pro-inhal®

**for the adjuvant
treatment of bronchial asthma**

Following years of intensive medical research, a new adjuvant treatment for bronchial asthma has been developed.

It is based on selective adaptive training of the disordered oxidative status of asthma patients. This training is achieved by the use of the innovative inhaler, *pro-inhal*®.

pro-inhal® selectively generates low-dosed gaseous superoxide anions $O_2^{\bullet -}$. On nasal application, these are administered into the nasal and pharyngeal cavities and produce local and systemic effects which change the oxidative status in the direction of normalisation.

The effect has been confirmed in a clinical pilot study. Overall, 85% of asthma patients benefited from the treatment.

pro-inhal® is a compact device designed for use in doctors' surgeries or in the patient's home environment. *pro-inhal*® is easy to use, easy to clean and has an electronic function control.

Treatment Regimen

pro-inhal® treatment is administered alongside conventional medical treatment. The maximum therapeutic effect of adaptive training is achieved when one of the following two recommended treatment regimes is followed:

a) Daily home use for 8 minutes with a 2-day break per week for a period of 10 weeks.

b) Use in a doctor's surgery for 15 minutes 3 days a week for a period of 6 weeks.

pro-inhal® treatment is carried out in at least two treatment cycles, each lasting 10 or 6 weeks respectively. A third cycle is recommended if necessary. The cycles should be separated by a two-week interval.

Side Effects

After the first few days' treatment, short-lived irritation of the nasal and pharyngeal cavities may occur. This subsides spontaneously without the treatment having to be interrupted or its success being affected.

Interactions

pro-inhal® administration may potentiate the antinociceptive and sedative effects of analgesics and sedatives.

Contraindications

The inhalation treatment is contraindicated in wearers of cardiac pacemakers.

Until extensive clinical experience has been obtained, inhalation treatment should be avoided in the following patient groups:

- exacerbation of infection with clinical deterioration,
- in pregnancy or lactation,
- in cerebral fits,
- in severe renal, hepatic or cardiovascular diseases,
- in acute episodes of rheumatism,
- in active tuberculosis,
- in patients at risk of thrombosis.

Indications

Bronchial asthma (and non-specific chronic bronchitis).
In elderly patients, for example those over the age of approximately 65 years, low therapeutic success should be expected in view of the generally lower reactivity of the regulatory mechanisms.

Mode of Action

Lipoperoxidation is an important component of every inflammatory response, which is accompanied by leukocyte activation. In bronchial asthma, the severity of functional and morphological changes correlates with the intensity of the endogenous oxidative stress. A causal relationship exists between bronchial hyperreactivity on the one hand and structural changes in the cell membrane and cell lipid composition on the other hand. Nasal inhalation of low-dosed gaseous superoxide anions serves to stimulate adaptive changes in the oxidative status of the body in the direction of normalisation. This brings about the subsidence of inflammation as well as a reduction in the tone and hyperreactivity of the bronchial musculature. It is this principle on which the successful treatment of bronchial asthma with *pro-inhal*® is based.

Most Important Results of the Clinical Pilot Study

The connection between the improvement in oxidative status and the improvement in lung function in bronchial asthma patients has been demonstrated in a clinical pilot study. The principal results of the study are as follows:

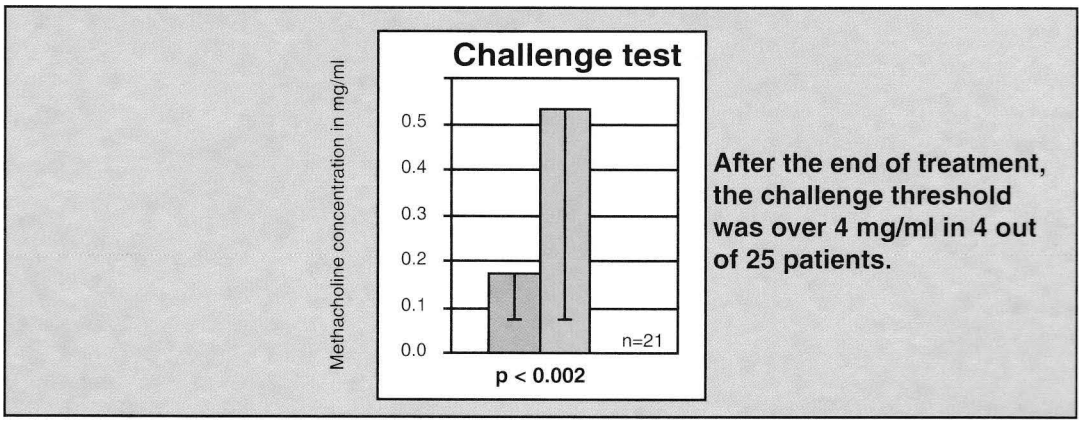
- **a reduction in the hyperreactivity and tone of the bronchial musculature**,
- **an improvement in spirometric values**,
- **an increase in the cortisol level**,
- **a decrease in endogenous oxidative stress**,
- **a reduction in medication**.

Overall, 85% of the asthma patients benefited from inhalation treatment according to the criteria of reduced hyperreactivity, improved lung function and/or a reduction in medication.

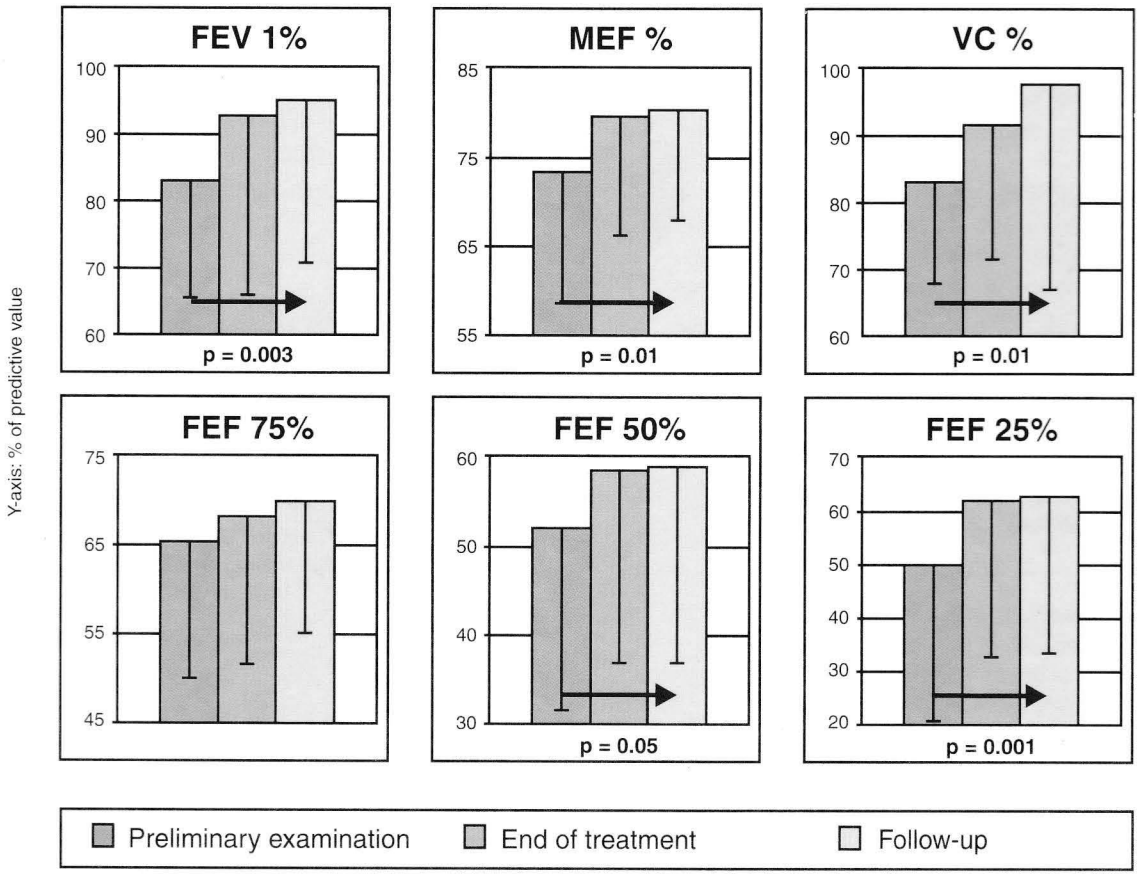
A secondary finding was a decrease in systolic and diastolic blood pressure as well as a reduction in the pulse rate in patients with elevated systolic blood pressure values.

pro-inhal®

reduces bronchial hyperreactivity:



improves spirometric parameters:



Source: Pullmologie, **49,** 1995, page 338 and Internal research report **SORIT 1 - P 5/95**

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