



a new
generation

Kamada is pleased to introduce a new generation – Alpha-1 Antitrypsin (AAT) product

Indication

Respira, Alpha-1 Antitrypsin (AAT) by Kamada, is indicated as replacement therapy for individuals with congenital deficiency of Alpha-1 Antitrypsin.

AAT deficiency leads to various health problems, including a significant reduction in lung function, lung inflammation, shortness of breath, and recurrent exacerbations. The result is clinically demonstrable panacinar emphysema.

AAT is administered by intravenous infusion. The aim of the replacement therapy is to elevate the serum AAT level above the protective threshold level of 0.8 g/L.

Replacement therapy with AAT

- > **AAT** administration elevates the serum AAT level and thus reduces potential Neutrophil Elastase damage to the lungs⁽¹⁾
- > **AAT** has been shown to improve survival rate and slow down FEV1 decline^(2,3)
- > **AAT** appears to be associated with a marked reduction in the frequency and severity of lung infections⁽⁴⁾
- > **AAT** is well tolerated- no major side effects reported



Respira by Kamada - advantages

- > **Highly purified** - at least 90% of active Alpha-1 Antitrypsin
- > **Excellent safety profile** - from selection of plasma donors to final product:
 - All donors are subject to extensive testing in order to determine their suitability as donors, according to US FDA (Federal Drug Administration) and/or EMEA (European Medicines Evaluation Agency) requirements.
 - The manufacturing process is performed under strict cGMP conditions.
 - The multistep manufacturing process includes two viral elimination steps, Nanofiltration and Solvent Detergent treatment.
- > **Easy to use** - Respira is the first preparation for AAT replacement therapy in a liquid, ready to use form
- > **No need for reconstitution**
- > **Preservative/ stabilizer free**

Kamada offers

- > Extensive patient support and education program.
- > Information for physicians.
- > Extensive clinical trials program for the second generation Alpha-1 Antitrypsin inhaled product.

Dosing information

- > Respira is administered at a dose of 60mg/kg once a week.
- > Respira is supplied in 50 ml vials as a ready to use 2% solution of active AAT in phosphate buffered saline.
- > Respira can be stored for 24 months at 2-8°C.

For more information please contact ATT@kamada.com
or visit our web site at www.kamada.com

* Please see prescribing information before use.

References:

- Wessers MD, Casolaro MA, Sellers SE, et al. Replacement therapy for alpha1-antitrypsin deficiency associated with emphysema. *N Engl J Med*. 1987;316:1055-1062.
- Survival and FEV1 decline in individuals with severe deficiency of alpha1-antitrypsin. The Alpha-1-Antitrypsin Deficiency Registry Study Group. *Am J Respir Crit Care Med*. 1998;158:49-59.
- Schwolinske M, Vogelmeier C, Fruttmann G. Long-term augmentation therapy in twenty patients with severe alpha-1-antitrypsin deficiency-three-year follow-up. *Respiration*. 1997;64:10-15.
- Lieberman J. Augmentation Therapy Reduces Frequency of Lung Infections in Antitrypsin Deficiency: A New Hypothesis With Supporting Data. *CHEST* 2000; 118(5):1480-1485.



life saving
biopharmaceuticals



www.kamada.com

Head Office > 7 Sapir St., Kiryat Weizmann Science Park,
P.O. Box 4081, Ness Ziona 74036, Israel

Tel: 972 8 9406472, Fax: 972 8 9406473

Plant > Kibbutz Beit Kama, M.P Negev 85325, Israel

Tel: 972 8 9913111, Fax: 972 8 9912083 kamadeal@kamada.com

All rights reserved to Kamada 2007