

ARALAST NP
[Alpha₁-Proteinase Inhibitor (Human)]

Indication

ARALAST NP is indicated for chronic augmentation therapy in patients having congenital deficiency of A₁-PI with clinically evident emphysema. ARALAST NP is not indicated as therapy for lung disease patients in whom congenital A₁-PI deficiency has not been established.

Important Risk Information for ARALAST NP

ARALAST NP is contraindicated in individuals with selective IgA deficiencies (IgA level less than 15 mg/dL) who have known antibody against IgA, since they may experience severe reactions, including anaphylaxis.

ARALAST NP is derived from pooled human plasma. It may carry a risk of transmitting infectious agents, e.g., viruses and theoretically, the Creutzfeldt-Jakob disease (CJD) agent.

The recommended rate of administration ($\leq 0.08\text{mL/kg/min}$) should be closely followed and vital signs monitored continuously. **If anaphylactic or severe anaphylactic reactions occur, the infusion should be discontinued immediately.**

ARALAST NP should be administered at room temperature within three (3) hours after reconstitution and should be administered alone, without mixing with other agents or diluting solutions.

The safety of ARALAST NP was evaluated with ARALAST in a crossover clinical PK comparability study. The most common adverse events deemed related to ARALAST NP included headache and musculoskeletal discomfort. No serious adverse reactions or deaths were reported in the study. In the ARALAST pivotal study, the most common adverse events were headache and somnolence.

Please see accompanying ARALAST NP Prescribing Information for full prescribing details.