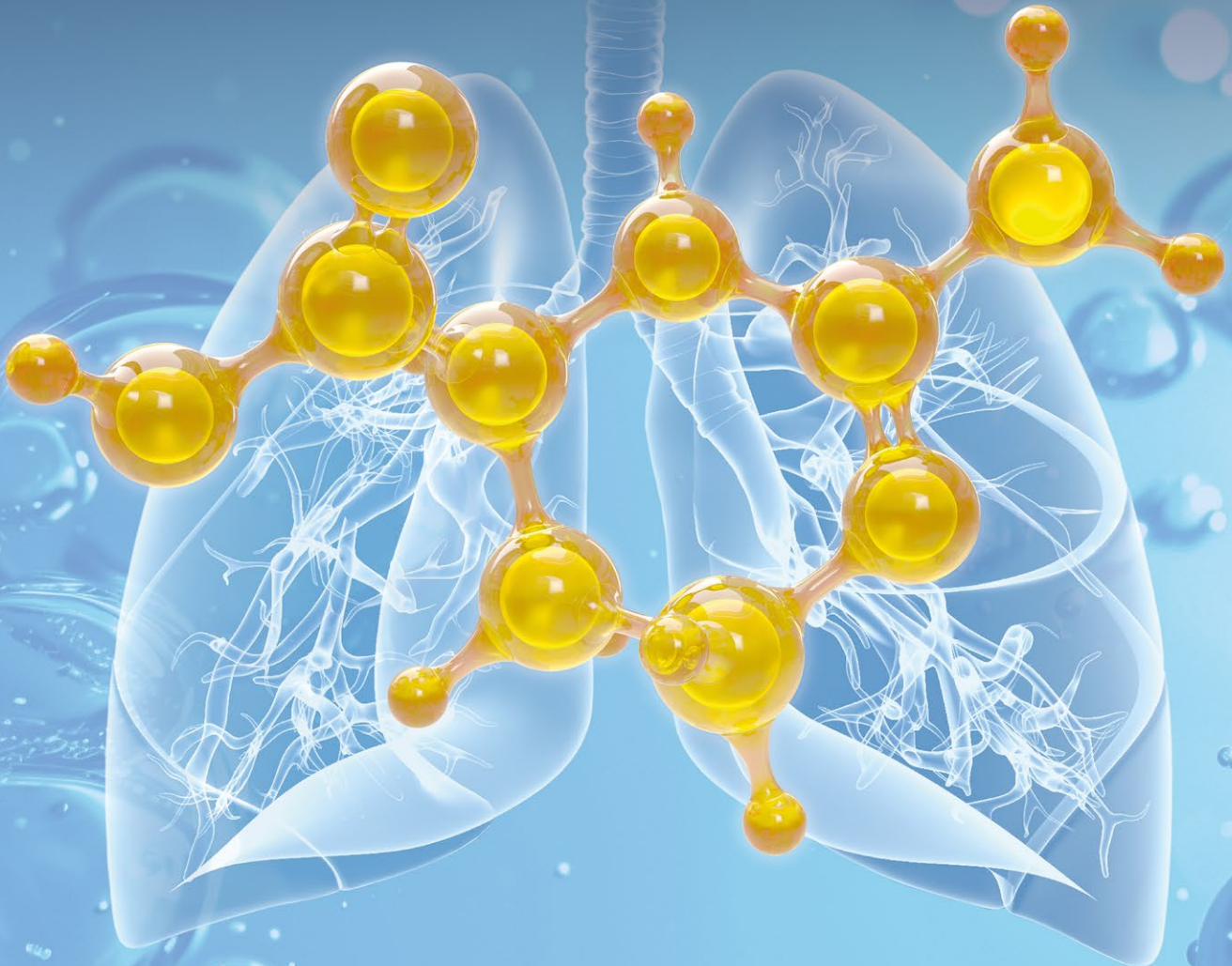


medEctoin[®]

COUGH & COLD
White Label Medical Devices
Study Overview





medEctoïn® OTC Product Range



medEctoïn® Mouth & Throat Spray

- Reduces symptoms of acute Pharyngitis and/ or Laryngitis
- Reduces the duration of a sore throat/ hoarseness
- Hydrates dry and irritated epithelia
- Soothes irritations and alleviates the urge to cough

Packaging:
20 ml in MDU bottle (3K system)

medEctoïn® Lozenges

- Reduces the danger of a bacterial or viral infection in the mouth and throat
- Relieve hoarseness, sore throat or pain on swallowing
- Soothes irritations and alleviates the urge to cough
- Available in three flavours

Packaging:
1, 2, 3 or 4 blister strips
containing 8 lozenges à 2.3 g

For all Cough & Cold symptoms



medEctoin® Rhinitis Nasal Spray

- Effectively decongests the nose and sinuses on a natural way
- Clinically proven to work as effective as common decongesting nasal spray drugs (with e.g. Xylometazoline)
- Supports the regeneration process of irritated nasal mucosa
- No habituation effect

Packaging:

20 ml bottle with dosage pump (3K System)



medEctoin® Inhalation Solution

- Supportive treatment and symptom reduction of inflammatory airway diseases
- Bronchitis, Asthma and COPD
- Protects and moisturizes the mucosa of the airways
- Dilutes thick mucus and makes it easier to cough it up

Packaging:

2.5 ml solution in single-dose units (SDU) for jet, mesh, or ultrasound nebulizers



medEcto[®] Mouth & Throat Spray

A common cold often comes along with an inflamed and irritated throat. Mucous membranes are swollen and red which causes pain on swallowing. Moreover, the irritation causes dry cough and hoarseness.

medEcto[®] Mouth & Throat Spray effectively reduces symptoms like sore throat, hoarseness, dry cough, and pain on swallowing. Moreover, it hydrates the dry and irritated epithelia and supports the regeneration process.

Claims

Mouth and Throat Spray for the treatment of dry and irritated epithelia in mouth and throat.

Prevention

- Recommended to start usage at the first signs of hoarseness, dry cough, swollen lymph nodes and a sore throat.
- The medEcto[®] Hydro Complex and the stabilized mucosal barrier structure help to reduce bacterial, viral and allergen ingressions.*

Treatment

- Reduces symptoms of acute Pharyngitis and/ or Laryngitis, such as sore throat, hoarseness, cough, and pain on swallowing.
- Relieves first symptoms such as hoarseness, dry cough, swollen lymph nodes and a sore throat and prevents worsening.
- Supports the reduction of inflammations of the mucous membranes in mouth and throat.

Regeneration

- Hydrates dry and irritated epithelia and supports regeneration by stabilization of mucosal barrier structure.
- Reduces the duration of a sore throat and hoarseness.

Safety & Usability

- Effect is based on 100% natural ingredients.
- Preservative free.
- With pleasant Mint-Salvia flavour.

*based on preclinical data



Clinical Results

Product	Study Design	Top Line Results Superior	Reference
medEctoin® Mouth and Throat Spray Mint	N = 95, non-interventional prospective, controlled, multicenter study in comparison to Emser Pastillen® (contains natural salt)	Efficacy in treating acute pharyngitis and/ or laryngitis compared to mineral salt pastilles (Emser Pastillen®)	Müller et al. 2016

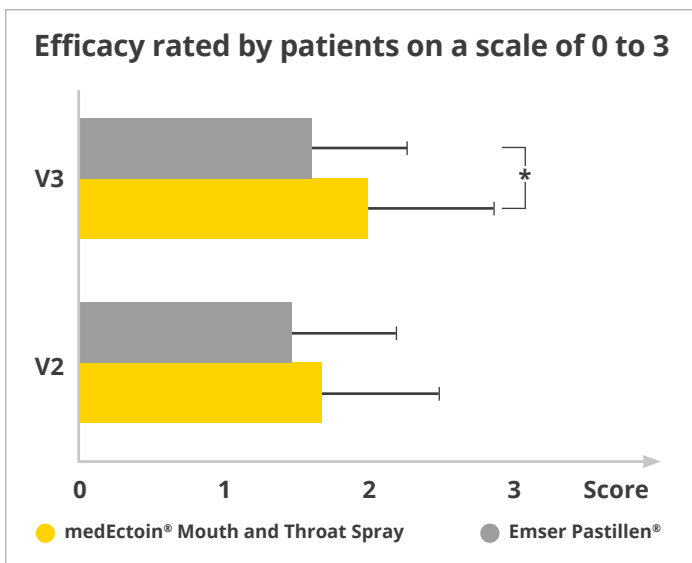


Figure 1. Efficacy of investigational products rated by patients between visits 2 and 3. Scores: 0 = poor, 1 = satisfactory, 2 = good, 3 = very good. * marks statistical significance (p<0.05). Ref. Müller et al. 2016

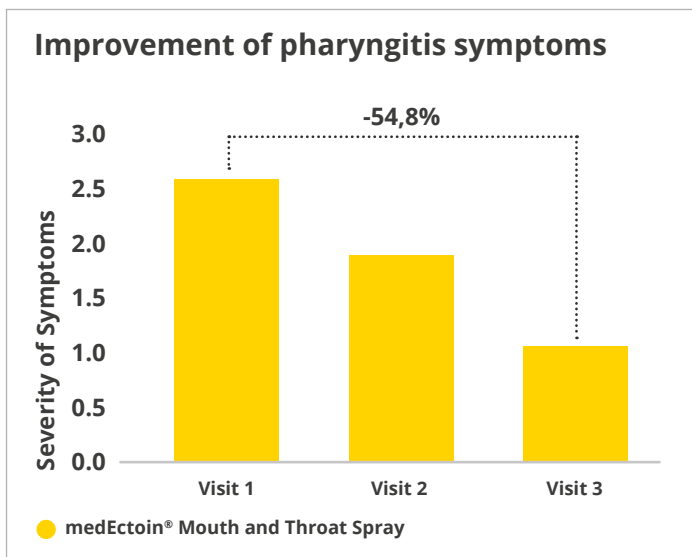


Figure 2. Analysis after 7 days of the pharyngitis symptom score (swollen palatine tonsils, swollen cervical lymph nodes, fever, and cough). Significant reduction in severity of the symptoms by -54,8%. Ref. Müller et al. 2016



Medical Device Class:
IIb MDN Code: 1213 (MDR)



Shelf Life:
36 months



Packaging:
20 ml in MDU bottle
(3K system)

Pa0:
3 months



medEctoⁱⁿ® Lozenges

Irritations in the mouth and throat are caused by multiple factors such as voice overuse, air conditioning or a common cold. The most common symptoms are sore throat, hoarseness, and pain on swallowing.

The medEctoⁱⁿ® Lozenges not only hydrate the irritated mucous membranes, they also help to prevent irritations. The lozenges are the perfect companion to keep your throat and voice smooth throughout the day.

Claims

Lozenges for the treatment and prevention of common cold symptoms, dry mouth and throat, and hoarseness.

Prevention

- Reduces the danger of a bacterial or viral infection in the mouth and throat.
- Reduces and prevents irritations of the mucous membranes such as voice fatigue, tickly throat, or dryness caused by voice overuse, allergens or dry air resulting from e.g. heating, cold, air conditioning, or smoke.
- Recommended to start usage at the first signs of hoarseness, dry cough and a sore throat.
- Relieves first symptoms such as hoarseness, dry cough and a sore throat and prevents worsening.

Treatment

- Forms a protective shield called “medEctoⁱⁿ® Hydro Complex” on mucous membranes in mouth and throat.
- Reduces inflammations and stabilizes the mucous membranes in mouth and throat.
- Reduces symptoms of acute Pharyngitis, such as hoarseness, sore throat, and pain on swallowing.
- Soothes irritations and alleviates the urge to cough.

Regeneration

- Hydrates dry and irritated epithelia and supports their regeneration.
- Increases saliva production and supports free breathing.

Flavours

- Honey Lemon & Mint.
- Honey & Salt (Mucolytic properties: dissolves thick and compact mucous).
- Forrest Berry & Cherry.



Clinical Results

Product	Study Design	Top Line Results Superior	Reference
medEctoïn® Soft Lozenges Wildberry	N = 90 patients with acute viral pharyngitis • 35 x medEctoïn® Soft Lozenges Wildberry • 35 x HA-containing lozenges • 20 x saltwater gargling solution	<ul style="list-style-type: none"> medEctoïn® Soft Lozenges Wildberry significantly improve pharyngitis symptoms. Significant superiority compared to HA-containing lozenges (GeloRevoice®) in reducing redness of the mucosa in mouth and throat. 	Dao et al. 2019
medEctoïn® Lozenges Honey Lemon	N = 102 patients with acute viral pharyngitis • 51 x medEctoïn® Lozenges • 51 x Isla® med akut pastillen	<ul style="list-style-type: none"> 86% of patients reported improvement in symptoms using medEctoïn® Lozenges Quick symptom relieve: the medEctoïn® Lozenges improve the patients' general condition significantly better than the comparator in the first 5 days. 	btph-014-2018-EHT02

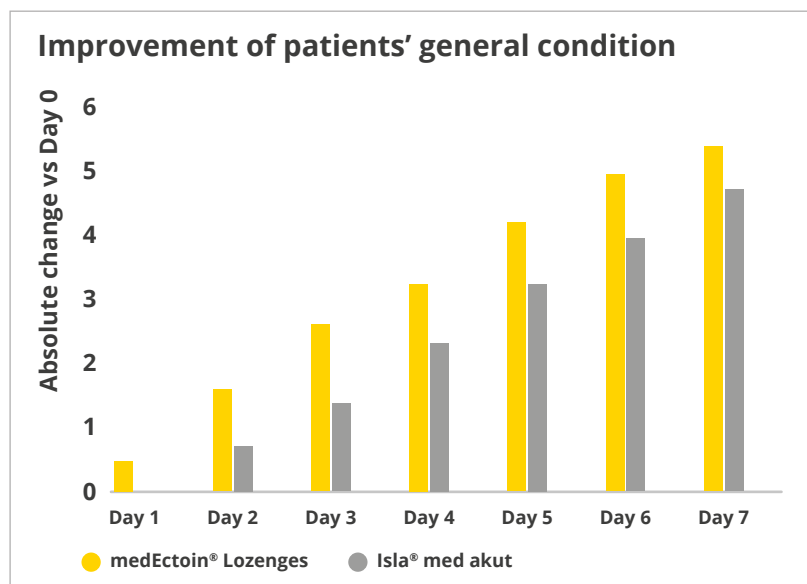


Figure 3. Significant better improvement of patients' general condition with medEctoïn® Lozenges than with the comparator on day 1 to day 5.
Ref. btph-014-2018-EHT02



Medical Device Class:

I



Shelf Life:

24 months



Packaging:

1, 2, 3 or 4 blister strips containing 8 lozenges à 2.3 g

Pa0:

N.a.



medEctoïn® Rhinitis Nasal Spray

A blocked or runny nose, sneezing and facial pain are caused by inflammation of the nasal and sinus mucosa. These rhinitis and rhinosinusitis symptoms are typically treated with drug-based nasal decongestants or corticosteroids, which are associated with well-known side effects.

medEctoïn® Rhinitis Nasal Spray works as effective as common decongesting nasal sprays (with e.g. Xylometazoline). It reduces typical symptoms of a common cold with a 4-in-1 effect and supports the regeneration process of irritated nasal mucosa without a habituation effect.

Claims

Nasal Spray for the treatment and prevention of rhinitis or rhinosinusitis symptoms.

Prevention

- Reduces the need for pharmaceutical decongestant sprays (e.g. with Xylometazoline).
- The medEctoïn® Hydro Complex and the stabilized mucosal barrier structure help to reduce viral ingressión.*
- Cleans and moistens the nasal mucosa.

Treatment

- 4-in-1 effect: Significantly reduces blocked nose, runny nose, facial pain/ headache, and loss in smell and taste.
- Effectively decongests the nose and sinuses on a natural way.
- Reduces inflammations of the irritated nasal mucosa and sinuses caused by rhinitis and rhinosinusitis (common cold).
- Clinically proven to work as effective as common decongesting nasal spray drugs (with e.g. Xylometazoline).
- Alleviates typical symptoms such as dry and wound nasal epithelium, sneezing, itching and crust formation.
- Reduces negative side effects of common decongesting nasal sprays, e.g. the dehydration of the nasal mucous membranes.

Regeneration

- Supports the regeneration process of irritated nasal mucosa.
- Negative side effects of common nasal sprays like dehydration of the nasal mucous membranes are reduced.

Safety & Usability

- Suitable for the use in children.
- No habituation effect.
- Preservative-free.
- Efficacy clinically proven.



Clinical Results

Product	Study Design	Top Line Results Superior	Reference
medEctoin® Rhinitis Nasal Spray	N = 65, multi-center study in comparison to Sinupret® forte	<ul style="list-style-type: none"> Significant reduction of primary symptoms of acute rhinosinusitis. Equivalent efficacy of medEctoin® Rhinitis Nasal Spray to the German OTC best-seller Sinupret® forte. 	Eichel et al. 2013
medEctoin® Rhinitis Nasal Spray	N = 168, multi-center multi-center, non-interventional study in comparison with a Xylometazoline-containing Nasal Spray. Either as monotherapy or as adjuvant therapy.	<ul style="list-style-type: none"> Equal reduction of symptoms around 65% of medEctoin® Rhinitis Nasal Spray and the comparator. medEctoin® Rhinitis Nasal Spray improves the dryness of the nasal mucosa by 47% after 7 days 	Werkhäuser et al. 2021

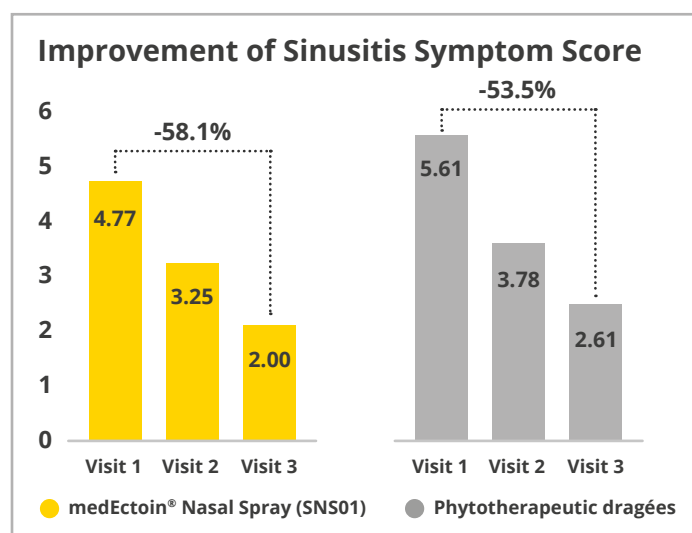


Figure 4. Effective reduction of rhinitis symptoms.
Ref: Eichel et al. 2013

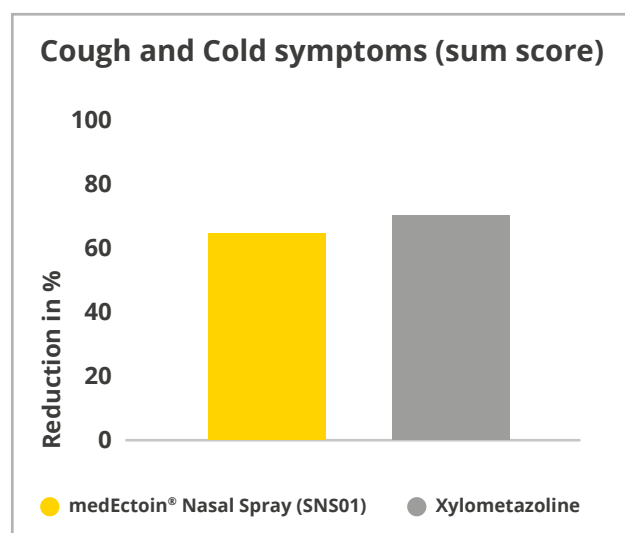


Figure 5. The reduction of Cough and Cold symptoms is equivalent to the comparator.
Ref. Werkhäuser et al. 2021



Medical Device Class:

I



Packaging:

20 ml bottle with dosage pump (3K System)



Shelf Life:

36 months

Pa0:

3 months





medEctoⁱⁿ® Inhalation Solution

Acute bronchitis, asthma and chronic obstructive pulmonary disease are widespread diseases with increasing incidences. Depending on the condition, patients are treated with pharmaceuticals which can have severe side effects or saline solutions that are lacking high effectiveness.

The medEctoⁱⁿ® Inhalation Solution combines preventative and therapeutic properties. It dilutes thick mucus, improves expectoration, and helps to prevent symptoms induced by allergens or airborne particles.

Claims

Inhalation solution for the supportive treatment to reduce inflammations of the airways in case of bronchitis, asthma, or Chronic Obstructive Pulmonary Disease (COPD).

Prevention

- Prevents drying of the mucous membranes, dilutes tenacious mucus so that it can be coughed-up more easily.
- Prevents symptoms of allergic reactions of the respiratory system while suffering from e. g. allergic asthma, house-dust allergy, etc.
- Prevention of bronchitis symptoms.

Treatment

- Supportive treatment and symptom alleviation of diseases of the airways, such as allergic or non-allergic asthma, bronchitis, or Chronic Obstructive Pulmonary Disease (COPD).
- Protects and moisturizes the mucosa of the airways (e.g. when exposed to particulate matter, pollen, dust or to dry air in heated or air-conditioned rooms).

Safety & Usability

- For administration with jet, mesh, and ultrasound nebulizers.



Clinical Results

	Asthma (New Study!)	Asthma	Bronchitis	COPD
Study Design	Multi-centre, prospective, open label, single arm, post market, clinical follow-up study	Open label, single group, dose finding and safety study	Non-interventional, comparative, multicentre study	Double-blind, randomized, placebo-controlled cross-over study
Study Population	204 patients with clinical history of asthma for at least six months	18 patients with mild bronchial asthma	135 patients with respiratory tract infections and/or acute bronchitis	36 patients with chronic obstruction and inflammation in the lung
Treatment Duration	3 weeks	5 – 7 days	7 – 10 days plus 7 days additional treatment on patients' decision	4 weeks
Assessment	Physician and patient assessment	Physician and patient assessment	Physician and patient assessment	Physician and patient assessment
Evaluated Symptoms	Morning Peak Expiratory Flow	Lung function parameters, exhaled nitric oxide, and inflammation markers in sputum	Change in Bronchitis Severity Score Evaluation of tolerability	Lung function parameters and inflammation markers in sputum and serum
Main Results	Ectoin® Inhalation Solution provides a significant clinical benefit as supportive treatment in asthmatic patients aged 6 years and over with no safety concern. Instantly noticeable improvement in quality of life and asthma control after only 3 weeks of treatment	Ectoin® Isotonic Inhalation Solution demonstrates efficacy in the investigated endpoints and a good safety profile. The medium dose level 1.3 % exhibits the best efficacy on several endpoints including a significant decrease of exhaled nitric oxide.	Ectoin® Inhalation Solution significantly improves the Bronchitis Severity Score . Ectoin® Inhalation Solution is significantly superior to isotonic NaCl solution in improving dyspnoea and auscultation findings.	Ectoin® Inhalation Solution demonstrates beneficial effects on inflammatory sputum makers . Ectoin® Inhalation Solution significantly reduces nitrogen oxides (nitrate and nitrite) in sputum compared to placebo.
Publication	bthp-046-2021-EIL07	Kappeler et al. 2011	Tran et al. 2019	Unfried et al. 2016

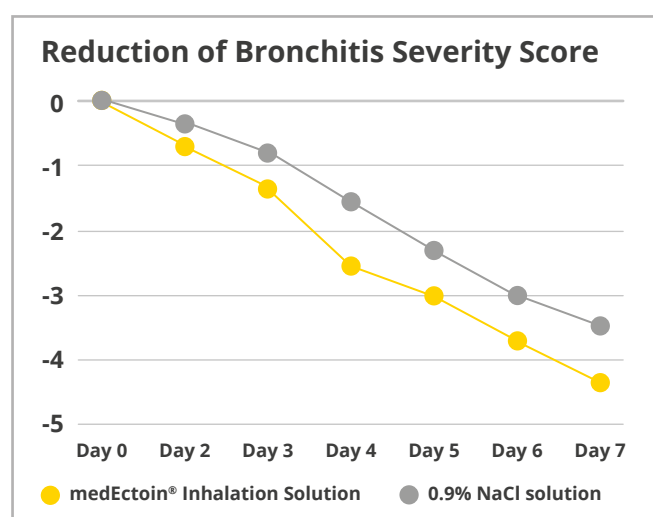


Figure 6.: Time related reduction of Bronchitis Severity Score (patients' assessment)
Ref. Tran et al. 2019



Medical Device Class:

Ila



Packaging:

2.5 ml solution in single-dose units (SDU) for jet, mesh, or ultrasound nebulizers



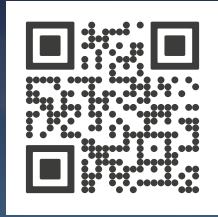
Shelf Life:

SDU: 36 months

Pa0:

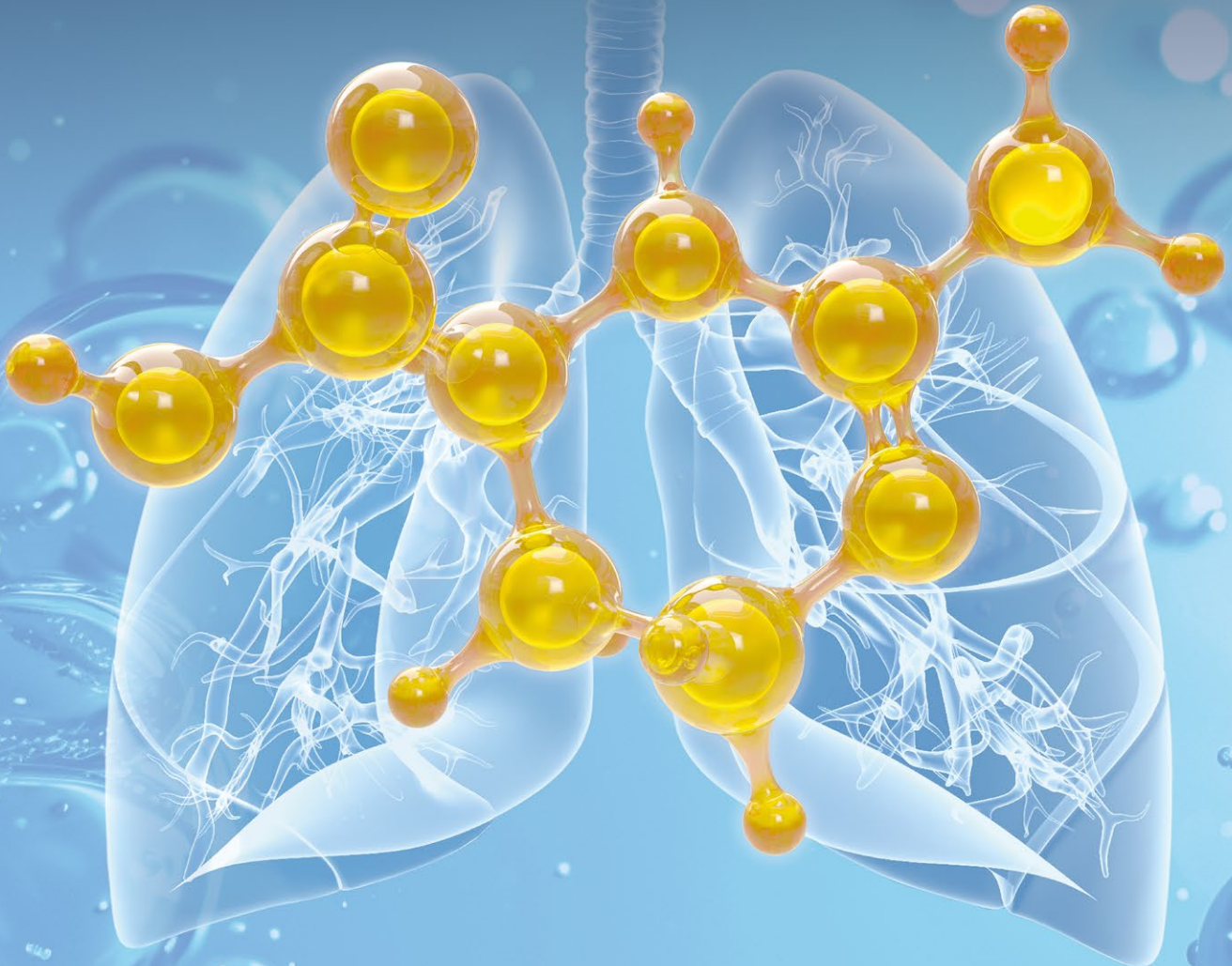
SDU: N.a.

Scan to contact our sales team



Let's talk

bitop AG
Carlo-Schmid-Allee 5
44263 Dortmund
bd@bitop.de
www.bitop.de



www.bitop.de

bitop
The Ectoin® Company