CSL Behring

Product fact sheet

Indication

Alpha$_1$-Proteinase Inhibitor (Human), ZEMAIRA® is indicated for chronic augmentation and maintenance therapy in adults with alpha$_1$-proteinase inhibitor (A_1-PI) deficiency and clinical evidence of emphysema. The effect of augmentation therapy with ZEMAIRA or any A_1-PI product on pulmonary exacerbations and progression of emphysema in A_1-PI deficiency has not been demonstrated in randomized, controlled clinical studies.

ZEMAIRA is not indicated for lung disease patients in whom severe A_1-PI deficiency has not been established.

Please see Important Safety Information on page 3 and full prescribing information for ZEMAIRA.

Healthcare Systems

Zemaira®
alpha$_1$-proteinase inhibitor (Human)

Product information

Brand name	ZEMAIRA	
Generic name	Alpha$_1$-proteinase inhibitor (human)	
HCPCS J-code	J0256	
NDCs	**Package size**	**Kit NDC number**
	1000 mg of functionally active A_1-PI	0053-7201-02
	4000 mg of functionally active A_1-PI	0053-7202-02
	5000 mg of functionally active A_1-PI	0053-7203-02
Component NDCs	**Package size**	**Component NDC number**
	1000 mg of functionally active A_1-PI	• ZEMAIRA in a single-dose vial (NDC 0053-7211-01) • 20 mL vial of Sterile Water for Injection, USP (NDC 0053-7653-20) • One Mix2Vial® filter transfer set for reconstitution
	4000 mg of functionally active A_1-PI	• ZEMAIRA in a single-dose vial (NDC 0053-7212-01) • 76 mL vial of Sterile Water for Injection, USP (NDC 0053-7653-80) • One Mix2Vial filter transfer set for reconstitution
	5000 mg of functionally active A_1-PI	• ZEMAIRA in a single-dose vial (NDC 0053-7213-01) • 95 mL vial of Sterile Water for Injection, USP (NDC 0053-7653-12) • One Mix2Vial filter transfer set for reconstitution
Storage and handling	• When stored up to 25 °C (77 °F), ZEMAIRA is stable for the period indicated by the expiration date on its vial label and carton • Avoid freezing, which may damage the diluent vial • Discard any unused product and all used disposable supplies	
How supplied	ZEMAIRA is supplied in a single-dose vial containing approximately 1000 mg, 4000 mg, or 5000 mg of functionally active A_1-PI as a white to off-white lyophilized powder for reconstitution with 20 mL, 76 mL, or 95 mL of Sterile Water for Injection, USP. The amount of functional A_1-PI is printed on the vial label and carton.	

HCPCS, Healthcare Common Procedure Coding System; NDC, National Drug Code.

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Zemaira® alpha$_1$-proteinase inhibitor (Human)

Important Safety Information

Alpha$_1$-Proteinase Inhibitor (Human), ZEMAIRA® is contraindicated in patients with a history of severe systemic reactions to the product or to A_1-PI protein, including anaphylaxis. Due to the risk of severe hypersensitivity, ZEMAIRA is also contraindicated in immunoglobulin A-deficient patients with antibodies against IgA.

Use caution in administering ZEMAIRA to patients who have experienced anaphylaxis or severe systemic reactions to another A_1-PI product. Patients with selective or severe IgA deficiency can develop antibodies to IgA and are at greater risk of such reactions. If anaphylactic or severe anaphylactoid reactions occur during infusion, discontinue immediately.

In pre-licensure clinical studies, the following adverse reactions were reported in at least 5% of subjects receiving ZEMAIRA: headache, sinusitis, upper respiratory infection, bronchitis, asthenia, increased cough, fever, injection-site hemorrhage, rhinitis, sore throat, and vasodilation.

ZEMAIRA is derived from human plasma. The risk of transmission of infectious agents, including viruses and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent and its variant (vCJD), cannot be completely eliminated.

Indications

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ZEMAIRA is not indicated for lung disease patients in whom severe A_1-PI deficiency has not been established.

Please see accompanying full prescribing information for ZEMAIRA.

To report SUSPECTED ADVERSE REACTIONS, contact the CSL Behring Pharmacovigilance Department at 1-866-915-6958 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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