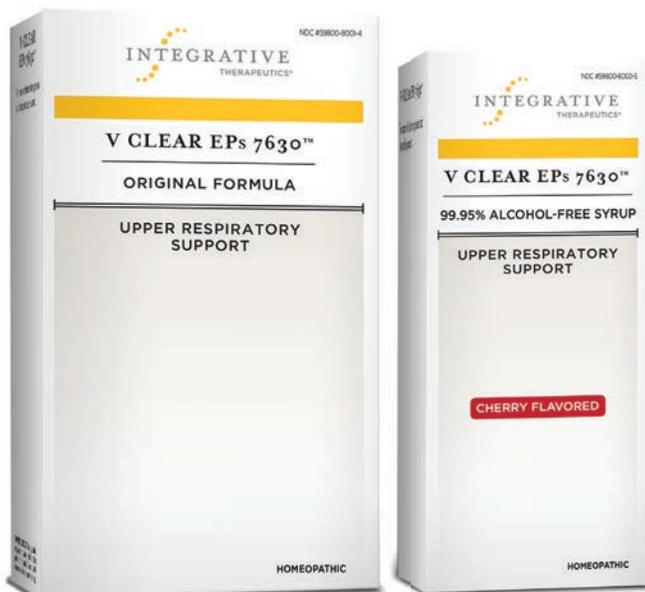
Clinical Overview

EPs 7630 has been shown to reduce the duration and severity of acute respiratory tract irritations, including the common cold.^{2,8} The efficacy and tolerability of EPs 7630 has been demonstrated in over 9,000 patients, including 3,900 children, in both controlled double-blind studies as well as open-label and post-marketing surveillance studies.

Bronchial Irritations

A meta-analysis was published in 2008 of six randomized, controlled clinical studies demonstrating the tolerability and efficacy of EPs 7630 in both adults and children.⁹ While one study compared EPs 7630 against N-acetylcysteine, the other five were placebo-controlled trials. All studies treated patients for 7 days. The primary outcome measure was a severity score called BSS, which evaluates changes in cough, sputum, rales/rhonchi, chest pain during coughing, and dyspnea.

The authors concluded that all studies demonstrated a significant decrease in the BSS after 7 days of treatment with EPs 7630. In one study with 468 adult patients, onset of relief was noted within 4 days after beginning treatment in 53.6% of those taking EPs 7630 compared to only 36.2% in the placebo group.¹⁰ On day 7, the BSS had decreased by 5.9 ± 2.9 in the EPs 7630 group and by 3.2 ± 4.1 in the placebo group compared to baseline ($p < 0.0001$). Another study ($n = 124$) found an improvement in the BSS of 7.2 for the EPs 7630 group compared to 4.9 for the placebo group ($p < 0.0001$).¹¹ Finally, in a third study ($n = 217$) complete remission in cough was noted after 7 days in 51.9% of those taking EPs 7630 compared to only 11.9% in the placebo group.¹² No serious adverse events were reported in any of the studies reviewed. The authors of the review conclude, "Currently available data from six high quality randomized clinical trials suggests there is encouraging evidence that *P. sidoides* is effective compared to placebo."



Additional clinical studies have focused on the efficacy and tolerability of EPs 7630 for bronchial irritation and bronchitis specific symptoms (BSS) in children and adolescents.¹³⁻¹⁸ In a 2010 randomized, double-blind, placebo-controlled trial, the dose response to EPs 7630 compared to a placebo was studied on male and female subjects ages 6-18 years ($n=399$).¹³ Subjects enrolled in the study had a < 48 hr onset and >5 symptom score of individual BSS symptoms at screening: coughing, sputum production, pulmonary rates at auscultation, chest pain while coughing and dyspnea. Subjects received EPs 7630 in doses of either 30 mg/day ($n=100$), 60 mg/day ($n=99$), 90 mg/day ($n=99$), or placebo ($n=101$) for a mean duration of 7 days. The primary outcome measure was BSS total score from day 0 to day 7. The authors concluded that the

decrease in BSS symptoms was significantly better in the EPs 7630 groups (60 mg/day): 4.4 ± 2.4 and EPs 7630 (90 mg/day): 5.0 ± 1.9 , between day 0 and day 7, compared with the placebo group. The mean reduction of individual symptoms of the BSS score was distinctly more evident in the EPs 7630 (60 mg) and EPs 7630 (90 mg) groups than the placebo group. The EPs 7630 groups demonstrated a significant dose-dependent improvement compared with placebo for 'coughing' ($p < 0.0001$), 'sputum' ($p < 0.0016$), and 'pulmonary rates at auscultation' ($p < 0.0001$). A significant benefit of early relief from BSS symptoms over placebo was noted, with onset observed on days 3-5 in the EPs 7630 (60 mg): $p < 0.0060$, and EPs 7630 (90 mg): $p < 0.0001$, treatment groups. No serious adverse events were reported. The authors conclude that EPs 7630 is well tolerated and effective at reducing severity of BSS symptoms with quicker recovery, compared with placebo.

Sore Throat

In a randomized, double-blind, placebo-controlled trial, 143 children ages 6-10 years, with non-strep (group A beta-hemolytic streptococcus) sore throat, received either EPs 7630 or a placebo for 6 days.¹⁹ The primary outcome was the change in a severity score called TSS. TSS measures two subjective features—sore throat and functional impairment (difficulty swallowing).

The decrease of TSS from baseline (day 0) to day 4 was 7.0 ± 2.4 points in the EPs 7630 group and 2.9 ± 2.4 points in the placebo group ($p < 0.0001$). On day 2, TSS decreased from 10.3 ± 1.2 to 6.8 ± 2.2 in the EPs 7630 group compared to 9.7 ± 1.4 to 8.2 ± 2.8 in the placebo group ($p < 0.0001$)—suggesting an early response in the EPs 7630 group. By day 6, the number of patients returning to school was 80.8% in the EPs 7630 group compared with 21.4% in the placebo group ($p < 0.0001$).

Nasal Irritation

A randomized, placebo-controlled study with 103 adult patients with acute nasal irritation and congestion studied EPs 7630 for 21 days.²⁰ The dose of EPs 7630 was 3 mL three times per day. The primary outcome measure was the change in a severity score called SSS, which measures the following symptoms: headache; maxillary pain; maxillary pain worse on bending forward, percussion, or pressure; nasal obstruction; purulent nasal secretion; and purulent nasal discharge.

The decrease in SSS was 5.5 points in the EPs 7630 group compared to 3.0 points in the placebo group ($p < 0.0001$). No serious adverse event occurred during the study.

Common Cold

Multiple studies have demonstrated the efficacy and tolerability of EPs 7630 for symptoms associated with the common cold.²¹⁻²³ Using a liquid extract of *Pelargonium sidoides* (EPs) closely related to EPs 7630, a randomized, placebo-controlled study involving 103 patients determined the efficacy of the herbal ingredient for the treatment of the common cold.²¹ The primary outcome measure was the sum of symptom intensity differences (SSID) of the cold intensity score (CIS) from day 1 to day 5. The CIS consists of ten symptoms associated with the common cold (nasal discharge, sore throat, and minor symptoms including nasal congestion, sneezing, scratchy throat, hoarseness, cough, headache, muscle aches, and fever).

From baseline to day 5, the mean SSID improved by 14.6 ± 5.3 points in the EPs group compared with 7.6 ± 7.5 points in the placebo group ($p < 0.0001$). The mean CIS decreased by 10.4 ± 3.0 points and 5.6 ± 4.3 point in the EPs and placebo groups, respectively. After 10 days, 78.8% of the EPs group were "clinically cured" (CIS equal to zero points or complete resolution of all but a maximum of one cold symptom) compared to 31.4% in the placebo group ($p < 0.0001$). The mean duration of inability to work was significantly lower in the EPs group (6.9 ± 1.8 days) compared to the placebo group (8.2 ± 2.1 days; $p = 0.0003$). No serious adverse events were reported.

In 2015 a prospective, open-label trial studied the tolerability and treatment effects of a tablet form of EPs 7630 in 120 adults with the common cold.²² The dose of EPs 7630 was 20 mg three times per day for ten days. Treatment effectiveness outcome was measured by daily investigator observation of common cold symptoms (CCS) and daily self-rating by participants of CCS and related symptoms of chilliness, chest pain during coughing, loss of appetite, restless sleep, limitation of usual daily activities, and muscle aches. By day ten 42% of patients reported full recovery and 42% showed significant improvement in symptoms. No serious adverse events were reported.

References

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V CLEAR EPs 7630™ ORIGINAL

Drug Facts

| Active ingredient (116.85 mg in each dose - 1.5 mL) | Purpose |
|---|--|
| <i>Pelargonium sidoides</i> 1X (EPs 7630) | Shortens duration and reduces severity of upper respiratory symptoms |

Uses

Shortens duration and reduces severity of symptoms associated with common colds and throat/nasal/bronchial irritations:

- congestion
- cough
- hoarseness
- sore throat

Warnings

Sore throat warning: severe or persistent sore throat for more than 2 days or if accompanied by high fever, headache, nausea, vomiting or rash may be serious. Consult a physician promptly.

Ask a doctor before use if you have

■ a persistent or chronic cough that lasts, is chronic such as occurs with smoking, asthma, chronic bronchitis, or emphysema or is accompanied by excessive phlegm (mucus).

Stop use and consult a doctor if

■ new symptoms occur, symptoms worsen or do not get better within 7 days ■ fever worsens or lasts more than 3 days ■ cough lasts more than 7 days or occurs with rash or persistent headache. These could be signs of a serious condition.

If pregnant or breast-feeding, ask a healthcare professional before use.

Keep out of the reach of children. In case of overdose, seek medical help or contact a Poison Control Center immediately.

Directions

For best results, use at the first sign of symptoms and continue to use for an additional 48 hours after symptoms cease.

| Age | Dose |
|---|--------------------------------|
| Adults & children 12 years of age and older | Take 1.5 mL three times daily. |
| Children under 12 years of age | Consult a doctor. |

Other information

Store at room temperature 20-25°C (68-77°F) in a dry place out of direct sunlight.

Inactive ingredients ethyl alcohol, glycerin, purified water.

Integrative Therapeutics

ORIGINAL - 780011

V CLEAR EPs 7630™ CHERRY

Drug Facts

| Active ingredient (111 mg in 1 1/2 teaspoons (tsp) = 7.5 mL) | Purpose |
|--|--|
| <i>Pelargonium sidoides</i> 1X (EPs 7630) | Shortens duration and reduces severity of upper respiratory symptoms |

Uses

Shortens duration and reduces severity of symptoms associated with common colds and throat/nasal/bronchial irritations:

- congestion
- cough
- hoarseness
- sore throat

Warnings

Sore throat warning: severe or persistent sore throat for more than 2 days or if accompanied by high fever, headache, nausea, vomiting or rash may be serious. Consult a physician promptly.

Ask a doctor before use if you have

■ a persistent or chronic cough that lasts, is chronic such as occurs with smoking, asthma, chronic bronchitis, or emphysema or is accompanied by excessive phlegm (mucus).

Stop use and consult a doctor if

■ new symptoms occur, symptoms worsen or do not get better within 7 days ■ fever worsens or lasts more than 3 days ■ cough lasts more than 7 days or occurs with rash or persistent headache. These could be signs of a serious condition.

If pregnant or breast-feeding, ask a healthcare professional before use. **Keep out of the reach of children.** In case of overdose, seek medical help or contact a Poison Control Center immediately.

Directions

For best results, use at first sign of symptoms and continue to use for an additional 48 hours after symptoms cease.

Use only with enclosed dosage cup.

| Age | Dose |
|---|---|
| Adults & children 12 years of age and older | Take 1 1/2 teaspoons (tsp) (7.5 mL) three times daily |
| Children 6-12 years of age | Take 1 teaspoon (5 mL) three times daily |
| Children under 6 years of age | Consult a doctor |

Other information

Store at room temperature 20-25°C (68-77°F) in a dry place out of direct sunlight.

Each teaspoon (tsp) contains potassium 10 mg

Inactive ingredients

aronia juice, citric acid, ethyl alcohol, fructose, maltodextrin, natural flavor, potassium citrate, purified water

Integrative Therapeutics

CHERRY - 780024