

Sodium Pyruvate Nasal Spray Studies: Safety and Efficacy Data submitted to the FDA

Clinical Trial 1: *Twenty-four subjects.* All subjects completed the study, and none opted to return to their normal nasal spray therapy during this period. The data obtained from the rhinoscopic examinations indicated that the Sodium Pyruvate + Saline Nasal Spray did not induce dermal irritation and was effective in significantly ($p=0.006$) reducing the erythema in subjects who normally use either saline or non-saline nasal sprays like steroids, when pre-test ratings were compared to post-test ratings.

Clinical Trial 2: *Thirty-nine subjects who were regular nasal spray users due to chronic sinusitis or allergic rhinitis were recruited for this one-week open label, in home-use trial.* Thirty-eight subjects completed the study. The data obtained from the rhinoscopic examinations indicated that Sodium Pyruvate + Saline Nasal Spray did not induce dermal irritation and was effective in reducing the erythema in subjects who normally use either saline or non-saline nasal sprays when pre-test ratings were compared to post-test ratings.

Clinical Trial 3: *Fourteen-Day In-Use Evaluation of Nasal Sprays Containing Sodium Pyruvate and Reduced Steroids.* “Reduced-Strength Flonase®” and “Reduced-Strength Nasacort®” Test Product nasal sprays with sodium pyruvate were found to be as effective as the “full-strength” (i.e., commercial) Flonase® and more effective than the commercial Nasacort® when the reduced commercial “active ingredients” were delivered to the subjects.

Clinical Trial 4: *Fifty-three subjects. Treatment Effect of Sodium Pyruvate nasal saline spray on allergic Rhinitis. Randomized Placebo controlled study.* Results Sodium pyruvate nasal spray was effective in attenuating rhino conjunctivitis symptoms and reducing rescue medications use in allergic rhinitis patients.

Clinical Trial 5: *One hundred and thirty subjects. Blinded saline placebo controlled nasal spray study against a sodium pyruvate formulation in allergic Rhinitis patients. Results:* The sodium pyruvate formulation was clinically and statistically superior to saline in reducing nasal inflammation and congestion.

Clinical Trial 6: *Sixty subjects. Random and positive controlled clinical trial to evaluate the efficacy and safety of the sodium pyruvate nasal spray in the treatment of Chronic Rhinitis (allergic and non-allergic) Results:* The use of a Sodium pyruvate nasal spray was safe and effective and clinically superior to saline in reducing nasal symptoms in these patients.

Clinical study 7: *Seventy-seven subjects. Research on the efficacy of sodium pyruvate nasal spray to treat mild to moderate Allergic Rhinitis. Results:* Sodium pyruvate nasal spray, as a non-drug treatment, can effectively improve the symptoms of mild to moderate AR.

Clinical Trial 8: *Human Mucociliary clearance time (MCT) studies.* Several studies have shown the effect of nasal saline on MCT. Our investigators have found isotonic saline sped clearance time by 2%, while the Sodium pyruvate nasal formula sped clearance by 17% 10-20 minutes after treatment in 32 adults.

Summary

In all patients tested, (92%) of these patients stated that the Pyruvate Saline Nasal Spray opened their nasal passages and cleared their congestion for over 12 hours. In each study the Sodium Pyruvate Saline Nasal Sprays were objectively and subjectively judged to be “Comparable To” or “Better Than” both Saline or Steroid-based commercial nasal sprays. To date millions of Patients have inhaled Sodium Pyruvate with no adverse events reported.