



The New Wave in SINUSitis Therapy

*Focus on
Cystic
Fibrosis*



PARI SINUS

Pulsating Aerosol –

For the precise, effective and
gentle treatment of sinusitis

Inhalation treatment for acute and chronic
diseases of the upper airways

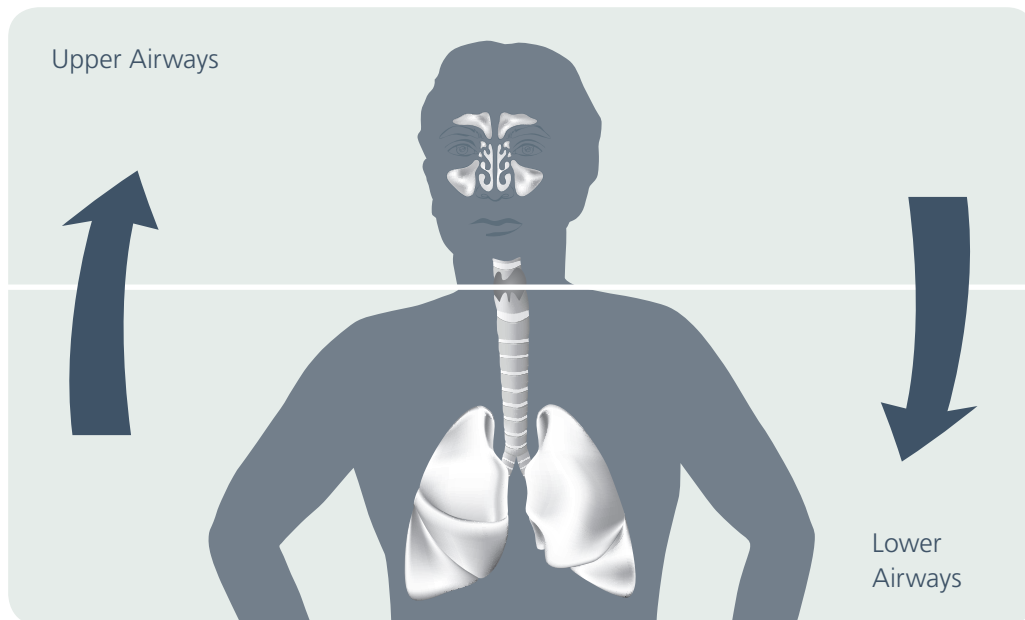
www.pari.com/de-en

Specialists in effective inhalation



The Concept of the United Airways

“One Airway – One Disease”



“The upper and lower airways form an anatomical continuum that is also relevant for microorganisms and inflammatory mediators.”

Prof. Niels Høiby, Copenhagen University Hospital, Denmark

Importance of the Upper Airways for Cystic Fibrosis patients:

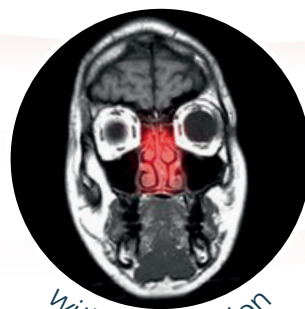
“In practice, almost all CF patients experience problems with their upper airways: their mucociliary clearance does not work, their nose runs and their sense of smell is impaired. The genetic defect of Cystic Fibrosis Transmembrane Conductance Regulators also affects the function of the upper airways.”

PD Dr. Jochen G. Mainz, Jena University Hospital, Germany

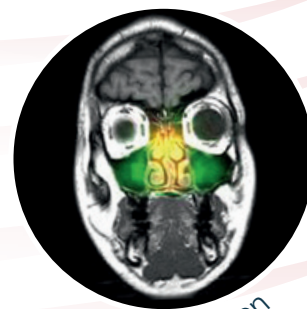
PARI SINUS –

Targeted Inhalation Therapy

Pulsating inhalation therapy –
specifically designed to treat sinusitis



Without pulsation



With pulsation

Pulsating aerosol – for the precise
deposition of the active agent ^{1,2,#}

	Nasal Spray	PARI SINUS
Nasal deposition, %	96.5*	21.5*
Deposition in the paranasal cavities in %	0.45*	12.5*

* Deposition (in %) of the applied active agent.

**Around 28 times more effective
than the nasal spray**

Second to none – pulsating aerosol effectively deposits
the active agent in the paranasal sinuses ^{1,2}

1. Möller W. et al, Rhinology, 2009

2. Schuschnig U et al, Respiratory Drug Delivery, 2006

Gamma camera images overlaid with MRI Images

Pulsating Aerosol –

Realising treatment goals for your Cystic Fibrosis Patients

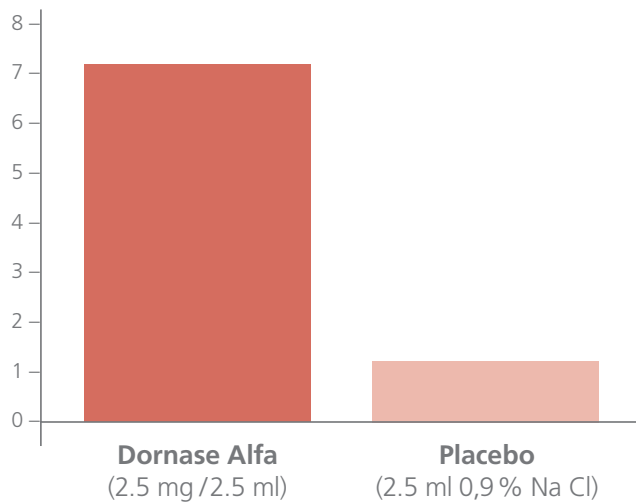
A: Mobilisation of Secretion³

Results:

Marked Improvement

Overall score SNOT-20 GAV (SNOT= Sino-Nasal Outcome Test 20, German Adapted Version)

Unchanged



Study Design:

Double-blind, placebo-controlled, crossover study:

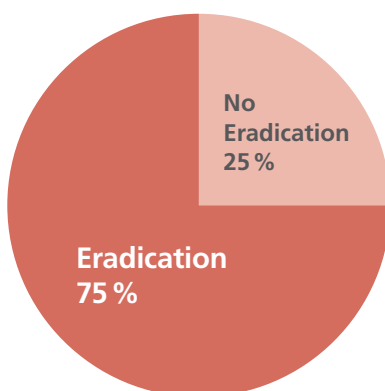
23 CF patients with chronic rhinosinusitis (CRS) inhaled Dornase Alfa and isotonic saline via PARI SINUS for 28 days.

Primary endpoint: primary nasal symptom score in the disease-specific quality of life Sino-Nasal Outcome Test (SNOT-20).

Significant improvement in overall SNOT-20 scores as in the primary nasal symptoms (runny nose, post-nasal discharge and thick-nasal discharge) after treatment with Dornase alfa via PARI SINUS. This resulted in an improvement in Quality of Life.

B: Eradication of Pathogens⁴

Results:



Treatment Protocol:

N = 8 CF children (with an average age of 11 years) from the Royal London Children's Hospital. In all cases their upper airways were colonised with *P. aeruginosa*.

Administered Substances

To treat *P. aeruginosa* infection

Duration:

Oral antibiotic (Ciprofloxacin)	3 weeks
Inhalation of 150mg tobramycin to the paranasal cavities via PARI SINUS and further 150 mg of tobramycin to the lungs.	28 days
Pulmonary inhalation of 1-2 MIU of Colistin	2 months

The combined antibiotic treatment of the upper airways via PARI SINUS as well as for the lower airways resulted in an eradication of *p. aeruginosa* amongst 75 % of those patients treated.

3. Mainz et al, Journal of Cystic Fibrosis 13, 2014

4. Wilson P et al, Journal of Cystic Fibrosis 13, 2014

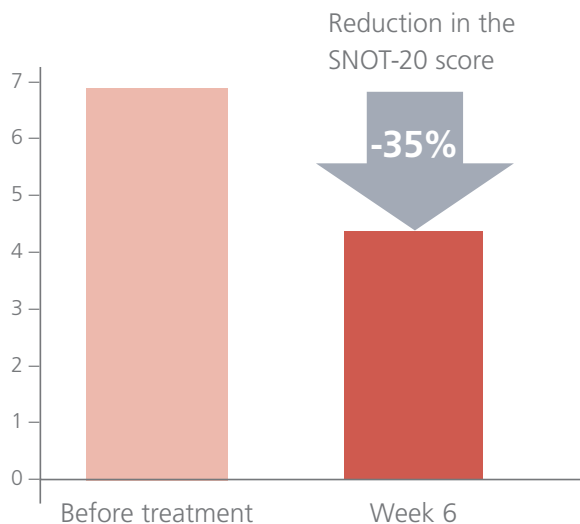
C: Reduction of Inflammation⁵

Results:

Severe symptoms

Rated according to SNOT 20GAV* (0–9)*

No symptoms



Treatment Protocol:

N = 7 patients with chronic rhinosinusitis (CRS)

- Fluticasonpropionat (Flutide forte 2mg/2ml suspension)
- Inhalation to the paranasal sinuses 1 x daily with PARI SINUS
- Duration: 6 weeks
- Primary endpoint: change in the primary nasal symptoms according to the SNOT-20 score

Impressive symptom relief and clear improvement in Quality of Life after the application of steroids via PARI SINUS.

D: Treatment of Bacterial Infection⁶

	Patient 1	Patient 2
Pre Lung Transplantation:	Identical <i>P. aeruginosa</i> genotypes evident in both the upper and lower airways	Identical <i>P. aeruginosa</i> genotypes evident in both the upper and lower airways
Treatment protocol post Lung Transplantation to avoid pulmonary colonisation with <i>Pseudomonas aeruginosa</i>	<p>Upper Airways (UAW)</p> <ul style="list-style-type: none"> • Repeated treatment cycles with intravenous antibiotics <p>Lower Airways (LAW)</p> <ul style="list-style-type: none"> • Repeated treatment cycles with intravenous antibiotics • Inhalation of antibiotics to the lung 	<p>Upper Airways (UAW)</p> <ul style="list-style-type: none"> • Sinonasal inhalation of 1 MIU Colomycin once daily with PARI SINUS 4 - 6 minutes per nostril <p>Lower Airways (LAW)</p> <ul style="list-style-type: none"> • Inhalation of 1 MIU Colomycin, twice daily
Infection status over 36 months post Transplantation	Identical <i>P. aeruginosa</i> genotypes in both upper and lower airways (as before)	Identical <i>P. aeruginosa</i> genotypes in upper airways (as before) No colonisation of the lower airways with <i>P. aeruginosa</i>

Antibiotic therapy of the upper airways via PARI SINUS can, in combination with an antibiotic therapy of the lower airways, result in an infection of the transplanted organ being avoided.

5. Hanga D et al, 83. Jahresversammlung der deutschen Gesellschaft für HNO, 2013

6. Mainz et al, Drug Des Devel Ther. 2014

PARI SINUS – Targeted Inhalation Therapy

- Second to none – pulsating aerosol effectively deposits the active agent in the paranasal sinuses^{1,2}
- Convincing – impressive symptom relief and clear improvement in quality of life⁵
- Suitable for the realisation of treatment goals for your Cystic Fibrosis Patients



1. Möller W. et al, Rhinology, 2009
2. Schuschnig U et al, Respiratory Drug Delivery, 2006
3. Mainz et al, Journal of Cystic Fibrosis 13, 2014
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