GeloMuc[®] respiratory therapy device

GeloMuc® is a respiratory therapy device used for the mobilization of tight, viscous bronchial mucus (also in the case of narrowed airways), for example in patients with respiratory diseases such as chronic bronchitis, chronic obstructive pulmonary disease (COPD), bronchial asthma, pulmonary emphysema, bronchiectasia or mucoviscidosis.

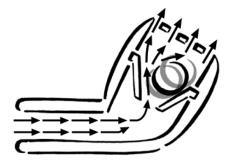
Components:

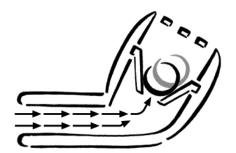
- 1. Main part with mouthpiece
- 2. Funnel
- 3. Rustproof steel ball, weight 28 g
- 4. Screw-off headpiece with holes

What is the mode of action of GeloMuc®?

As the patient starts exhaling through the device, the pressure in the respiratory tract increases, due to the initial block of the airflow.

As the GeloMuc® steel ball is pushed upwards, the pressure then decreases. The steel ball rolls back in its original blocking position. This repeating sequence generates an oscillating positive expiratory pressure (PEP), which causes Gelo-Muc® to increase pressure in the bronchi, open the respiratory tract, mobilize bronchial mucus, eventually leading to a reduction of unproductive coughing. More efficient coughing leads to higher cleaning rates of the respiratory system. With regular long-term use, lung functions can be strengthened.





GeloMuc® leads to a positive course of disease and improves quality of life

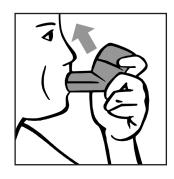
GeloMuc® should be used several times a day, which increases the therapeutic effect. Its sturdy build and compact size make GeloMuc® easy to use wherever and whenever it is necessary.

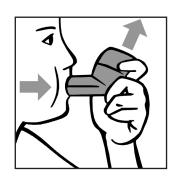


Optimal therapy – Simple to use

- 1. You should be seated at a table and relaxed. Rest an elbow on the tabletop. Take GeloMuc® into this hand, taking care not to cover the holes on the GeloMuc® headpiece.
- 2. Take the mouth piece between the lips, inhale deeply through your nose. Hold your breath for 1–2 seconds.
- 3. Exhale slowly and preferably as long as possible into the GeloMuc® mouth piece, taking care to avoid puffing out your cheeks.
- 4. Repeat this procedure. Optimize your position if necessary.
- 5. Using this exercise several times a day is recommended.









Simple to clean

Patient's home: disassemble GeloMuc®, clean with hot water and soap, and dry all parts. Or simply put it in your dishwasher.

Hospital: additional disinfection by using instrument disinfectant or autoclave is possible (for correct disinfection see package insert).

GeloMuc® - advantages

- ✓ Physical therapy approach
- ✓ Self-therapy (vs. classic physiotherapy)
- ✓ Immediate effect ("feel it work")
- ✓ Simple to use (also for children)
- ✓ Simple to clean (patient`s home or in hospital)
- ✓ GeloMuc® efficacy is well documented.
- ✓ GeloMuc® is very safe and can be used in addition to other mucolytic therapies.
- ✓ Patients with chronic respiratory diseases are able to improve their health status by independently using a simple, handy, non-electric physiotherapy device

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GeloMuc

Respiratory Therapy Device

Dear Patient.

Please read these instructions for use carefully because they contain important information that you should pay attention to while using this medical device.

If you have any questions, please ask your doctor or pharmacist.

Components

GeloMuc consists of the following parts:

- 1. Main Part with Mouthpiece
- 2. Funnel
- 3. Steel ball
- 4. Screw-On Headpiece with a Number of Vents

Fields of Application

GeloMuc is a respiratory therapy device for mobilization of sticky, viscous bronchial mucus (also in cases of constricted respiratory tract), e.g. in patients with chronic bronchitis, chronic obstructive pulmonary disease (COPD), bronchial asthma, pulmonary emphysema, bronchiectasis or cystic fibrosis.

Mechanism of Action

Using the GeloMuc creates a positive expiratory pressure (PEP) in the bronchia, which prevents the collapse of airways even deep within the bronchial branches.

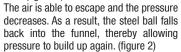
Breathing out through the GeloMuc causes oscillations of pressure within the bronchial tubes and expiratory airflow, making the bronchial tubes vibrate, thereby loosening mucus from the bronchial walls and making transport towards the mouth easier. With long-term regular use, lung function can also be improved.

Fig.1

Fig.2

How it works

GeloMuc is a small pipe-like device that consists of a mouthpiece, a funnel, a steel ball and a headpiece with vents. Before exhaling, the steel ball closes the funnel. Upon breathing out, the patient creates positive pressure inside GeloMuc and hence also within his/her own airways. until the pressure is increased to such an extent that the ball rolls up the funnel wall. (figure 1)



Rapid repetition of this sequence when breathing out causes the bronchial tubes to vibrate due to oscillating positive expiratory pressure (PEP). By raising or lowering GeloMuc, the rate at which the steel ball moves up and down can be regulated.



GeloMuc must not be used if pneumothorax is present at the time of use. (Accumulation of air in the pleural space, i.e. between the two layers of the lung lining. This results in partial or complete lobar collapse, i.e. one half of the lung collapses.)

Warnings

GeloMuc consists of impact-resistant material, but it is not unbreakable. Please note that the device can be damaged if dropped onto a hard surface (e.g. tiles).

Please do not put the individual parts of GeloMuc (particularly the steel ball) into your mouth.

The device is not suitable for gas sterilization with ethylene oxide or sterilization via dry heat, hydrogen peroxide or radiation!

Sterilization in a so-called microwave vaporizer is not possible. GeloMuc would melt and thus be destroyed.

Side Effects

If used as directed, GeloMuc does not cause any side effects.

Breathing in and out too rapidly (hyperventilation) can cause slight dizziness and numbness around the mouth and in the hands. If you become aware of such symptoms, please take a pause. After normalization of your breathing pattern, the symptoms should disappear within a few minutes. Dangerous levels of high pressure cannot be produced within the lungs, since in cases forceful exhalation, the steel ball will roll out of the funnel, allowing air to escape. When breathing is slow and relaxed, only a light increase in pressure is produced in the airways (pressure fluctuations of approximately 10-25 cm water column). Even patients with a sensitive bronchial system, such as asthma sufferers, can benefit from use of this device without irritating the airways.

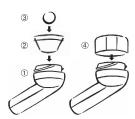
Directions for use

Please pay attention to the following instructions to ensure successful respiratory therapy.

Before using GeloMuc

Before first-time use, we recommend that you thoroughly clean GeloMuc with hot water and soap or dish washing liquid, rinsing thoroughly. After allowing the device to dry, therapy can begin, First. please make sure that the respiratory therapy device is assembled correctly. Pick up the main part with the mouthpiece ① and place the funnel @ into the trough.

Now, place the steel ball 3 inside the funnel and tightly screw the headpiece @ onto the main part. The headpiece is correctly screwed on when the two triangular marks on the headpiece and main part are above each other. Now, you can start treatment.



Using GeloMuc

- 1. In order to ensure optimum therapy, we recommend that you sit down at a table in a relaxed position placing your elbows on the table top. Pick up GeloMuc, making sure that the vents on the headpiece are not covered.
- 2. Put the mouthpiece into your mouth and inhale slowly, steadily and deeply through your nose. Hold your breath for a moment (1-2 seconds).
- 3. Exhale slowly and deeply through your mouth and into the GeloMuc. Try not to puff out your cheeks: keep them taut by tensing the muscles.
- 4. Maintain the mouthpiece of GeloMuc in your mouth, inhaling again through your nose, briefly holding your breath (1-2 seconds). Slowly exhale once again through the device for as long as possible. Now repeat this sequence for a short while. Try to avoid breathing too quickly and too heavily.
- 5. Checking correct application

When GeloMuc is used correctly, you will feel a strong, throbbing vibration in the chest, If necessary, you may need to raise or to lower the GeloMuc slightly to find the ideal position.

6. Tickly Throat

If you have a fit of coughing, you should try to "huff up" the mudus. By using the huffing technique, you will avoid strenuous coughing, which makes getting rid of mucus from the constricted bronchial tubes more difficult. When huffing, imagine that you are steaming up a windowpane. You will soon see that the mucus can be removed much better by this method than by coughing.







Regimen for use

We recommend that you use the GeloMuc several times a day.

Cleaning the GeloMuc

For hygienic reasons, we recommend use of the GeloMuc on an individual basis.

1. Cleaning at home

To avoid microbial contamination of GeloMuc, we recommend that you clean your respiratory therapy device daily as follows:

- Take the GeloMuc apart.
- If it is heavily soiled, a pre-cleansing step should be undertaken with hot water and soap or dish washing liquid.
- Now put all 4 components for 3 minutes in boiling tap water. Please make sure that all parts are completely covered with water.
- Let the individual parts dry under a clean cloth in a warm place, preferably overnight, and then put it back together

GeloMuc can also be placed in the dishwasher.

2. Cleaning in the clinical setting, etc.

Disinfection in an immersion bath is possible, with an appropriate instrument disinfectant in accordance with the manufacturer's instructions. For example, Korsolex® plus has been shown to be effective in experiments. Equally, cleaning by means of a vaporizer is recommended. In addition to cleaning, sterilization with superheated steam (autoclaving) up to 134 °C is possible. GeloMuc can also be placed in the dishwasher.

Storage instructions

Date of information: 03/2016

Store medical devices carefully. Keep out of reach of children.



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LOT





Follow instructions









