

**Randomized, Double-Blind, Placebo-Controlled, Parallel Group Study To Evaluate
The Effect of 500 mg Once a Day EpiCor On Allergy Symptoms**

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Abstract/Summary

EpiCor®, an immunogenic fermentate product and once a day dietary supplement, demonstrated a significant ability to reduce the risk and duration of cold and flu-like symptoms in two previous large randomized controlled trials. EpiCor also seemed to provide simultaneous immune enhancement and a balanced immune surveillance and coverage during these studies. Thus, testing EpiCor against common allergens or seasonal allergies seemed to be an appropriate follow-up clinical trial to the previous observed positive results against cold and flu. In this current clinical trial, 84 healthy subjects that tested positive for seasonal allergies were randomized to once a day EpiCor versus placebo during the 12 week time period of spring and summer when total pollen counts are high. The highest total pollen counts occurred during the first 6 weeks of the clinical trial. The pollen counts during this period were significantly ($p=0.0003$) higher compared to weeks 7-12 of the study. Because of this, the first 6 weeks were looked at since most allergy-related symptoms would occur during times of high pollen count. During this high pollen count period, EpiCor significantly ($p=0.03$) reduced the mean severity of nasal symptoms, including a significant ($p=0.005$) reduction in runny nose, and a significant ($p=0.04$) reduction in nasal congestion. EpiCor reduced both eye discharge severity ($p=0.0641$) and the number of days with eye discharge ($p=0.0646$) compared to placebo. EpiCor also demonstrated the greatest reductions in symptom severity when total pollen counts were highest. The severity of runny nose, congestion, and total nasal symptoms were significantly reduced in all of these circumstances ($p=0.003$; $p=0.006$; $p=0.004$). The largest symptomatic impact occurred with nasal congestion where the EpiCor group experienced approximately a total of 6 fewer congestive days compared to placebo (17 days vs. 23, $p=0.04$). Subjects were also asked to record when they used rescue prescription or over the counter allergy medication for severe allergies. Subjects taking EpiCor utilized significantly ($p=0.04$) less rescue

medication for allergies compared to placebo during the highest pollen count period (the first 6 weeks) of the study. Serum and especially nasal smear data mirrored the effectiveness observed in the allergy diary and questionnaire. Nasal eosinophils were lower ($p < 0.06$) in the EpiCor versus the placebo group. Side effects throughout the clinical trial period were statistically similar to placebo. The consistent robust positive results and safety of EpiCor from now a total of 4 randomized trials, including against the most common allergy symptoms in this current report, is impressive and should set a new standard of efficacy for effective over the counter (OTC) preparations.