



## EVALUATION OF EFFICACY AND SAFETY OF RESPIMET SYRUP IN THE TREATMENT OF UPPER RESPIRATORY DISORDERS

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### ABSTRACT

The present study was conducted to evaluate the safety and efficacy of Respimet Syrup in upper respiratory disorders. There was a highly significant reduction in mean scores for symptomatic evaluation of sneezing, nasal congestion, itching of the eyes and nose, rhinorrhea, watery eyes and total rhinitis symptom score, at the end of study. There was also a significant reduction in mean scores for symptomatic evaluation of chest tightness, daily asthmatic symptoms, wheezing, shortness of breath, cough, sputum production and total asthma

symptom score at the end of study. The increased levels of WBC, eosinophils, lymphocytes polymorphs and ESR, at the time of the enrollment, were decreased significantly.

**KEYWORDS:** Morbidity, Bronchitis, Allergy, Mast cells.

### INTRODUCTION

Increasing prevalence of upper and lower respiratory tract allergic diseases (rhinitis, bronchitis and asthma) is a serious health issue affecting a major chunk of global population as these diseases are responsible for a significant morbidity and have severe economic impact. This impact is even more severe in children due to associated long-term compromises in the quality of life. The available treatment options for upper and lower respiratory tract allergic diseases have major limitations due to low efficacy, associated adverse events and compliance issues. Antihistamines, sympathomimetics, xanthine derivatives are commonly used as the first-line treatment for symptomatic management, but they do not prevent recurrent episodes. Use of glucocorticosteroids and anticholinergics is questionable due to long-term adverse effects. Prophylactic use of mast cell stabilizers has the disadvantage of frequent administration. Decongestant drugs are effective in the treatment of nasal obstruction; however do not improve other symptoms of rhinitis and have high incidence of

adverse effects. Studies with the leukotriene receptor antagonists as a sole therapy in these allergic diseases have proved disappointing. Respimet Syrup is a polyherbal formulation indicated for the management of upper and lower respiratory tract allergic diseases. Respimet Syrup contain extracts of *Curcuma longa*, *Ocimum sanctum*, *Adhatoda vasica*, *Trikatu*, *Triphala*, *Embelia ribes* and many other plants.

“Tulsi” or the holy basil is famous throughout the globe for its healing and other medicinal properties. Its leaves are helpful in sharpening memory and in curing fever and common cold. They also act as an anti stress agent and also help in purifying blood. This, in turn, helps in reducing the risk of heart attacks and also lowers the cholesterol level. The leaves of the basil are also effective in reducing mouth ulcer and other infections of the mouth. Used against respiratory ailments including bronchitis and tuberculosis. Used for rhinitis (inflammation of nasal mucus membrane). Can serve as a cure and prophylactic as well for the severe acute respiratory syndrome (SARS) – The root of the tulsi plant should be crushed and boiled with turmeric powder for a few minutes, after which it should be filtered. Consuming two spoonfuls of this potion twice daily will cure SARS and prevent contracting of the disease. Tulsi tea with honey is a good expectorant especially in cases where fever is involved. The juice of the leaves is given in catarrh and bronchitis in children. Chewing the leaves relieves cold and flu. A decoction of the leaves, cloves and common salt also gives immediate relief in case of influenza.

The fresh juice of rhizome is given in bronchitis. In rhinitis and cough boil *Haridra* in milk and mixed with jiggery given internally. In catarrhal cough, sore throat, and throat infection the decoction of rhizome is used for gargle and also the piece of rhizome is slightly burnt and given for chewing.<sup>[11]</sup> The chemical constituents of *Curcuma longa* like Tumerones, curcuminoids, Curcumin and tetrahydrocurcumin has an anti-asthmatic action.<sup>[16]</sup> In asthma and congestion, fumes of *Haridradi dhumvarti* (fumes wick) is given

*Adhatoda Vasica* is useful in treating bronchitis, tuberculosis and other lung and bronchiole disorders. A decoction of the leaves can be used as an herbal treatment for cough and other symptoms of colds. The soothing action helps irritation in the throat and the expectorant will help loosen phlegm deposits in the airway which makes *adhatoda* a good remedy for sore throat. *Adhatoda Vasica* has been used to control both internal and external bleeding such as peptic ulcers, piles and bleeding gums. A poultice of the leaves may be applied to wounds for their antibacterial and antiinflammatory properties. The leaves, roots and the flowers are

extensively used in indigenous medicine as a remedy for cold, cough, bronchitis and asthma. Bronchitis and Asthma In acute stages of bronchitis it gives unfailing relief. especially where the sputum is thick and sticky. It liquifies tilt sputum so that it is brought up more easily. For relief in asthma, the dried leaves should be smoked. Tuberculosis In Ayurveda, a preparation made from vasaka flowers, known as gulkand is used to treat tuberculosis. A few fresh petals of vasaka flowers should be bruised and put in a pot of chill3 clay. Some sugar crystals are added and the jar kept in the sun. It should be stirred every morning and evening. The preserve is ready for use in about a month. Even the juice from its leaves is useful in treating tuberculosis. About 30 ml of the juice is taken thrice a day with honey. It relieves the irritable cough by its soothing action on the nerve and by liquefying the sputum, which makes expectoration easier.

For coughs, 7 leaves of the plant are boiled in water, strained and mixed with 24 grams of honey. This decoction provides relief. Similarly a confection of vasaka flowers eaten in doses of 12 grams twice daily relieves cough. About 60 grams of flowers and 180 grams of jaggery should be mixed for preparing this confection. The cough suppressive activity of *E.officinalis* is dose-dependent. We could also demonstrate that the antitussive activity of *E. officinalis* is less effective than shown by the classical narcotic antitussive drug codeine, but more effective than the non-narcotic antitussive agent dropropizine. It is supposed that the antitussive activity of the dry extract of *Embllica officinalis* is due not only to antiphlogistic, antispasmodic and antioxidant efficacy effects, but also to its effect on mucus secretion in the airways.

## MATERIALS AND METHOD

This open study was planned to evaluate the efficacy and safety of Respimet syrup in children (in the age group of 3 to 12 years), suffering from allergic bronchitis or asthmatic bronchitis. Twenty five children in the age group of 3 to 12 years who presented with symptoms of rhinitis (sneezing, nasal congestion, itching of the eyes and nose, rhinorrhoea and watery eyes) symptoms or bronchitis (allergic and asthmatic) symptoms (chest tightness, wheezing, productive cough and nocturnal asthma) were included in the study. These children were given a dose of 1 teaspoonful Of Respimet Syrup twice daily for 6 weeks. All children were followed up fortnightly for a period of 6 weeks. At each follow-up visit, clinical examination was done for, evaluating the following parameters: symptomatic improvement of rhinitis (sneezing, nasal congestion, itching of the eyes and nose, rhinorrhea

and watery eyes), total rhinitis symptom score (0-nil, 1-mild, 2-moderate, 3-severe), symptomatic improvement of asthmatic and allergic bronchitis (chest tightness, wheezing, cough, sputum production and nocturnal asthma), total asthmatic symptoms score (0-nil, 1-mild, 2-moderate, 3-severe) and reduction in daily usage of number of bronchodilator inhalations. All children were investigated by hematological and biochemical tests (Hb, WBC, DLC, ESR, SC, SGPT and SB).

## RESULTS

There was a highly significant reduction in mean scores for symptomatic evaluation of sneezing, nasal congestion, itching of the eyes and nose, rhinorrhea, watery eyes and total rhinitis symptom score, at the end of study. There was also a significant reduction in mean scores for symptomatic evaluation of chest tightness, daily asthmatic symptoms, wheezing, shortness of breath, cough, sputum production and total asthma symptom score at the end of study. The increased levels of WBC, eosinophils, lymphocytes polymorphs and ESR, at the time of the enrollment, were decreased significantly at the end of the study. There were no significant changes in mean baseline values of Hb, SGPT, SB and SC, when compared to the values at the end of study. There was a significant subjective evaluation of the treatment and reduction in severity of symptoms as evident from global evaluation.

S.No	Symptoms	Basal value	Two Weeks	Four Weeks	Six Weeks
1.	Sneezing	0.62±0.1	0.07±0.01	0.05±0.02	0.02±0.001
2.	Nasal Congestion	0.54±0.23	0.04±0.0121	0.03±0.01	0.01±0.02
3.	Itching Of Eyes	0.34±0.15	0.05±0.03	0.04±0.02	0.00±0.03
4.	Itching Of Nose	0.88±0.13	0.08±0.02	0.05±0.01	0.00±0.00
5.	Rhinorrhea	0.56±0.17	0.04±0.03	0.03±0.01	0.02±0.002

## DISCUSSION

The natural history of upper and lower respiratory tract allergic diseases is complex and is influenced by multifactorial pathological processes. Exposure to an allergen activates CD4+ T-lymphocytes leading to release of cytokines (IL-3, -4 and -5), increased IgE production and infiltration of specific cells (plasma cells, mast cells and eosinophils). This study observed an excellent and rapid symptomatic control, which was evident by significant reduction in the mean scores for sneezing, nasal congestion, itching of the eyes and nose, postnasal drip, rhinorrhea, watery eyes and total rhinitis symptom score, at the end of study. There was also a significant reduction in mean scores for symptomatic evaluation of chest tightness, daily

asthmatic symptoms, wheezing, shortness of breath, cough, sputum production and total asthma symptom score at the end of study.

## CONCLUSION

Therefore, it can be concluded that Respimet Syrup is clinically effective and safe in children suffering from AR or allergic bronchitis or asthmatic bronchitis.

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