



GMep
MEDICAL TECHNOLOGY



ORIGINAL RESEARCH
INNOVATIVE FORMULATION
HIGH-CONC. PRODUCT

AMBROSPRAY®

Ambroxol Hydrochloride Oral Spray

World's First Ambroxol Hydrochloride Spray
for individuals aged 6 and above

5%

ULTRA-
CONCENTRATED SPRAY

Postoperative
airway mucus
management

Mucus viscosity
caused by various
conditions

Improves lung
function and
relieves breathing
difficulty

AmbroSpray®

Ultra-Concentrated Formulation with Dual Mechanism of Action

Ambroxol hydrochloride spray



Local Action

- Relieves sore throat
- Alleviates coughing

Systemic Action

- Thins and clears mucus
- Supports lung function during recovery and perioperative periods
- Provides anti-inflammatory and antioxidant effects
- Enhances antibiotic efficacy

- Developed and manufactured in EU
- Meets strict EU pharmaceutical standards
- 5% ultra-concentrated expectorant formulation

Premium European Quality

- The most concentrated ambroxol formulations available
- Mucosolvan: 0.6%
- Oral solution: 0.3%
- Spray: 5%

Ultra-concentrated formulation

- Extended 360° rotating nozzle design
- Ensures rapid and accurate drug delivery
- 13 ml bottle, 50 mg/ml
- Each spray delivers 0.2 ml = 10 mg

Precision Dosing

- Compact design for easy use on-the-go
- Suitable for a wide range of users and settings

User-Friendly & Portable

AmbroSpray® — Dual Action: Anesthetic & Analgesic Relief

Ambroxol hydrochloride spray

Common Causes of Acute Sore Throat

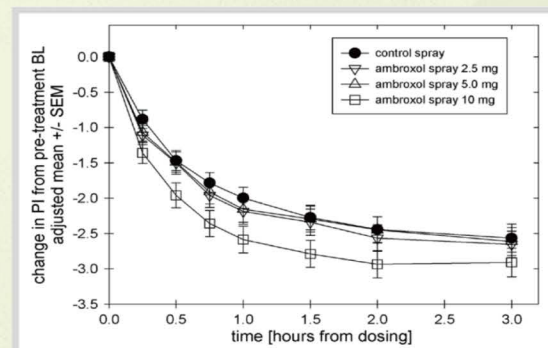
- Common cold
- Viral pharyngitis
- Herpetic angina
- Pharyngoconjunctivitis
- Bacterial pharyngitis

Mechanism of Action: Local Anesthetic & Analgesic Effects

- Blocks sodium channels on sensory neurons to relieve pain
- Approximately 10× more potent than benzocaine as a local anesthetic
- Effective for both acute and chronic pain
- High bioavailability with excellent safety profile

A randomized, double-blind, placebo-controlled clinical trial demonstrated:

- Significant pain reduction with Ambroxol spray (2.5 mg, 5 mg, 10 mg)
- Rapid onset of action
- Well tolerated with no serious side effects



Change in pain intensity (SEM) after placebo vs. ambroxol spray (2.5 mg, 5 mg, 10 mg)

AmbroSpray®

High Bioavailability – Ideal for Respiratory Mucus Hypersecretion Conditions

Ambroxol hydrochloride spray

Included diseases (n=164)

Acute bronchitis
(n=21,28%)

Acute URTI
(n=13,17.33%)

Acute pneumonia
(n=37,49.33%)

Other
(n=4,5.33%)

Comparative Study: Ambroxol Spray vs. Oral Solution

1/ Effectiveness

- Greater improvement in cough score, severity, and quality of life with spray vs. oral solution
- Statistically significant difference ($P < 0.0001$)

2/ Safety

No significant difference in drug safety

3/ Compliance

- Significantly higher adherence and patient compliance in the spray group
- Good adherence:
- Spray: 100% ($P < 0.0001$)

TABLE 3 Secondary outcomes including cough severity at day 1, 4, and end of treatment, quality of life assessment, and medication adherence.

	Ambroxol spray (N = 75)	Ambroxol solution (N = 79)	P-value
Cough severity measured using VAS			
Mean at baseline, mean (SD)	6.8 (1.93)	6.8 (1.79)	
Change from baseline at day 1, mean (SD)	0.0 (0.56)	-0.2 (0.70)	0.82
- Least-squares mean difference vs. solution arm (95% CI) — liters	-0.033 (-0.323,0.257)		
Change from baseline at day 4, mean (SD)	-4.3 (2.32)	-3.9 (1.87)	0.03
- Least-squares mean difference vs. solution arm (95% CI) — liters	-0.276 (-0.520,-0.032)		
Change from baseline at end of treatment, mean (SD)	-5.7 (2.09)	-5.2 (2.04)	0.01
- Least-squares mean difference vs. solution arm (95% CI) — liters	-0.600 (-1.030,-0.170)		
Quality of life assessment measured using the PAC-QoL questionnaire			
Mean at baseline, mean (SD)	23.7 (7.67)	24.2 (9.11)	
Change from baseline at end of treatment, mean (SD)	-16.4 (9.14)	-12.4 (10.17)	<0.01
Acceptable adherence			
Good adherence, n (%)	75 (100.0)	39 (49.37)	<0.01
Medication adherence			
Good adherence, n (%)	75 (100.0)	64 (81.01)	<0.01

AmbroSpray® : Enhancing Perioperative Airway Management

Ambroxol hydrochloride spray

Perioperative use of ambroxol spray helps reduce lung complications and hospitalization costs after lobectomy.

Lungs complication

13% ▼

overall complication

14% ▼

Compared with untreated patients

- Postoperative cardiopulmonary complications were lower in patients treated with ambroxol
- Postoperative pulmonary complications were reduced, with statistical significance between the two groups

Common Risk Factors During Perioperative Care:

Throat pain

Bed rest

Aspiration pneumonia

Difficulty swallowing

Hospitalization time

2.5 days ▼

Hospitalization cost

2765 Euro ▼

2.5 days and 2765 Euros, respectively, in the ambroxol group. explained by higher ICU costs in the untreated group.

- Innovative nozzle design ideal for bedridden patients
- 0.2 ml per spray — prevents swallowing reflex
- Helps prevent aspiration pneumonia

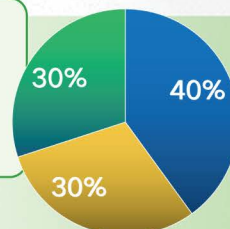
AmbroSpray® — Versatile Use — Suitable for a Wide Range of Patients

Ambroxol hydrochloride spray



⚡ Thick Sputum Relief (30%)

- Ideal for asthma, COPD, bronchitis, and pneumonia.
- Fast-acting, portable, and user friendly.
- Effective for mucus due to dryness, smoking, or pollution.



🌐 Perioperative Airway Management (40%)

- Reduces post-op lung complications and sputum retention.
- Prevents coughing-induced airway/wound issues.
- Easy self use reduces caregiver dependency.

🏠 Bedridden Patients & Special Populations (30%)

- Easy oral spray for elderly, children, and dysphagic patients.
- Precise dosing enhances safety and compliance.
- Minimizes risks of choking, spillage, and vomiting.

One bottle provides approx. 5–7 days of treatment.
(5–7 days per bottle)

AmbroSpray® — Prescribing Information

Ambroxol hydrochloride spray

Active ingredients	Each gram of product contains 50 mg of ambroxol hydrochloride. Each spray delivers 10 mg of ambroxol hydrochloride. Each spray contains 1 mg of ethanol.
Indications	For individuals aged 6 years and above with thick sputum and difficulty expectorating due to acute or chronic bronchial and pulmonary conditions.
Pharmacological Action	Ambroxol enhances mucociliary clearance by regulating bronchial secretions, stimulating epithelial cilia activity, and promoting type II surfactant production. It also exhibits antioxidant and anti-inflammatory effects by inhibiting neutrophil-driven inflammation and the release of histamine, leukotrienes, and cytokines—helping protect lung tissue from oxidative damage.
Specifications and dosage forms	13ml, 50mg/ml
How to use	Three times a day, three sprays each time, each dose is equivalent to 10mg ambroxol
Route of administration	Oral spray
Shelf life	36 months
Authorized Holder	GMep Medical Technology GmbH Königsallee 2b, 40212 Düsseldorf, Germany

References:

Ambroxol hydrochloride spray

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- [2] Riet-Nales DA, Hussain N, Sundberg KA, et al. Regulatory incentives to ensure better medicines for older people: From ICH E7 to the EMA reflection paper on quality aspects. Int J Pharm. 2016;512(2):343-351.
- [3] Mey C, Patel J, Lakha DR, Richter E, Koelsch S. Efficacy and Safety of an Oral Ambroxol Spray in the Treatment of Acute Uncomplicated Sore Throat. Drug Res (Stuttg). 2015;65(12):658-667.
- [4] Refai M, Brunelli A, Xiumé F, et al. Short-term perioperative treatment with ambroxol reduces pulmonary complications and hospital costs after pulmonary lobectomy: a randomized trial. Eur J Cardiothorac Surg. 2009;35(3):469-473.

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