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Ongoing Benefit of Pelargonium: Acute Rhinopharyngitis & Review of Safety

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What is Already Known

- traditionally used in South Africa particularly as a gastrointestinal astringent, and used after WW2 in Germany for respiratory infections
- *Pelargonium sidoides* root preparation shown in clinical studies to:
  - reduce symptom scores and duration of illness in patients with acute bronchitis not requiring antibiotics
  - improve symptoms in acute and chronic sinusitis
  - improve severity of symptoms in acute tonsillopharyngitis
  - reduce severity of symptoms and duration of illness in common cold
- dosage: usually 0.4-0.8 g/day for adults and adolescents (although up to 1.6 g/day prescribed for the first 2 days in sinusitis trial); 0.27 g/day for children
- additional clinical research has shown Pelargonium:
  - may decrease frequency of asthma attacks in children with existing upper respiratory tract viral infections
  - reduced exacerbations and improved quality of life in chronic obstructive pulmonary disease
  - improved salivary IgA and decreased the cytokines IL-6 and IL-15 in healthy athletes
- good safety profile with minor gastrointestinal complaints occurring occasionally; no convincing causal evidence linking the herb to a small number of reported cases of idiosyncratic hepatotoxicity

Continuing Benefit & Tolerability: Acute Rhinopharyngitis

A postmarketing surveillance study evaluated the effectiveness and safety of *Pelargonium sidoides* root in a clinical setting with adult patients experiencing symptoms of acute rhinopharyngitis.[1] Participants had a clinical diagnosis of acute rhinopharyngitis and at least 2 out of 10 common cold symptoms (nasal discharge, sore throat, nasal congestion, sneezing, scratchy throat, hoarseness, coughing, headache, malaise, fever). They were required not to take common cold medications during the study, but in the event of fever, they could take paracetamol. Three patients withdrew over the duration of the study, with 117 patients completing the 10 days of treatment.

The dosage of extract corresponded to 0.54 g/day of *Pelargonium sidoides* dried root.

Investigators rated common cold symptoms and other acute rhinopharyngitis-associated complaints (including pulmonary rales at auscultation, sputum production, chest pain during coughing, chilliness, exhaustion, loss of appetite, diarrhoea, muscle aches) on a 4-point rating scale – *the results are summarised in Table 1*. Patients assessed a set of 15 complaints (runny nose, congested nose, sneezing, sore throat, scratchy throat, hoarseness, coughing, headache, malaise, chilliness, chest pain during coughing, loss of appetite, restless sleep, limitation of usual daily activities, muscle ache) each day, which were recorded in their diaries. Overall recovery (rated by patients and investigators) and patients' satisfaction with the treatment were also noted. Tolerability was determined by questioning patients for adverse events of any kind and laboratory tests were conducted including for liver function and coagulation parameters.

Additional Therapeutic Results

- Patient diary ratings indicated a decrease of symptom intensity over the treatment period. Mean summary score for acute rhinopharyngitis-associated symptoms was 22.1 points at baseline, 11.4 points at day 5 and 3.8 points at day 10. The percentage of patients who felt only mildly ill or not ill at all increased from 15.3% at baseline to 58.6% at day 5 and to 94.6% at day 10.
- At the end of treatment, investigators rated 42% of patients as completely recovered, and 42% as showing major improvements. Patient's ratings were very similar.
- Of the 82 patients with valid data, 74% indicated they were satisfied or very much satisfied with Pelargonium treatment.
- During the study, 2 patients required antibiotic treatment and 22 patients took paracetamol at least once (average intake was 2.5 x 500-mg tablets).

	Average Total Score*		
	Baseline	**Day 5**	**Day 10**
Common cold symptoms	10.8	5.1	2.2
Other acute rhinopharyngitis-associated complaints	3.4	1.3	0.5

Table 1. Total scores for common cold and other acute rhinopharyngitis-associated symptoms as rated by the study investigators.

* The changes from baseline to day 5 and to day 10 were statistically significant ($p < 0.001$) for both sets of symptoms.

Safety & Tolerability

- During treatment with Pelargonium, 15 of 120 participants reported 18 adverse events, 10 of these were regarded as potentially treatment-related. Considering a cumulative exposure of 1064 treatment days, these numbers correspond to 1 adverse event in 71 days of treatment for all events, and to 1 event in 106 treatment days for potentially-related events.
- Among the 10 events for which a causal relationship with Pelargonium treatment could not be excluded, only one allergic dermatitis event was assessed to be possibly related and all other events were considered to be improbably related. None were defined as serious. Five events were gastrointestinal disorders (diarrhoea, flatulence, abdominal pain).
- Except for one case of prolonged activated partial thromboplastin time (reported as an adverse event with unlikely causal relationship to treatment with Pelargonium), the laboratory measures did not produce significant changes. Bleeding complications (for example, epistaxis and gingival bleeding) or elevated liver enzyme values were not observed during this study.

Review of Safety

A review of the safety of *Pelargonium sidoides* root documented in 13 double-blind, placebo-controlled trials has been published. Data was compared for 2006 patients treated with Pelargonium and 1386 patients treated with placebo from trials of acute bronchitis (8), acute rhinosinusitis (2) and acute tonsillopharyngitis (3). In these studies, 2227 were adults and 1165 were children and adolescents.[2]

- No serious adverse reactions to Pelargonium were reported in any of the trials.
- The type and incidence rate of adverse events observed in patients treated with Pelargonium was similar to the events reported in patients who received placebo, with only a slight increase of the risk of gastrointestinal disorders and epistaxis.
  - The difference in risk for gastrointestinal complaints was 2.8% for patients treated with Pelargonium compared to placebo, for all reported events, and was 0.6% for epistaxis. (The differences in risk are lower when potentially-related events, rather than all reported events, are considered: 1.7% and 0.4% for gastrointestinal complaints and epistaxis, respectively.)
- The risk difference for all reported events of hypersensitivity reactions, gingival bleeding and liver-associated events did not reach 0.5%.

Key Points at a Glance

- A postmarketing surveillance study found treatment with Pelargonium significantly relieved symptoms of acute rhinopharyngitis. Pelargonium was also well tolerated.
- A review of 13 placebo-controlled trials found no serious adverse reactions occurred for treatment with Pelargonium. There was a slight increase in the risk of gastrointestinal disorders and nose bleed compared to placebo. On the basis of these results, Pelargonium is regarded as safe and well tolerated.

REFERENCES

[1] Keck T, Strobl A, Stracke B. *Altern Integr Med* 2015; **4**(4): 204
[2] Matthys H, Lehmacher W, Zimmermann A et al. *J Lung Pulm Respir Res* 2016; **3**(1): 00068