Ordering Guide

ANDEMBRY® garadacimab-gxii

A once-monthly LTP treatment for hereditary angioedema (HAE)

How Supplied

ANDEMBRY® (garadacimab-gxii) injection is a ready-to-use, slightly opalescent to clear, brownish-yellow to yellow solution supplied in a single-dose prefilled autoinjector containing 200 mg/1.2 mL of garadacimab-gxii. ANDEMBRY should be refrigerated at 36 °F to 46 °F (2-8 °C).

Presentation	Strength	Unit Count	NDC (Device)	NDC (Carton)
Prefilled autoinjector	ANDEMBRY 200 mg/1.2 mL	1	63833-925-20	63833-925-01

ANDEMBRY Dosing and Administration

The recommended dosage of ANDEMBRY is an initial loading dose of 400 mg (two injections of 200 mg) administered subcutaneously on the first day of treatment followed by a maintenance dosage of 200 mg administered subcutaneously every month.

ANDEMBRY is intended for self-administration or administration by a caregiver. Prior to treatment initiation, train patients/caregivers on proper preparation and subcutaneous administration technique of ANDEMBRY.

ANDEMBRY is available as a 200 mg/1.2 mL solution in a single-dose prefilled autoinjector.

Simple administration allows for subcutaneous self-injection delivered in ≤15 seconds via an autoinjector.

LTP, long-term prophylaxis; NDC, National Drug Code.

Please see Important Safety Information on next page and full prescribing information for ANDEMBRY.

About ANDEMBRY® (garadacimab-gxii)

CSL Behring's activated Factor XII (FXIIa) inhibitor (monoclonal antibody) treatment, ANDEMBRY, is a once-monthly subcutaneous injection indicated for prophylaxis to prevent HAE attacks in adult and pediatric patients aged 12 years and older. ANDEMBRY has no contraindications.

ANDEMBRY, a recombinant, fully human, monoclonal antibody (IgG4/λ-light chain), is proven to lower the monthly HAE attack rate vs placebo. It is also proven to reduce the monthly rate of HAE attacks requiring on-demand treatment, as well as the monthly rate of moderate or severe HAE attacks.

Important Safety Information

ANDEMBRY® (garadacimab-gxii) injection, for subcutaneous use, is an activated Factor XII (FXIIa) inhibitor (monoclonal antibody) indicated for prophylaxis to prevent attacks of hereditary angioedema (HAE) in adult and pediatric patients aged 12 years and older.

The most common adverse reactions in the pivotal trial (incidence ≥7%) were nasopharyngitis and abdominal pain. In the pivotal trial and the open-label extension study, injection-site reactions (eg, injection-site bruising, injection-site erythema, injection-site hematoma, injection-site pruritus, injection-site urticaria) were reported in 23 (14%) patients.

No dedicated drug interaction studies have been conducted, nor is there data concerning the use of ANDEMBRY in women who are pregnant or breastfeeding. The safety and efficacy of ANDEMBRY in patients under 12 years of age have not been established.

Drug Interference with Laboratory Test: ANDEMBRY can prolong activated partial thromboplastin time (aPTT) due to an interaction of garadacimab-gxii with the aPTT assay.

Please see full prescribing information for ANDEMBRY.

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.

CSL Behring

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