

Rx **Erdozyd** **AB**
Erdosteine 300 mg+ Acebrophylline 100 mg Tablets

Superior Mucus Clearance. Free Airways



**PRODUCT
MONOGRAPH**



CONTENT

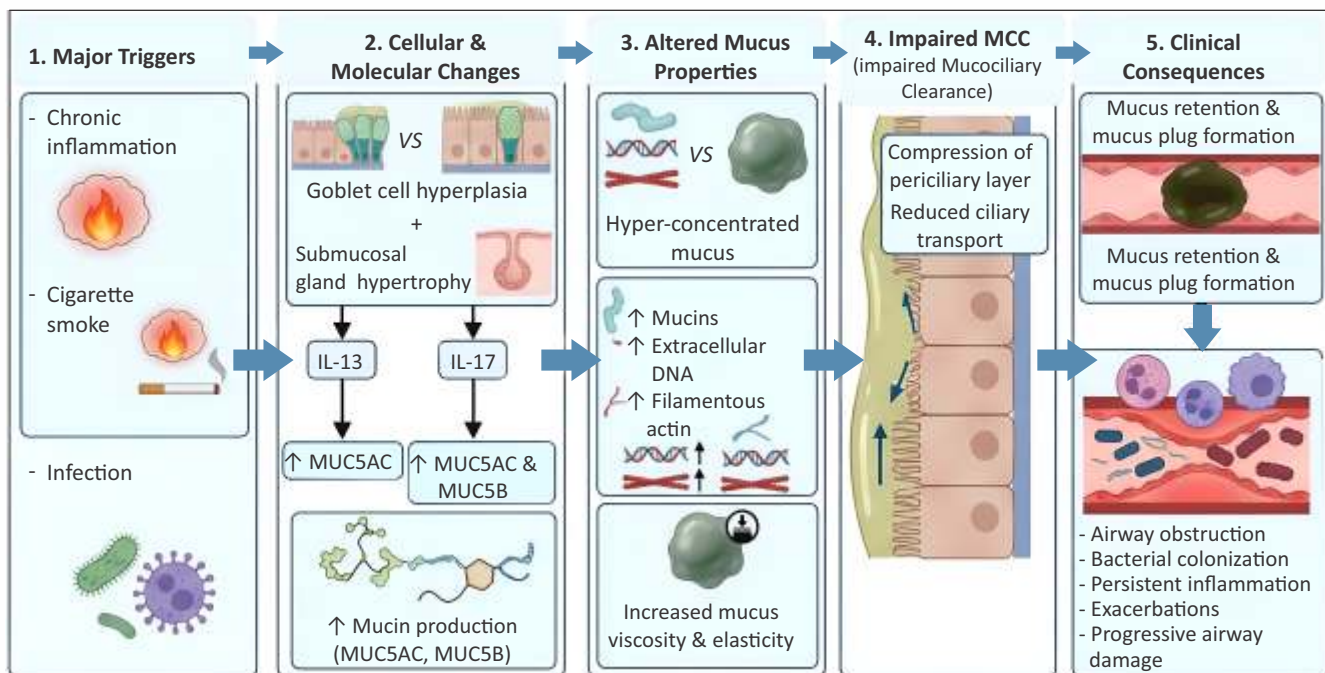
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1. Introduction

1.1 Mucus Hypersecretion

Mucus hypersecretion is a key feature of chronic airway diseases, contributing to airway obstruction, mucus plugging, infection, inflammation, and disease progression (Fig. 1).¹

Figure 1: Pathophysiology of mucus hypersecretion in airway diseases.¹



IL-13 – Interleukin-13, IL-17 – Interleukin-17, MUC5AC – Mucin 5AC (Mucin 5 subtype AC), MUC5B – Mucin 5B, MCC – Mucociliary Clearance, DNA – Deoxyribonucleic Acid.

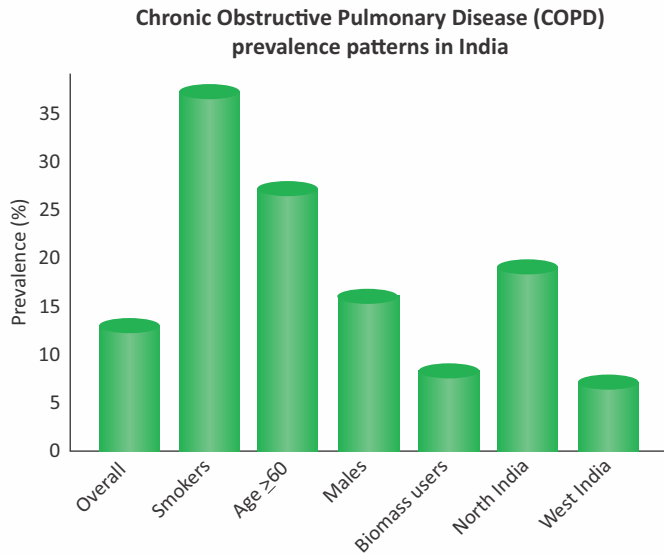
2. Disease Conditions Associated with Impaired Mucociliary Clearance

Mucus hypersecretion/ impaired mucociliary clearance is observed across multiple chronic airway diseases, where it contributes to airflow limitation, infection, exacerbations, and disease progression.

2.1 Chronic Obstructive Pulmonary Disease (COPD)

COPD is characterized by chronic respiratory symptoms (dyspnea, cough, sputum production and/or exacerbations) arising due to airway abnormalities (bronchitis, bronchiolitis) and/or alveolar abnormalities (emphysema) leading to airflow obstruction.² COPD is highly prevalent in low- and middle-income countries, with India and China together contributing >50% of the total burden.³ In India, COPD shows a substantial and heterogeneous burden across populations and regions. Key prevalence patterns are summarized in Fig. 2.⁴

Figure 2: COPD prevalence patterns in India⁴



COPD: The Menacing Numbers!

- 20% of severe COPD admissions are undiagnosed⁵
- 47% of COPD hospital admissions are smokers⁵
- Rheumatoid arthritis increases COPD hospitalization risk by 47%⁶
- Uncontrolled exacerbations increase mortality risk by 21%⁷
- 1 in 3 severe COPD patients have bronchiectasis at diagnosis⁸
- More than 50% of severe COPD patients develop bronchiectasis over time.⁸
- Nearly 27–35% COPD patients have chronic bronchitis.⁹

2.2 Chronic rhinosinusitis (CRS)

CRS is characterized by mucin hypersecretion leading to mucus accumulation and impaired mucociliary clearance.¹⁰ It is a chronic inflammatory disease of the sinonasal mucosa often associated with endoscopic findings of nasal polyps, mucopurulent discharge in the middle meatus, and oedema/obstruction of the middle meatus.¹¹

- Affects ~11% of the global population¹¹
- Reported prevalence in India: ~46.1% (study-based estimates)¹¹
- Anatomical variations present in ~64–99.8% of cases¹¹

2.3 Chronic Suppurative Otitis Media (CSOM)

CSOM is a chronic inflammatory disease of the middle ear/mastoid cavity associated with biofilm-forming bacteria (e.g., *S. aureus*, *P. aeruginosa*, *S. pneumoniae*). It is characterized by persistent ear discharge, tympanic membrane perforation, edematous external auditory canal, and granulation tissue in the middle ear cleft.¹²

- Global incidence in children: ~41 cases per 100,000/year.
- Estimated 65–330 million individuals affected worldwide, with ~56% experiencing significant hearing impairment.
- Higher prevalence in developing countries like India and in rural populations.
- Treatment aims to reduce bacterial colonies in the middle ear

3. Clinical Implications of Impaired Mucociliary Clearance

The clinical implications of mucus hypersecretion/ impaired mucociliary clearance span multiple domains from airflow obstruction to oxidative stress each carrying distinct patient-level consequences. Some of these clinical implications are summarized in Table 1.

Table 1: Clinical Manifestations of Mucus Hypersecretion in Chronic Airway Disorders

	Key Features	Impact
Airflow Limitation²	Persistent obstruction from airway/alveolar pathology; dyspnea, cough, sputum	Progressive decline in lung function
Oxidative Stress³	ROS generation from smoking and air pollution leading to cellular aging, DNA damage, and airway dysfunction; ↑ mucus hypersecretion	↑ bronchoconstriction, exacerbations, and ↑ FEV ₁ decline; reduction in inhaled drug deposition
Chronic Sputum & Exacerbations¹³	≥3 months sputum for 2 years; exacerbations accelerate FEV1 decline	↑ Mortality, faster disease progression
Mucus Plugging¹⁴	Seen in ~67% on CT; often “silent” without cough/phlegm	Worse airflow, QoL, ↑ mortality
Mucus Hypersecretion¹⁵	Goblet cell hypertrophy/hyperplasia; submucosal gland enlargement	Sustained mucus hypersecretion, impaired clearance
Comorbid Burden²	Cardiac, metabolic, systemic diseases	Mimic/exacerbate COPD events, complicate care

4. Managing Mucus-related Airway Disorders: The GOLD 2026 Recommendations

4.1 Role of Mucolytics in COPD Management

The GOLD 2026 guidelines state that in selected patients with a chronic bronchitis phenotype or those who continue to have frequent exacerbations despite optimal inhaled therapy, mucolytics are recommended as add-on (adjunct) therapy.²

GOLD 2026 recommended Mucolytic Agents¹ (mainly act by improving mucus clearance and reducing sputum viscosity)

Erdosteine

N-acetylcysteine (NAC)

Carbocysteine

4.2 Erdosteine in Chronic Rhinosinusitis with Nasal Polyposis²⁴

Erdosteine has been reported to reduce SNOT-22 score and nasal polyposis stage.

5. Erdosteine: More than “Just-a-Mucolytic”

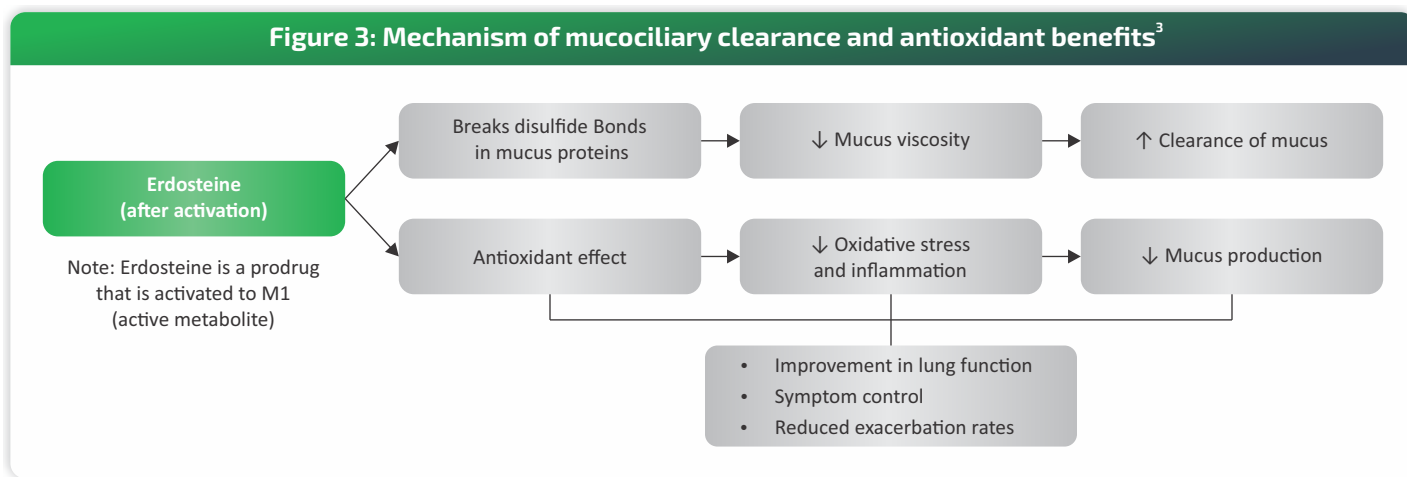
5.1 Pharmacokinetics Data.¹⁶

Parameter	Details
Absorption	Rapid oral absorption
First-pass metabolism	Converted to active metabolite M1
T_{max}	Erdosteine: ~1.2 h; M1: ~1.5 h
C_{max}	Erdosteine: ~1.26 µg/mL; M1: ~3.46 µg/mL (300 mg dose)
Food effect	None
Distribution	Kidney, liver, bone; present in lung (BAL fluid)
Protein binding	~64.5%
Half-life (t_{1/2})	~1.5–1.6 h
Excretion	Urine (M1 + sulphates); minimal feces
Accumulation	None (even with repeated dosing)
Age effect	No significant effect

5.2 The Mechanism of Action (Pharmacodynamics)

Erdosteine is a thiol-containing mucolytic prodrug rapidly absorbed and converted *via* first-pass metabolism to its active metabolite, N-thiodiglycolyl-homocysteine (M1/MET1). The liberated sulfhydryl (–SH) group mediates its mucolytic, antioxidant, anti-inflammatory, and antibacterial effects, improving mucus clearance, reducing airway inflammation, and decreasing COPD exacerbations.³

- **Mucolytic (Mucociliary clearance) and Antioxidant activity:** Cleaves disulfide bonds in mucin glycoproteins, reducing mucus viscosity and enhancing mucociliary clearance. Simultaneously scavenges reactive oxygen species (ROS), attenuates oxidative stress–induced epithelial injury, preserves α 1-antitrypsin activity, and reduces mucus hypersecretion (Fig. 3).³



- **Anti-inflammatory activity:** Downregulates pro-inflammatory cytokine release and protease activity, decreases the levels of pro-inflammatory proteins and activation of transcription factors to suppress airway inflammation.³
- **Antibacterial activity:** It inhibits bacterial adhesion on epithelium and biofilm formation while improving antibiotic penetration, thereby supporting antibacterial activity.³

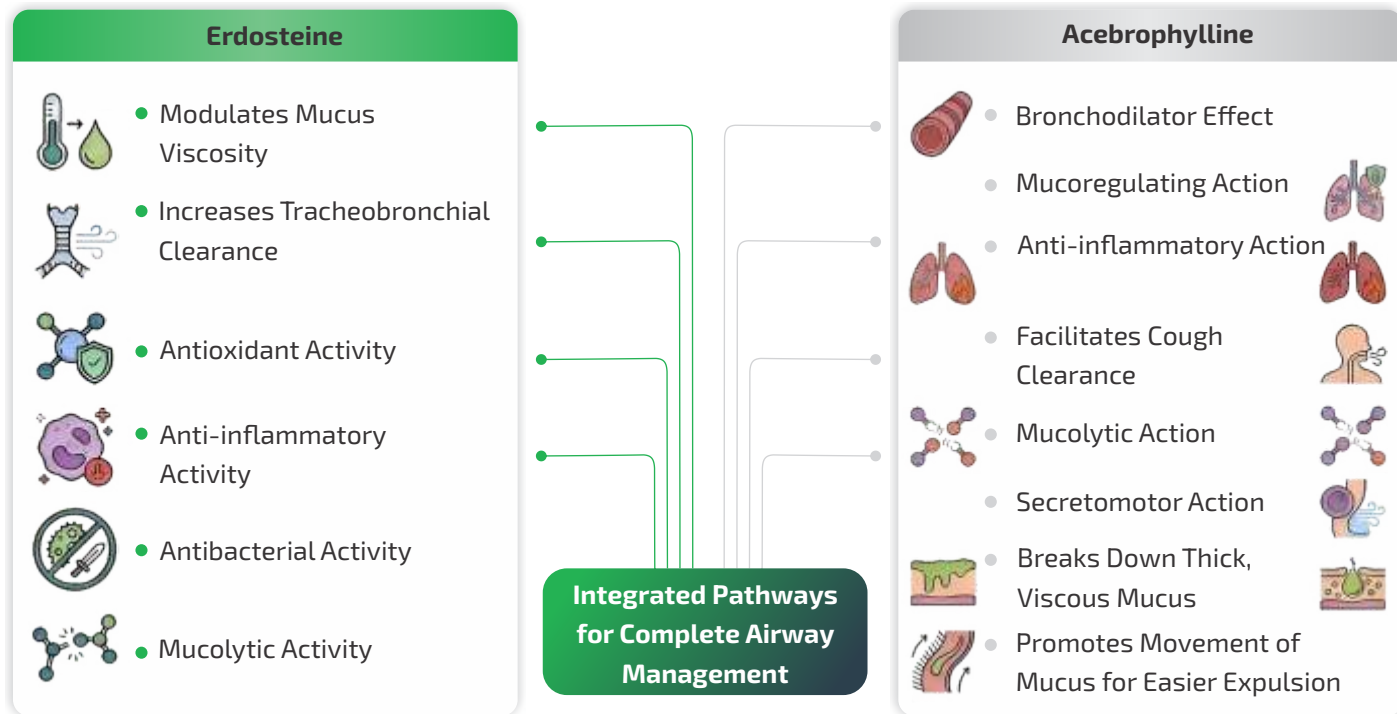
6. Synergistic Benefits of Erdosteine + Acebrophylline

6.1 Rationale for Combination¹⁷

- **Erdosteine:** reduces mucus viscosity, enhances mucociliary clearance; antioxidant, anti-inflammatory, and mucolytic actions
- **Acebrophylline:** bronchodilation (theophylline derivative) + mucoregulation and secretomotor effects (ambroxol)

6.2 Key Benefits¹⁷

- ↓ mucus hypersecretion and viscosity
- ↓ airway inflammation
- ↑ mucociliary clearance and expectoration
- Bronchodilation → improved airflow
- Overall: **Broader symptom improvement in chronic bronchitis/COPD**

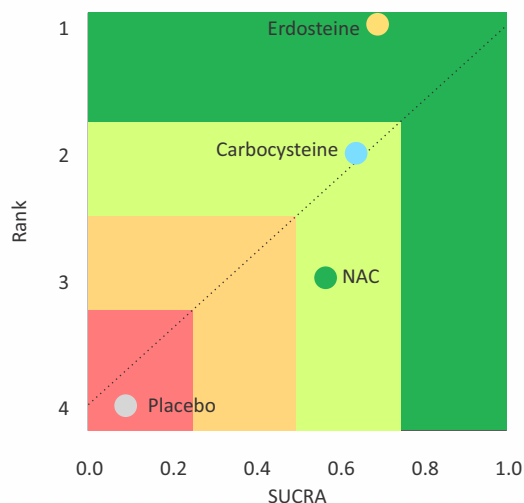


7. Erdosteine: The Superior Mucolytic Agent

7.1 Superior Clinical Efficacy

Among currently available mucolytics, Erdosteine demonstrates the greatest efficacy in COPD exacerbation prevention. A network **meta-analysis including 2,753 patients from 7 randomized controlled trials ranked mucolytic effectiveness** based on SUCRA analysis, indicating the highest probability of benefit with Erdosteine (Fig. 4).¹⁸

Figure 4: Erdosteine demonstrates better efficacy profile than Carbocysteine and NAC



Ranking plot resulting from the network meta-analysis in which treatments were plotted on X-axis according to SUCRA (score of 1 being the most effective) and on Y-axis according to the rank of being the best treatment (score of 1 being the most effective). #P < 0.1, *P < 0.05, **P < 0.01, and ***P < 0.001. SUCRA surface under the cumulative ranking curve

Erdosteine > Carbocysteine > N-acetylcysteine (NAC)

7.2 Reduction in Exacerbations and Hospitalization

Among the mucolytic/antioxidant agents evaluated in the network meta-analysis, erdosteine was the only agent that significantly reduced both the risk of experiencing at least one AECOPD and the risk of hospitalization due to AECOPD.¹⁸

7.3 Prolonged Duration of Action.²

Mucolytic Agents	Duration of Action
Erdosteine	12 hours
Carbocysteine	6-8 hours
N-acetylcysteine	2-6 hours

7.4 Favorable Safety and Tolerability

Erdosteine is generally **well tolerated**, with adverse events reported as mild and comparable to other mucolytic agents.¹⁸

7.5 Guideline Recognition

- The **Global Initiative for Chronic Obstructive Lung Disease (GOLD) 2026**
 - ✦ Recognizes erdosteine among mucolytic/antioxidant agents used in selected COPD patients, noting its potential to reduce mild exacerbations.²
- **American Academy of Otolaryngology–Head and Neck Surgery Foundation (AAO–HNSF) Adult Sinusitis Clinical Practice Guideline Update¹⁹**
 - ✦ Palliative medications including mucolytics can be used alone or in combinations for symptom relief in viral rhinosinusitis.
- **Canadian Clinical Practice Guidelines for Acute and Chronic Rhinosinusitis²⁰**
 - ✦ Use of mucolytics is an approach that may benefit symptoms of CRS

Erdosteine can be considered as the preferred mucolytic agent in COPD due to superior exacerbation reduction, hospitalization benefit, longer duration of action, and favorable tolerability.

8. Clinical Evidences

8.1 Erdosteine in Chronic Obstructive Pulmonary Disease (COPD)

RESTORE Trial: The RESTORE (Reducing Exacerbations and Symptoms by Treatment with Oral Erdosteine in COPD) study assessed impact of long-term treatment with Erdosteine at its standard dose on exacerbation rate, duration of exacerbations and time to next exacerbation event.²¹

Study Design

- Randomized, double-blind, placebo-controlled trial, n = 445
- 12 months duration
- GOLD II/III COPD patients (40–80 yrs)

Outcomes assessed

- Annual rate of acute COPD exacerbations

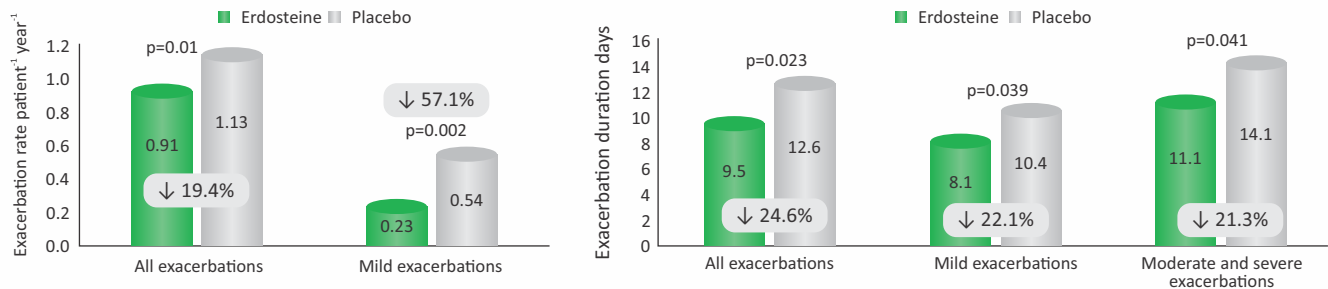
Treatment

- Erdosteine 300 mg BID + standard COPD therapy vs Placebo + standard therapy

Study Outcomes

- Reduced COPD exacerbations (especially mild events) (Fig. 5)
- Reduced duration of exacerbations (~21–25%) (Fig. 5)
- Improved symptom scores (patient + physician)
- Reduced rescue medication use
- Safe and well tolerated (similar AE rate vs placebo)

Figure 5: Reductions in COPD exacerbation frequency and duration with Erdosteine



Conclusion

- Erdosteine improves COPD control mainly by reducing frequency (especially mild events) and duration of exacerbations, with good tolerability.

8.2 Erdosteine in COPD Patients with Moderate Airflow Limitation

The post-hoc analysis of RESTORE study aimed to determine the effectiveness of Erdosteine on COPD exacerbations in patients with spirometrically-defined moderate COPD.²²

Study Population

- 254 patients with moderate COPD (FEV₁ 50–79% predicted) and a history of exacerbations

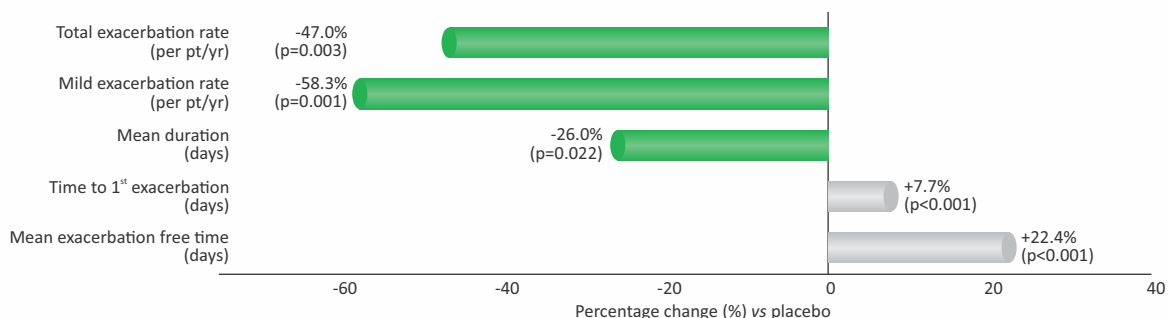
Outcomes assessed

- Exacerbation rate, severity, duration, time to first exacerbation, and exacerbation-free time

Study Outcomes

- Erdosteine reduced the number, rate, and duration of COPD exacerbations, while prolonging time to first event and exacerbation-free time (Fig. 6).

Figure 6: Improvements in COPD exacerbation frequency and duration with Erdosteine vs placebo



Erdosteine reduced mean exacerbation rate by 47% versus placebo: 0.27 vs 0.51 exacerbations/patient/year; p=0.003; Mild exacerbation rate was reduced by 58.3%: 0.23 vs 0.53 mild exacerbations/patient/year; p=0.001; Mean exacerbation duration was 26% shorter: 9.1 vs 12.3 days; p=0.022; Time to first exacerbation was prolonged by 13 days: 182 vs 169 days; p<0.001; Mean exacerbation-free time increased by 51 days: 279 vs 228 days; p<0.001

Conclusion

- Adding erdosteine to usual COPD maintenance therapy reduced the number of mild exacerbations and shortened the duration of all exacerbations in patients with moderate COPD and a history of exacerbations.

8.3 Erdosteine Enhances Antibacterial Efficacy of Antibiotics

This *in vitro* study was done to evaluate the effect of erdosteine + antibiotics against MSSA and MRSA biofilms.²³

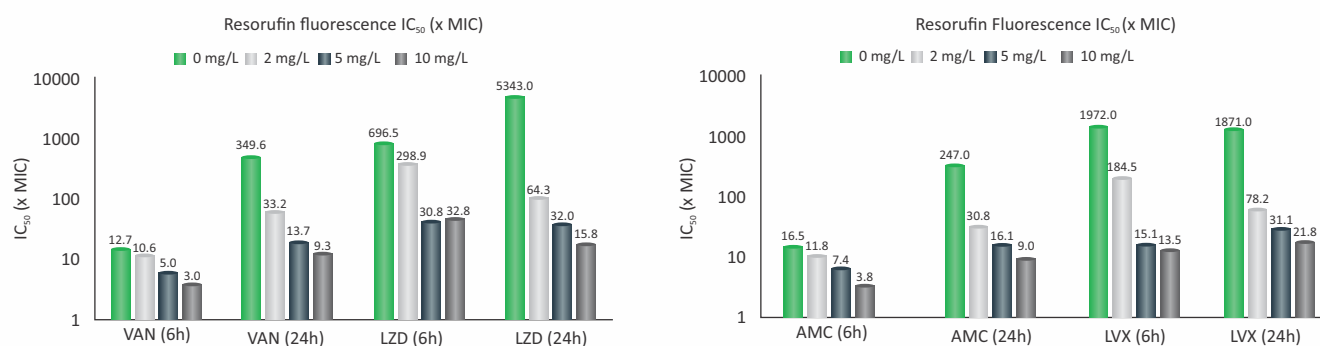
Study Details

- ***In vitro* study with bacterial biofilms grown for:** 6 h (young biofilms); 24 h (mature biofilms)
- **Bacterial biofilms of:** Methicillin-susceptible *Staphylococcus aureus* (MSSA), Methicillin-resistant *Staphylococcus aureus* (MRSA); Treated with antibiotics alone or combined with erdosteine (2, 5, or 10 mg/L).
- **Antibiotics tested:** MRSA: Vancomycin, Linezolid; MSSA: Amoxicillin/Clavulanate, Levofloxacin
- **Key Outcomes Measured:** Biofilm mass (crystal violet assay); Bacterial viability (resorufin assay)

Study Outcomes

- Erdosteine enhanced antibiotic activity against both MSSA and MRSA biofilms.
- Greater reductions in biofilm mass and bacterial viability were observed with the combination than with antibiotics alone.
- The benefit was particularly notable in 24-h mature biofilms, which were otherwise more resistant to treatment.

Figure 7: Effect of Erdosteine on bacterial viability in 6 and 24-h Biofilms of (A) MRSA and (B) MSSA



AMC: amoxicillin/clavulanate; LVX: levofloxacin; VAN: Vancomycin; LZD: Linezolid; IC_{50} : half-maximal inhibitory concentration; MIC: minimum inhibitory concentration.

Conclusion

- *In vitro* evidence suggests that erdosteine enhances antibiotic activity against MSSA and MRSA biofilms, supporting further investigation of its adjunctive role in biofilm-associated infections.

8.4 Erdosteine in the Treatment of Chronic Rhinosinusitis with Nasal Polyposis

Chronic rhinosinusitis is a persistent inflammatory condition where corticosteroids remain the mainstay, and macrolides are used for their cytokine-modulating effects. Given Erdosteine's multi-mechanism action—**mucolytic, antioxidant, antibacterial, and anti-inflammatory with TNF- α reduction**—it has been explored as a potential alternative or adjunct to conventional CRS therapies.²⁴

Study Design

- Prospective, non-interventional post-authorization pilot study.

Study Population

- Patients with chronic rhinosinusitis with nasal polyposis (CRSwNP).

Intervention

- Erdosteine alone vs erdosteine + nasal corticosteroid spray.

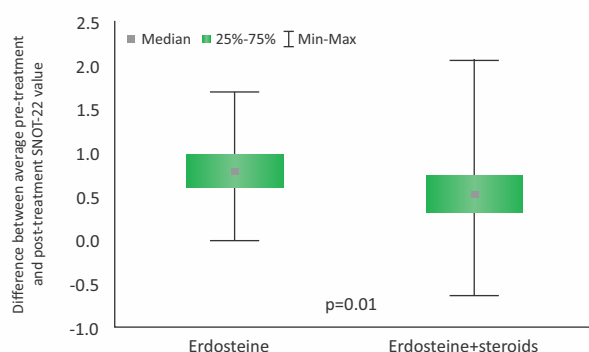
Outcomes assessed

- Endoscopic score changes.
- Symptom evaluation via 22-item Sinonasal Outcome Test (SNOT-22).

Study Outcomes

- Significant reduction in endoscopic and symptom scores in both groups (Fig. 8).
- Better response in the erdosteine-only group.
- No serious adverse effects were reported.

Figure 8: Change in SNOT-22 values between before and after treatment (p=0.02, Mann-Whitney).



Conclusion

- Pilot evidence suggests that erdosteine may improve endoscopic and symptom scores in CRSwNP and may represent a potential alternative to long-term macrolide or oral steroid therapy.

8.5 Erdosteine for Mucociliary Transport in Benign Chronic Suppurative Otitis Media (CSOM)

The Eustachian tube is essential for normal middle ear function, and effective mucociliary drainage is a key factor in successful treatment and outcomes of middle ear reconstructive surgery. In Chronic Suppurative Otitis Media, inflammation leads to epithelial damage, increased oxidant release, and excessive mucus production, all of which impair mucociliary clearance. Mucolytics reduce mucus viscosity by breaking mucopolysaccharide bonds, helping improve clearance and restore mucociliary function.²⁵

Based on this, the study evaluated the effectiveness of Erdosteine in improving mucociliary transport in patients with benign CSOM.

Study Design

- Experimental study; Pretest–posttest control group design; Random sampling

Sample size

- 16 patients with benign CSOM

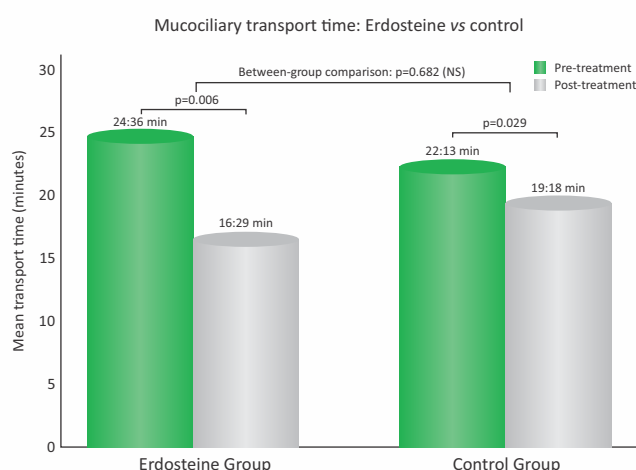
Intervention

- Group 1: Erdosteine + ciprofloxacin + aural toilet
- Group 2: Ciprofloxacin + aural toilet without erdosteine

Outcomes assessed

- Mucociliary transport time in the middle ear/Eustachian tube

Figure 9: Significant Reduction in mucociliary transport time



Conclusion

- Erdosteine was associated with faster mucociliary transport in benign CSOM; however, the improvement was not significantly different *versus* the control group.

8.6 Erdosteine in Children and Adults with Bronchiectasis (BETTER trial)

The BETTER trial is an international multicentre, double-blind, placebo-controlled RCT evaluating whether Erdosteine reduces exacerbations in patients aged 2–49 years with Bronchiectasis. The study aims to determine whether regular erdosteine therapy improves clinical outcomes in bronchiectasis.²⁶

- **Participants:** 194 children and adults
- **Sites:** Australia, Malaysia, Philippines
- **Intervention:** Erdosteine vs placebo for 12 months
- **Primary outcome:** Rate of respiratory exacerbations
- **Secondary outcomes:** Quality of life, exacerbation duration, time to next exacerbation, hospitalisations, lung function, adverse events, and cost-effectiveness.

8.7 Synergistic Mucociliary Clearance Benefits of Erdosteine and Acebrophylline in Chronic Bronchitis

The study evaluated the efficacy and safety of FDC of erdosteine 300 mg and acebrophylline 100 mg tablet versus FDC acebrophylline 100 mg and acetylcysteine 600 mg tablet in treatment of Chronic Bronchitis (CB) in participants with COPD.¹⁷

Study Design

- Prospective, randomized, open-label, parallel-group, multicentre phase 3 trial
- 21-day treatment period

Compared:

- Erdosteine 300 mg + Acebrophylline 100 mg vs Acebrophylline 100 mg + Acetylcysteine 600 mg

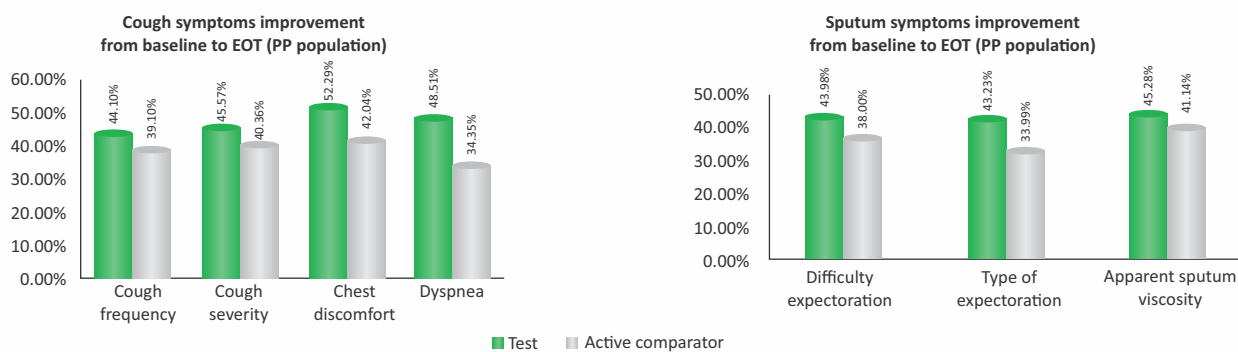
Participants

- N= 204; Stable Chronic Obstructive Pulmonary Disease with chronic bronchitis

Study Outcomes

- Erdosteine + acebrophylline showed greater reduction in
 - ▲ Cough symptoms (Fig. 10)
 - ▲ Sputum symptoms (Fig. 10)
 - ▲ Dyspnea and chest discomfort
 - ▲ Sputum viscosity and expectoration difficulty
- Comparable improvement in post-bronchodilator FEV₁

Figure 10: Significant Reduction in Cough and Sputum symptoms with Erdosteine/ Acebrophylline versus Acebrophylline/Acetylcysteine



Conclusion

- Erdosteine 300 mg + acebrophylline 100 mg demonstrated superior improvement in cough and sputum symptoms compared with acebrophylline 100 mg + acetylcysteine 600 mg, with a comparable and well-tolerated safety profile.

9. Erdozyd/ ErdozydAB – Product Information

Dosage & Therapeutic Indications¹⁶

Dosage (Adults/Elderly)	Erdozyd: 300 mg capsule twice daily (600 mg/day) for maximum 10 days; Erdozyd AB: Acebrophylline 100mg + Erdosteine 300mg tablet twice daily for adults or as directed by physician.
Administration	Swallow whole with water; do not crush or chew
Erdozyd	As an expectorant. For the symptomatic treatment of acute exacerbations of chronic bronchitis in adults.
Erdozyd AB	In the Treatment of Chronic Bronchitis in Patients with Chronic Obstructive Pulmonary Disease.

Safety Information	Erdozyd (Erdosteine) ¹⁶	Erdozyd AB (Acebrophylline + Erdosteine) ²⁷
Contraindications	Hypersensitivity to drug/excipients; CrCl <25 mL/min (not recommended); severe hepatic failure; active peptic ulcer	Acebrophylline: Tachyarrhythmias, hypotension, hemodynamic instability, recent MI; renal/hepatic disease. Erdosteine: Hypersensitivity
Warnings & Precautions	Mild hepatic impairment: do not exceed 300 mg/day; caution in renal/hepatic impairment	Careful monitoring in CHF, chronic alcoholism, hepatic dysfunction, viral infections; caution in renal/hepatic impairment
Drug Interactions	No clinically significant interactions reported	Quinolones, cimetidine, erythromycin, oxytetracycline, lincomycin, cephalixin: May increase acebrophylline plasma concentrations; Reserpine: May increase heart rate (rarely used currently); Barbiturates and phenytoin: May decrease acebrophylline plasma concentrations, reducing efficacy; Furosemide (furosemide): May enhance diuresis, leading to more frequent urination; Corticosteroids: May worsen hypokalemia when used with acebrophylline.
Pregnancy & Lactation	Not recommended during pregnancy or breastfeeding	
Children <2 years	Not recommended	
Effects on Driving	Minimal or no influence	
Adverse Effects	Erdosteine:- Gastrointestinal: Epigastric pain, taste alteration, nausea, vomiting, diarrhoea; Neurological: Headache; Hypersensitivity: Angioedema, urticaria, oedema, erythema, eczema.	Acebrophylline:- Common: Nausea, dizziness, abdominal discomfort/distension, abdominal pain, vomiting, diarrhoea, constipation, heartburn, loss of appetite; Others: Rash, urticaria, pruritus, drowsiness, dyspnoea, nasal inflammation, leucocytosis, oesophageal bleeding; Rare: Headache, numbness, insomnia, tachycardia, fatigue, hypertension/hypotension, albuminuria, glycosuria, hyperglycaemia; Serious: Fever and chills warrant immediate discontinuation. Erdosteine:- Gastrointestinal: Epigastric pain, taste alteration, nausea, vomiting, diarrhoea; Neurological: Headache; Hypersensitivity: Angioedema, urticaria, oedema, erythema, eczema.
Overdose	Pancreatitis if abdominal pain persists; Restlessness; Hypertonia; Symptomatic treatment should be provided; Nausea, vomiting	

10. Summary

COPD/ Moderate COPD^{21,22}

↓ Exacerbations, ↓ exacerbation duration, prolonged time to next exacerbation

Chronic Bronchitis in COPD¹⁷

↓ Cough and sputum symptoms; improved mucus clearance

Chronic Rhinosinusitis (CRS)²⁴

↓ SNOT-22 score; improvement in nasal polypsis

Chronic Suppurative Otitis Media (CSOM)²⁵

Improved mucociliary transport and mucus clearance^{*}

Mucus Hypersecretion/ Productive Cough¹⁷

Mucus viscosity; enhanced expectoration and mucociliary clearance

References:1. Cazzola M, Rogliani, Ora J, Calzetta L, Matera MG. Mucus as a treatable trait in chronic airway diseases. *Drugs*. 2026;86(4):443-463.; 2. Global Initiative for Chronic Obstructive Lung Disease (GOLD). Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease: 2026 pocket guide. GOLD; 2025. Available at: https://goldcopd.org/wp-content/uploads/2026/01/GOLD-Pocket-Guide-2026-v1.1-20Nov2025_WMV2.pdf. Accessed May 20, 2026.; 3. Vora A, Tiwaskar M, Prajapati C, Jose A, Qamra A, Muralidharan P. Erdosteine: reigniting a thiol mucolytic for management of chronic obstructive pulmonary disease. *J Assoc Physicians India*. 2025;73(1):29-34.; 4. Halder P, Khaliwal R, Goel S, Kumar N, Sarkar M, Soni M, Nongkynrith B, Prabhakar MC, Mangai A, Rathor S. Burden of chronic obstructive pulmonary disease among Indian adults: systematic review and meta-analysis. *BMC Pulm Med*. 2026;26:112.; 5. Guccamburu M, Klein E, Verdy C, et al. Factors associated with undiagnosed COPD in patients hospitalised for severe COPD exacerbation. *BMJ Open Respir Res*. 2024;11:e002620.; 6. Mcguire K, Avila-Zubieta JA, Eddle JM, Sadatsafavi M, Sayre EC, Abrahamowicz M, Lacaille D. Risk of Incident Chronic Obstructive Pulmonary Disease in Rheumatoid Arthritis: A Population-Based Cohort Study. *Arthritis Care Res (Hoboken)*. 2019 May;71(5):602-610.; 7. Roche N, Molinari N, Watier L, Schmidt A, Panes A, Pagès N, Perrier S, Vataire AL, Marcardé-Fulcrand V, Bourdin A. Characteristics and real-world health clinical outcomes of uncontrolled COPD patients: population-based study in France. *ERJ Open Res*. 2025 Dec 15;11(6):00104-2025.; 8. Venkatakrishnan R, Sudheendranath A, Vijay A, Ramachandran D, Cleetus M, Somson HT, John S. A Prospective Observational Study Evaluating the Progression Of Bronchiectasis in COPD Patients - Results from the PROBE - COPD Study. *Int J Chron Obstruct Pulmon Dis*. 2026 Mar 24;21:571906.; 9. Widysanto A, Goldin J, Mathew G. Chronic Bronchitis. [Updated 2025 Feb 6]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2026 Jan-. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK482437/>; 10. Nandyal CB, Benola A. Evaluation of anatomical variations associated with chronic rhinosinusitis by computed tomography of paranasal sinuses. *Indian J Otolaryngol Head Neck Surg*. 2024;76(2):915-921.; 11. Zhai Z, Shao L, Lu Z, Yang Y, Wang J, Liu Z, Wang H, Zheng Y, Lu H, Song X, Zhang Y. Characteristics of mucus hypersecretion in different inflammatory patterns based on endotypes of chronic rhinosinusitis. *Clin Transl Allergy*. 2024; e12334.; 12. Savant OR, Khan TA. Chronic suppurative otitis media: a systematic review of treatment studies. *Int J Innov Sci Res Technol*. 2021;6(2):260. ISSN 2456-2165. Available from: www.ijisrt.com/IIJSRT1FEB126; 13. Kedia Y, Ish P, Rath V. Erdosteine in chronic obstructive pulmonary disease - Evidence and current role. *J Adv Lung Health*. 2025;5:51-2.; 14. Mettler SK, Nath HP, Grumley S, Orejas JL, et al. Silent airway mucus plugs in COPD and clinical implications. *Chest*. 2024;166(5):1010-1019.; 15. Ramos FL, Krahne JS, Kim V. Clinical issues of mucus accumulation in COPD. *Int J Chron Obstruct Pulmon Dis*. 2014;9:139-150.; 16. Erdotin 300 mg capsules. Summary of Product Characteristics. Electronic Medicines Compendium. Published May 20, 2026. Available at: <https://www.medicines.org.uk/emc/product/287/smpc#gref>. Accessed May 20, 2026.; 17. Mungantiwar A, Shrivastava P, Wattamwar T. A randomized, open-label, active-controlled, phase 3 clinical trial of fixed-dose combination erdosteine 300 mg and acebrophylline 100 mg tablet versus fixed-dose combination acebrophylline 100 mg and acetylcysteine 600 mg tablet in treatment of chronic bronchitis in participants with chronic obstructive pulmonary disease. *Int J Sci Res*. 2025;14(12):1-6.; 18. Rogliani P, Matera MG, Page C, Puxeddu E, Cazzola M, Calzetta L. Efficacy and safety profile of mucolytic/antioxidant agents in chronic obstructive pulmonary disease: a comparative analysis across erdosteine, carbocysteine, and N-acetylcysteine. *Respir Res*. 2019;20:104.; 19. Payne SC, McKenna M, Buckley J, Colandrea M, Chow A, Detwiler K, Donaldson A, Dubin M, Finestone S, Filip P, Khalid A, Peters AT, Rosenfeld R, Akrami Z, Dhepyasuan N. Clinical practice guideline: Adult sinusitis update. *Otolaryngol Head Neck Surg*. 2025;173.; 20. Desrosiers M, Evans GA, Keith PK, Wright ED, Kaplan A, Bouchard J, Ciavarella A, Doyle PW, Javer JR, Leith ES, Mukherji A, Schellenberg RR, Smal P, Witterick IJ. Canadian clinical practice guidelines for acute and chronic rhinosinusitis. *Allergy Asthma Clin Immunol*. 2011;7:2.; 21. Dai Negro RW, Wedzicha JA, Iversen M, et al. Effect of erdosteine on the rate and duration of COPD exacerbations: the RESTORE study. *Eur Respir J*. 2017; 50: 1700771.; 22. Calverley PMA, Page C, Dai Negro RW, Fontana G, Cazzola M, Cicero AF, Pozzi E, Wedzicha JA. Effect of erdosteine on COPD exacerbations in patients with moderate airflow limitation. *Int J Chron Obstruct Pulmon Dis*. 2019;14:2733-2744.; 23. Pani A, Lucini V, Dugrani S, Scaglione F. Erdosteine enhances antibiotic activity against bacteria within biofilm. *Int J Antimicrob Agents*. 2022 Mar;59(3):106529.; 24. Hozai J, Salzman R, Stárek I, Schalek P, Kellnerová R. Efficacy and safety of erdosteine in the treatment of chronic rhinosinusitis with nasal polypsis: a pilot study. *Rhinology*. 2013;51(4):323-327.; 25. Ridwan A, Haroen E, Alia D, Ilyas D. Erdosteine for mucociliary transport in benign chronic suppurative otitis media. *GSC Adv Res Rev*. 2022;13(3):91-96.; 26. Chang AB, Yerkovich ST, Baines KL, et al. Erdosteine in children and adults with bronchiectasis (BETTER trial): study protocol for a multicentre, double-blind, randomised controlled trial. *BMJ Open Respir Res*. 2024;11:e002216.; 27. Product Leaflet of Erdozyd AB.

^{*}however, between-group difference was not statistically significant

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1. Rogliani et al. Respiratory Research Page 4 of 11 (2019) 20:104 2 2. Accessed on <https://cdn.medpath.com/drug/instruction/20240511/8b3aafb55772be1ba113be690bc5cae2.pdf> dated 08/04/26 IST.

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