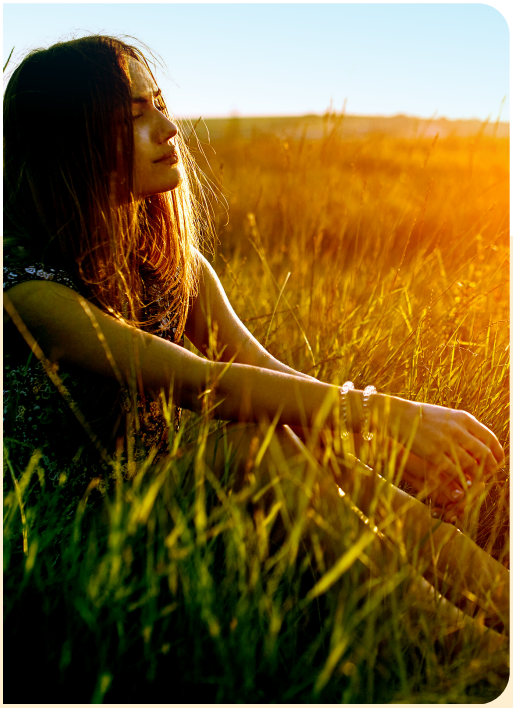
RESEARCH SUMMARY

EpiCor Effects on Seasonal Allergies

Moyad, M. A., *et al.* Immunogenic yeast-based fermentation product reduces allergic rhinitis-induced nasal congestion: a randomized, double-blind, placebo-controlled trial. *Adv Ther* **2009**, *26* (8), 795-804. Online reference: https://www.ncbi.nlm.nih.gov/pubmed/19672568



Introduction

Clinical studies indicate that EpiCor may help support and maintain a healthy immune system. This trial was designed to examine the effects of EpiCor on people who tested positive for seasonal grass allergies and have a known history of those symptoms [nasal congestion and other notable allergic rhinitis (AR) symptoms].

Key Findings Include:

- Nasal congestion severity and duration significantly reduced ($p=0.04$) with EpiCor vs placebo during the high pollen count period (weeks 1-6).
- Rhinorrhea or runny nose severity significantly reduced with EpiCor vs placebo ($p=0.005$).
- Mean number of days with nasal congestion significantly reduced by 25% with EpiCor (17.21 days) vs placebo (23.05 days) ($p=0.04$). Median number of days with nasal congestion was reduced by 43% with EpiCor (16.5 days) vs placebo (29 days).
- Rescue medication use for allergies significantly reduced with EpiCor vs placebo during the high pollen count period (weeks 1-6) ($p=0.04$).

Methods

This was a 12-week, randomized, double-blinded, placebo-controlled trial using subjects that tested positive for grass allergies and had self-reported nasal and/or ocular allergy symptoms on a seasonal basis. Ninety-six healthy adult subjects were randomized to take EpiCor (500 mg capsule/day) ($n=48$; mean age 39 $\pm$ 11.5) or a placebo ($n=48$; mean age 38 $\pm$ 12.5). A total of 78 subjects completed the study and were part of the per protocol analysis. The trial took place in South Dakota during the 2008 spring allergy season and total pollen counts during the first six weeks of the clinical trial were significantly higher than weeks 7-13 ($p=0.001$).

Using a diary, subjects self-reported the incidence and severity (on a scale from 0-3) of the following allergy symptoms: nasal congestion, runny nose, sneezing, eye discharge, eye wateriness, and eye itchiness (pruritus) as the primary outcome of the study. Subjects were also asked to record when they used rescue medication for severe allergy symptoms.

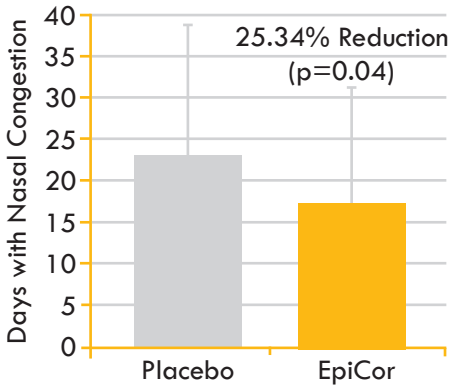
As a secondary endpoint, at baseline and weeks 6, 9, and 12, saliva and blood samples were taken to measure salivary secretory immunoglobulin A (sIgA) and immunoglobulin E (IgE), respectively.

As an addendum to the study, nasal smear biomarkers were recorded at 9 and 12 weeks, including lymphocytes, monocytes, and eosinophils.

Results

The EpiCor group showed statistically significant reductions in the incidence of symptoms commonly associated with seasonal allergies. Over the first 6 weeks there were significant reductions of severity of nasal congestion (p=0.04), runny nose (p=0.005) and of duration of nasal congestion (p=0.04) vs placebo. The largest symptomatic impact was seen on nasal congestion with EpiCor having a 43% reduction in the median number of days with nasal congestion with EpiCor (16.5 days) vs placebo (29 days). Also, the mean number of days with nasal congestion was significantly reduced by 25.34% with EpiCor (17.21 days) vs placebo (23.05 days) (p=0.04) (Figure 1). Rescue medication use for allergies significantly reduced with EpiCor vs placebo during the high pollen count period (weeks 1-6) (p=0.04).

FIGURE 1



There also was a reduction in the severity of runny nose with EpiCor compared to placebo during this time period (p=0.005) as well as over the entire 12-week period (p=0.03). For sneezing and ocular discharge, wateriness, or pruritus, there was no statistical difference in symptom severity or total days with symptoms between the EpiCor and placebo group during the whole 12-week trial.

Examination of secondary biomarkers at weeks 9 and 12 indicated a lower inflammatory response comparing EpiCor to placebo by showing:

- A significant reduction in the number of selective allergy-producing lymphocytes in the nasal smears ($p \leq 0.05$).
- A downward trend of mean eosinophil percentage in nasal smears (p=0.056).
- The IgE levels for the group were not significantly different between EpiCor and control throughout the study.

Throughout the 12-week study, subjects taking EpiCor had statistically significant increased levels of salivary sIgA compared to placebo (p=0.03), which may play a role in mucosal protection. Looking at the levels of IgE, which plays a role in inflammation, there were no significant differences between groups. These biomarker results may indicate EpiCor may help maintain a healthy immune system.

Conclusion

During times of seasonal elevated pollen counts, emerging science shows EpiCor helps improve symptoms such as occasional nasal congestion and may help support a healthy immune system.

Questions? Email EpiCorSales@cargill.com for more information.

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